

Compiled Public Comments on the Request for Information on Draft NIH Resources to Support Implantable Device Trials

Guide Notice Number: NOT-OD-26-061

March 25, 2026 – May 25, 2026

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1. Alik Widge

I am responding: On behalf of myself

Name: Alik Widge

Name of Organization: N/A

Type of Organization: Academic Institution

Role: Investigator/Researcher

Domain of research most important to you or your organization: Neurotechnology and implantable neural devices

Date Submitted: 3/31/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

It's reasonable. It contains materials that is basically in the published literature and considerations known to the field, but it's good to have in one place.

It does a good job of highlighting the strong ethical imperative to maintain device access for participants who benefit even if a trial fails.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

The coverage is reasonable; I did not identify specific concepts.

It should perhaps be made clear, in Elements 4 and 5, that it is not ethically or legally required to have all details of a plan solved in advance. In many cases, these plans are highly contingent on future landscapes that cannot be predicted.

1.3 Hurdles or barriers to broad use of this resource by the research community

Not by the research community, but something to carefully consider -- ICFs for these studies regularly run 30-50 pages already. Patients cannot digest this volume of information. It is not clear that adding even more material will be helpful, even though it does inform the patients.

As such, related to Resource 2, there needs to be some thinking about what information needs to be presented up front vs. potentially being delayed till the patient knows if they personally are benefiting.

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

It's reasonable, I appreciate the sample language.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

N/A

2.3 Hurdles or barriers to broad use of this resource by the research community

Probably none. I'd lift language from this. Remember to provide a Word version to make copy-pasting easier.

2.4 Other feedback relevant to this resource

N/A

2. Southlake Health

I am responding: On behalf of an organization

Name: Sharon Villani

Name of Organization: Southlake Health

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Domain of research most important to you or your organization: Cardiac Devices, Oncology

Date Submitted: 4/27/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

education for REB members

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Elements 1-5

1.3 Hurdles or barriers to broad use of this resource by the research community

None

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

Will consider suggested language when reviewing informed consent submissions

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component #3

2.3 Hurdles or barriers to broad use of this resource by the research community

None

2.4 Other feedback relevant to this resource

N/A

3. Neurotech Network

I am responding: On behalf of an organization

Name: Jennifer French

Name of Organization: Neurotech Network

Type of Organization: Research Participant/Patient Advocacy Organization/Patient Advocate/Caregiver

Role: Organizational Official

Domain of research most important to you or your organization: implanted neurotechnology devices

Date Submitted: 5/7/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

We applaud you for bringing this issue to light particularly as a funding agency. Resource 1 fills a long-standing gap in the clinical research ecosystem. There is no comparable NIH-level framework that systematically prompts investigators to think through post-trial obligations before a device study begins. The resource's core contribution is that post-trial care planning is not an afterthought but an integral component of study design.

The language throughout is appropriately non-prescriptive. The resource acknowledges that implant trials are highly heterogeneous — ranging from minimally invasive monitoring devices to modular neurostimulation systems — and it resists the temptation to impose one-size-fits-all requirements. The Preface and Introduction include compelling rationale grounded in real-world complexity: software incompatibility, manufacturer discontinuation, financial burden, and research team turnover. Citing Hendriks et al. (2023) and Harris and Gilbert (2024) in a footnote lends academic credibility and points investigators toward the emerging literature on this topic.

These concepts and components highlighted in Resource 1 can be useful but lacks some utility. The description is good but the implementation for an investigator appears to be potentially cumbersome. Investigators are told what to consider, but they are not given structured prompts, decision trees, or templates to actually construct a post-trial care plan. Without a companion worksheet or fillable planning template, it is easy to read the document and agree with its principles without translating them into documented commitments.

In addition, It may be useful to suggest a third approach which is offer the trial participant a market-available alternative post trial. The Hippocratic Oath focuses on "do no harm." In this context, investigators should offer the trial participant options that do not negatively impact the participants health and access to future health care. For example, if the study was a speech restoration implanted device, the investigators may offer a robust, EMG system for communication following the trial.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 1- Plan/Options for Device Explanation or Remaining In Situation

- The element does not ask investigators to address the process by which dispositional decisions will be communicated to participants over the course of the trial, including how and when participants will be re-informed if circumstances change after initial consent.
- There is no mention of post-mortem device management — what happens to the device if a participant dies during or after the trial. This is relevant for data integrity (e.g., device explantation for autopsy or data retrieval) and for tissue disposition regulations.
- The element would benefit from prompting investigators to describe the role of a participant advisory process or shared decision-making model in arriving at the dispositional plan, rather than framing this solely as an investigator-driven determination.

Element 2- Risks and Potential Benefits

- There is no explicit prompt to address cumulative or long-term biological risks of chronic implantation, such as chronic inflammation, or foreign body response that may evolve over years beyond the trial period. These risks are distinct from the acute surgical risks and device failure risks already mentioned.
- The element does not ask investigators to address risks to third parties that may arise from the implanted device — for example, electromagnetic interference from neurostimulators affecting other medical devices in close proximity, or biosecurity considerations for certain types of connected devices.

Element 3- Anticipated Participants' Needs

- In this section there is an important point as follows: "In so doing, outline the specific expertise needed for technical and clinical management of participants post-trial." This is a critical aspect of trial implementation. Personally, I have had an implanted device for more than 25 years and have a wallet card for clinicians to contact the research team for advice and guidance regarding the implanted device. I have used it a lot!
- In addition, this section should also address emergency care scenarios — what a participant should do if they experience a device-related emergency in a setting where no clinician familiar with the device is available.
- The element mentions psychosocial needs but does not elaborate on what this encompasses or how investigators should assess it.
- "Beyond care and support related to the implant, please consider how the implant may affect other care that the participant may need (e.g., whether the participant is eligible to receive other implants in the future, if the device is not magnetic resonance (MR) conditional, how this may affect the participant's overall healthcare)." For this statement, include "in the context of their condition, disease, or injury." Realizing that several device developers may have never interacted with a PWLE, it is important for investigators and the trial team to understand how the care pathway may be different for a person living with a complex health condition compared to a healthy individual.
- In addition, this section does not address the needs of legally authorized representatives (LARs) or caregivers who may be involved in device management for participants who lack capacity. In pediatric trials and in trials involving participants with neurodegenerative or psychiatric conditions, caregiver needs are substantive and should be anticipated in the plan.
- There is no discussion of geographic access needs. Participants who travel significant distances

for trial participation may face particular hardships accessing post-trial care if that care is only available at the enrolling institution. Investigators should be prompted to address how participants in remote or underserved communities will access device-related care after the trial.

- Referencing this quote in Element 3, "Consider the likely research-related clinical needs participants..." There is a fundamental difference between "consider" scenarios and "plan for" scenarios. The term "consider" may be perceived as a thought but not an action plan. The term "plan for" addresses the potential needs in that scenario. These example scenarios of possible outcomes of the research and regulatory status and commercial availability are real potential outcomes from a clinical trial. Planning can help to mitigate unanticipated reactions.

Element 4- Plans for Meeting Former Participants' Anticipated Needs

- This section has good questions for the planning process. You should be more explicit here. It seems this section will then create the question of "what are examples of how others have planned for these scenarios?" We recommend providing a reference with one or two examples of post-trial plans like these derived from clinical trial investigators and templates for investigators to follow for their planning process.

- This section also asks whether the research team will remain available but does not prompt investigators to describe a formal transition of care protocol — who specifically will assume responsibility, under what credentialing or training requirements, and how the transition will be documented and communicated to the participant and resources the participant can use with their primary care physician. Participants should also be aware of how the implanted device may impact their access to care, particular regarding payor decisions.

- There is no mention of device registry or longitudinal tracking systems that would allow investigators and public health agencies to monitor device performance and participant outcomes beyond the trial period. Investigators should be encouraged to consider whether enrollment in a post-market registry or a long-term follow-up study would be appropriate, along with consent from the participant.

- This section should also emphasize plans for participant re-contact if safety information about the device changes post-trial — for example, if a class-action recall is issued (for a commercial device used in an experimental trial) or if new long-term safety data emerges from other studies.

Element 5- Financial Plan

- "Note that NIH award funds cannot be used after the award period has ended." This could stifle innovation in the implanted medical device space. Consider allowing investigators to submit a financial plan as part of their grant submission for the funds to be set aside by the institution to be dedicated to post trial participants. Therefore, the funds will be used but dedicated to the care of the trial participant.

- This section also does not address the financial implications for participant's access to insurance coverage after the trial. The loss of insurance, transition from private to public coverage, or denial to address device-related care. Investigators should be prompted to address this risk in the financial plan

Element 6- Oversight of Long-Term Care Plan for Implantable Device Studies

- This section should address the interface between long-term care plan oversight and post-market surveillance requirements that may be imposed by FDA following device approval or clearance.

Coordinating these oversight functions rather than running them in parallel would reduce burden and improve data quality.

Best Practice Considerations

In this section, there are 3 recommendations:

- Incorporate a Shared Decision Making model or framework for investigators to work with PWLEs. SDMs are applied in other context for clinical use. These best practices would warrant SDMs. Literature references: Montori VM, Ruissen MM, Hargraves IG, Brito JP, Kunneman M. Shared decision-making as a method of care. *BMJ Evid-Based Med.* 2023;28(4):213-217. doi:10.1136/bmjebm-2022-112068; Sweeney J, Tichnell C, Christian S, et al. Characterizing Decision-Making Surrounding Exercise in ARVC: Analysis of Decisional Conflict, Decisional Regret, and Shared Decision-Making. *Circ Genomic Precis Med.* 2023;16(6). doi:10.1161/CIRCGEN.123.004133

- Also, include informing the participant of these best practices. In the 27 years of being in a clinical trial with an implanted device, I have seen and spoken with other trial participants who were either never informed of these considerations post-trial or do not remember. For instance, one option implemented in this trial is for those who keep the device to schedule an bi-annual visit with the research team, review the continued support, and review and sign an informed consent to continue using the device each year.

- The section should include a best practice addressing transparency with participants about the limits of the post-trial care plan itself — not just the financial limits, but the possibility that plans may need to be revised, that commitments may not be fulfilled due to unforeseen circumstances, and that participants should be kept informed of any material or funding changes to the plan after they enroll.

1.3 Hurdles or barriers to broad use of this resource by the research community

The resource states that investigators should consider developing a post-trial care plan "if such a plan is required by the NIH Institute, Center or Office," yet the document does not clarify whether NIH Institutes, Centers, and Offices will prospectively mandate post-trial care plans as a condition of funding for implantable device trials. NIH should either articulate the conditions under which ICOs will require a post-trial care plan — for example, as a function of device risk classification, trial duration, or anticipated participant dependency — or reframe the resource explicitly as a statement of good clinical research practice. The latter framing would more accurately position the resource within the broader landscape of research quality frameworks and would reduce the likelihood that the research community perceives post-trial planning primarily as an administrative burden rather than as an intrinsic obligation of participant protection.

A related and unresolved question concerns the availability of dedicated funding to support the implementation of post-trial care plans. The resource acknowledges that NIH award funds cannot be expended after the conclusion of the award period, yet it does not identify alternative mechanisms — such as supplemental funding opportunities or manufacturer-negotiated care agreements — through which investigators might realistically finance post-trial obligations. Without explicit guidance on funding pathways, the resource risks generating well-intentioned plans that are financially unexecutable, particularly for academic investigators at smaller institutions who lack the infrastructure or industry partnerships necessary to independently sustain long-term post-trial care commitments.

1.4 Other feedback relevant to this resource

The financial dimensions of post-trial device retention extend beyond direct maintenance or explantation costs and should be understood within the broader context of healthcare access and equity. The continued presence of an investigational implantable device — whether active or inactive — may impose clinically significant constraints on a former participant's eligibility for standard medical and surgical interventions unrelated to the original trial. For example, participants retaining devices in anatomically sensitive locations may be precluded from otherwise indicated surgical procedures, and those with devices that are not magnetic resonance imaging (MRI) conditional or compatible may face meaningful limitations in access to routine and advanced diagnostic imaging. These constraints represent a form of compounded burden in which former participants may have diminished access to standard healthcare resources available to the general population, with consequences that are likely to be most acute for individuals in underserved communities, those with limited insurance coverage, or those managing concurrent chronic conditions. Post-trial care plans should therefore explicitly address not only costs directly attributable to the investigational device but also the downstream effects of device retention on participants' broader healthcare access and eligibility.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

This suggestion is excellent. It is actionable and explicit for an investigator to execute for their given trial. "This resource also includes recommendations that investigators should consider providing participants with accessible versions of this information, including a fact sheet and/or an information card specific to the device (i.e., device card) that they can carry with them and share as needed, which summarizes information about the device and it's manufacturer and includes a contact for any post-trial care questions or issues related to the device that may arise after the study ends."

The sample language in this resource is excellent. It is actionable and specific. There may be an issue with IRBs and legal review. If this sample language has not been reviewed by a sample cohort of IRBs, it may be helpful for you to do so prior to publishing this resource.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1- Introduction/Purpose

- No comments

Component 2- Procedures

- No comments

Component 3- Long-Term Practical Considerations

- If the information is provided as a fact sheet, it should be a part of the ICF. The separation of the ICF and the fact sheet may be confusing to people. In addition, the ICF is signed and a means of acknowledgement by the participant.

- Regarding the information/fact sheet, the participant should have access to X-rays or scans of the actual implanted device for their "standard" care physician. They should also have some form of a device description that a participant can provide to any clinician to help describe the implanted device, whether they are still an active participant or a past participant. This should also include contact information so the clinician can ask any outstanding questions, risks, device compatibility/conflict (ie. MRI), etc.

- In your sample language: "After the surgery to place the device in your body you will need to alert [insert who e.g., security staff] that the device is present in certain situations." Also include protective measures that the participant may need to take, ie. taking antibiotics for dental work.

Component 4- Potential Risks

- No comments

Component 5- Potential Benefits

- No comments

Component 6- Alternatives

- In your example: "Alternatives may include current standard of care treatments, other therapies, or participation in other research studies." Another alternative may be entering into a follow-on Long-Term study. This will encourage investigators to think long term for an implanted device or temporary as the form factor of the device.

Component 7- Cost

- "We [will/may] not remove the [insert name of the device] from you at the end of the study [as it may continue to help you with your condition OR because the risk of removing it is more than the risk of leaving it in place.] There will likely be costs to continue to use and service the device. There may be costs with removing the device for medical reasons or at the end of its useful life. [Choose 1 or 2 below as relevant]: "

- For the points that follow the above statement, it would be helpful to provide an estimated cost. For the points below this section, insurance providers may not know anything about the device and not know how to assess it; therefore, leaving the former participant without coverage.

-

Component 8- Compensation for Research-Related Injury

- No comments

Component 9- Withdrawal

- No comments

Component 10- Questions

- No comments

2.3 Hurdles or barriers to broad use of this resource by the research community

It would be helpful to provide an estimated cost. For the points below, insurance providers may not know anything about the device and not know how to assess it.

2.4 Other feedback relevant to this resource

It would be helpful to highlight that these are "unique" points for Informed Consent of an implant trial participant. This should not be confused with standard surgical consent.

Under General Points of Consideration "please see [insert reference to best practices document] " It seems there is a reference and link provided here.

4. GIVE-A-HAND.tech

I am responding: On behalf of an organization

Name: Kevin Kilgore

Name of Organization: GIVE-A-HAND.tech

Type of Organization: Other

Type of Organization - Other: Non-Profit

Role: Investigator/Researcher

Domain of research most important to you or your organization: Individuals with active implantable medical devices that have been abandoned by the sponsors

Date Submitted: 5/13/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

Comments on NIH Publication: "Draft NIH Resource to Support Implantable Device Trials", issued March 2026 (via NOT-OD-26-061)

These comments represent the views of GIVE-A-HAND.tech, a non-profit established to address the difficulty of post-trial support of study participants with implanted devices.

We appreciate the opportunity to provide feedback to NIH regarding the document entitled "Draft NIH Resources to Support Implantable Device Trials" issued March 2026 (and hereafter referred to as NIH Resources"). The comments that follow present the view of GIVE-A-HAND.tech, a 501(c)(3) non-profit. GIVE-A-HAND.tech was established in March 2025 with the mission "to serve as an adoptive home for people with, or who could benefit from, abandoned implantable medical devices. GIVE-A-HAND.tech will enable people to gain access to, and keep benefitting from, these devices for the remainder of their lifetimes." Our board has a combined 100+ years of experience in long-term support of individuals with implantable devices. We are currently supporting a number of individuals who have been utilizing their implanted devices daily for more than 30 years. Our comments below are based on our ongoing experience in supporting these individuals and our analysis of the problems encountered in doing so.

We applaud NIH for identifying long-term support (or "post-trial needs") as an important issue in the implantable device field; and for assembling and distributing the draft document for comment. However, the document fails to concretely address the three most important issues related to long-term support (and only identifies, but does not solve, the fourth). These issues, in order of importance, include: 1) regulatory "allowance", 2) technology availability, 3) expertise availability, and 4) finances. The document, as currently conceived, provides no actual "resources", and minimal "guidance", to investigators who are seeking to find solutions to this difficult problem. In our comments, we will

address these four key issues and conclude with suggestions for practical and substantial resources that NIH could provide to help the field achieve a sustainable solution to this problem.

1. Regulatory “Allowance.” The NIH Resource fails to mention this most important difficulty in providing long-term support to individuals who want to continue to utilize and benefit from their implanted device beyond the end of a funded study. Specifically, the NIH Resource describes the support of individuals who have been implanted with Class II and Class III implantable medical devices within the U.S., typically under an Investigational Device Exemption (IDE) (but could also include 510k, PMA, HDE, etc.). Any effort to maintain the technology for these individuals remains under the oversight of the FDA (and often IRBs) despite the original study having ended. Thus, the first and most important issue is to address the need for, and maintenance of, regulatory oversight. As a common example, consider a study conducted under an IDE from the FDA. Often, the Principal Investigator (PI) of the study serves as the Sponsor-Investigator of that IDE. However, if the study is completed and funding has ended, then the PI has no resources to maintain the IDE beyond the end of grant funding. This means that adverse events may no longer be monitored, device inventory may no longer be tracked, and annual reports will not be filed. In these cases, the IDE becomes abandoned because there are no resources to maintain it. There are also cases where the PI retires or is otherwise unable to be involved in the study. Again, the IDE becomes abandoned. Once abandoned, it is extremely unlikely that an IDE could be “revived” by simply starting new annual reports and performing other reporting requirements. Instead, it is likely that a new IDE would have to be submitted and the approval process would need to be navigated all over again. Such an effort is costly, difficult, and requires someone with a high level of commitment and regulatory skills. At GIVE-A-HAND.tech, we recognize that the most critical aspect in providing support is to first ensure that the IDE does not become abandoned in the first place. Thus, we propose that GIVE-A-HAND.tech (or any other suitable non-profit) would become the Sponsor of these IDEs before they become abandoned. NIH could tangibly support investigators facing these situations by working together with the FDA to create designated “Long-term Support IDEs” with practical and realistic follow-up procedures. We strongly encourage NIH to come forward as the lead broker for this effort, working together with the FDA, investigators, companies, and non-profits to achieve a solution to the “Regulatory Allowance” problem. If this problem is not solved, none of the other efforts (listed below and also identified in the NIH Resource document) will provide any solution to the problem.

2. Technology Availability. Frequently, long-term support of users of an implantable device becomes practically impossible because the technology is no longer available. This is obviously the case in studies where the study sponsors are also the manufacturers of the device (or substantially modify a manufactured device). When that study sponsor is lost, the manufacturing of the device ceases and, in addition, often the documentation related to the design and operation of that technology is lost. If the long-term user has a component that breaks (either implanted or external), there is no longer any technology available to replace that component. It is important to note that frequently, even the design details are lost, such that there would not even be a way to find a new manufacturer of the device. This issue is much more critical, in most cases, than finding sufficient finances; even if a fully sufficient supply of financing were available, there is no longer any technology available for purchase. Creating and maintaining a supply of technology for availability to support users over the long-term (e.g. for many decades) faces many hurdles. Implantable technology often has a limited shelf life. Sterilized packaging likely expires within a few years and re-sterilization may not be an option (and requires addressing the

Regulatory Allowance issue first). Batteries within the implanted or even external devices will eventually expire. Further, the software utilized in these devices for operation and programming becomes outdated and difficult, if not impossible, to duplicate. As with the Regulatory Allowance issue, if technology availability is not assured for the ensuing years and decades during which users desire to continue utilizing their technology, then having a solution to the financing problem does not result in a practical solution to the overall the problem. At GIVE-A-HAND.tech, we propose working with investigators to identify solutions to the technology availability problem. These solutions include 1) banking inventory, i.e. implementing long shelf-life strategies under regulatory approval, and 2) identifying alternative technologies in advance of the study. Alternative technologies include open-source technologies that would be maintained in perpetuity by the non-profit. The significant advantage of open-source technologies is that the design, manufacturing, and operational documentation cannot be lost to the public. Such approaches place the responsibility for long-term technology availability onto an external sustainable entity (e.g. a non-profit), rather than on the backs of individual investigators who have limited professional lifetimes and limited resources. NIH can facilitate this solution by continuing to support open-source technologies that have the possibility of long-term relevance to the field.

3. Expertise Availability. In nearly all cases, the implementation and maintenance of implantable technology requires specialized expertise. This includes technical expertise related to the software and hardware (often the software, and sometimes the hardware, is built in-house with unique features), as well as surgical expertise related to device installation and replacement. In some cases, nursing expertise or occupational / physical therapy expertise is also needed. During the course of a study, these individuals are funded to actively enable the success of each individual user. However, once the study ends, how is that expertise maintained? The NIH Resource suggests that “Those responsible for planning and conducting the trial are encouraged to identify other individuals outside the research team with expertise in maintaining the device that can provide post-trial care in the absence of the research team.” Yet NIH provides no funding for such a hand-off and we are not aware of any source of funding that would support the ongoing availability of these experts. If studies end and experts are no longer supported, they will find other jobs and other careers and their expertise may be lost. Note that, to some extent, expertise is “encoded” in the IDE protocols and related technical documents such as the surgeon and user manuals and troubleshooting guides. Thus, if the Regulatory Allowance issue is solved, this may help significantly in the maintenance of expertise. This can be especially true if the regulatory documents are made open-source along with the technical design documents (see point “c” below).

4. Financing. The NIH Resource identifies multiple potential avenues for obtaining resources, none of which includes proposing that NIH provide any resources at all. Unfortunately, most of the identified avenues for providing financial resources in the “NIH Resource...” are impractical. For example, one option is “Whether the device manufacturer/sponsor has made a commitment to cover post-trial costs.” This seems to ignore the fact that, in most cases, the reason a technology has been abandoned is because the manufacturer/sponsor is no longer able to stay in business. A commitment to cover post-trial costs from a manufacturer who has gone out of business is hardly a viable plan for financial support. Further, as we have stated above, addressing finances is only useful after the top three issues have been addressed. For example, having some kind of long-term support insurance would seem like a possible solution, assuming such insurance exists. However, even if the insurance company were to provide a payout, how would the money be used to gain Regulatory Allowance, Technology

Availability, and Expertise Availability? Insurance companies are only set up to disburse funds, not develop implantable device programs. Here again, GIVE-A-HAND.tech proposes to address the top three issues and then help users, investigators, companies, and the entire field, find the means to obtain the necessary financial resources to maintain long-term use of individual implantable technologies.

Tangible Ways in Which NIH Could Offer Real Resources for Post-Trial Support. Despite the assertion in the NIH Resource that “NIH award funds cannot be used after the award period has ended”, this does not mean that NIH has no mechanism for providing financial support toward this issue. There are multiple approaches that NIH could take in providing tangible financial and practical support to the field in order to enable others to directly support individuals with implantable devices after the end of a funded study. We identify five approaches in the paragraphs that follow.

a. Encourage research into the long-term effects and impacts of implantable devices. There are many scientifically-relevant questions regarding long-term implants, particularly those implants with active electronics. These questions include: physiological issues, such as the body’s response over time to the presence of these devices; long-term failure modes and analysis of failure mechanisms; psychological and societal impact of devices; issues of aging with an implanted device; and long-term effectiveness of these systems in providing function and alleviating disease. NIH could develop a specific program supporting these areas of research which would allow researchers to obtain resources to continue studies, evaluate long-term effects, and continue support.

b. Encourage studies related to the ethics of device abandonment. There is a significant knowledge gap regarding implantable devices in long-term use and their impact on the individual. Even fundamental issues, such as the magnitude of the problem and the specific needs of the individuals involved, are largely unknown. NIH could fund studies that focus on these issues, possibly in partnership with other funding agencies and consumer advocacy groups.

c. Expand the support of open-source implantable hardware. The importance of open-source hardware to the long-term support problem is the assurance of long-term availability of technology. Obviously, there are no guarantees of long-term availability, but we do know that proprietary technology is always time-limited due to the fact that: 1) companies go out of business and take their technology with them into the abyss, or 2) companies change to a new product and bury the old system. Companies do not generally invest in older technologies that are no longer producing profits. Open-source hardware has the benefit of not being able to be “buried” by any private interests. Further, open-source hardware that finds broad use in the research community is much more likely to be sustained by that research community into the future. The NIH SPARC program led the way in supporting this approach with the HORNET program. NIH can encourage the further development of these programs by 1) issuing new RFPs for continued expansion of the concept and 2) by providing incentives for researchers to use open-source technologies in their research and contribute to their expansion. For example, the use of, or contribution to, open-source hardware and software could be a scorable criterion for certain proposals.

d. Support individual researchers and interested entities in interactions with the FDA regarding long-term support. NIH can take the lead in establishing open discussions between device researchers and the FDA regarding appropriate regulatory requirements for long-term support of individuals with implantable devices. At present, the IDE process is designed to support studies that are evaluating the safety and efficacy of a particular technology. By contrast, long-term support is rarely concerned with efficacy and would have different considerations concerning safety (e.g. short-term safety of the

technology has already been demonstrated). Long-term support may also be more concerned with how to troubleshoot and repair technologies – issues that do not have a specific research hypothesis associated with them.

e. Partner with emerging entities who are seeking to provide solutions to the long-term support problem. This includes evaluating existing (or proposed) programs and communicating these alternatives to the research community. For example, NIH could identify specific pre-approved approaches for long-term support that would partially or fully satisfy the “Post-Trial Transition Plan for Participants” section of proposals with clinical trials.

In summary, the initial draft of the “NIH Resource...” fails to sufficiently describe the problem of long-term support for implantable device trials, and falls short of providing researchers with any tangible “resources” related to that support. However, we feel that there is significant room to improve the document as a guide. Further, as we have identified, there are many different ways in which NIH could provide real resources to address this problem. We respectfully submit our comments and appreciate the opportunity to address this important problem.

Respectfully,
The GIVE-A-HAND.tech Board of Directors
Kevin Kilgore, President
Anne Bryden, Secretary
Brian Smith, Treasurer
Nathan Makowski, At Large
Website: give-a-hand.tech
Email Contact: Support@give-a-hand.tech

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified
N/A

1.3 Hurdles or barriers to broad use of this resource by the research community
N/A

1.4 Other feedback relevant to this resource
N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource
N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language
N/A

2.3 Hurdles or barriers to broad use of this resource by the research community

N/A

2.4 Other feedback relevant to this resource

N/A

Upload a File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/GIVE-A-HAND-Comments-on-NIH-Post-Trial-Resource.pdf>

Description: Letter describing comments related primarily to Resource 1.

Comments on NIH Publication: “Draft NIH Resource to Support Implantable Device Trials”, issued March 2026 (via NOT-OD-26-061)

These comments represent the views of GIVE-A-HAND.tech, a non-profit established to address the difficulty of post-trial support of study participants with implanted devices.

We appreciate the opportunity to provide feedback to NIH regarding the document entitled “Draft NIH Resources to Support Implantable Device Trials” issued March 2026 (and hereafter referred to as NIH Resources”). The comments that follow present the view of GIVE-A-HAND.tech, a 501(c)(3) non-profit. GIVE-A-HAND.tech was established in March 2025 with the mission “to serve as an adoptive home for people with, or who could benefit from, abandoned implantable medical devices. GIVE-A-HAND.tech will enable people to gain access to, and keep benefitting from, these devices for the remainder of their lifetimes.” Our board has a combined 100+ years of experience in long-term support of individuals with implantable devices. We are currently supporting a number of individuals who have been utilizing their implanted devices daily for more than 30 years. Our comments below are based on our ongoing experience in supporting these individuals and our analysis of the problems encountered in doing so.

We applaud NIH for identifying long-term support (or “post-trial needs”) as an important issue in the implantable device field; and for assembling and distributing the draft document for comment. However, the document fails to concretely address the three most important issues related to long-term support (and only identifies, but does not solve, the fourth). These issues, in order of importance, include: **1) regulatory “allowance”, 2) technology availability, 3) expertise availability, and 4) finances.** The document, as currently conceived, provides no actual “resources”, and minimal “guidance”, to investigators who are seeking to find solutions to this difficult problem. In our comments, we will address these four key issues and conclude with suggestions for practical and substantial resources that NIH could provide to help the field achieve a sustainable solution to this problem.

1. Regulatory “Allowance.” The NIH Resource fails to mention this most important difficulty in providing long-term support to individuals who want to continue to utilize and benefit from their implanted device beyond the end of a funded study. Specifically, the NIH Resource describes the support of individuals who have been implanted with Class II and Class III implantable medical devices within the U.S., typically under an Investigational Device Exemption (IDE) (but could also include 510k, PMA, HDE, etc.). Any effort to maintain the technology for these individuals *remains under the oversight of the FDA* (and often IRBs) despite the original study having ended. Thus, *the first and most important issue is to address the need for, and maintenance of, regulatory oversight.* As a common example, consider a study conducted under an IDE from the FDA. Often, the Principal Investigator (PI) of the study serves as the Sponsor-Investigator of that IDE. However, if the study is completed and funding has ended, then the PI has no resources to maintain the IDE beyond the end of grant funding. This means that adverse events may no longer be monitored, device inventory may no longer be tracked, and annual reports will not be filed. In these cases, the IDE becomes abandoned because there are no resources to maintain it. There are also cases where the PI retires or is otherwise unable to be involved in the study. Again, the IDE becomes abandoned. Once abandoned, it is extremely unlikely that an IDE could be “revived” by simply starting new annual reports and performing other reporting requirements. Instead, it is likely that a *new* IDE would have to be submitted and the approval process would need to be navigated all over again. Such an effort is costly, difficult, and requires someone with a high level of commitment and regulatory skills. At GIVE-A-HAND.tech, we recognize that the most critical aspect in

providing support is to first ensure that the IDE *does not become abandoned in the first place*. Thus, we propose that GIVE-A-HAND.tech (or any other suitable non-profit) would become the Sponsor of these IDEs *before they become abandoned*. NIH could tangibly support investigators facing these situations by working together with the FDA to create designated “Long-term Support IDEs” with practical and realistic follow-up procedures. ***We strongly encourage NIH to come forward as the lead broker for this effort, working together with the FDA, investigators, companies, and non-profits to achieve a solution to the “Regulatory Allowance” problem.*** If this problem is not solved, none of the other efforts (listed below and also identified in the NIH Resource document) will provide any solution to the problem.

2. Technology Availability. Frequently, long-term support of users of an implantable device becomes practically impossible because the technology is no longer available. This is obviously the case in studies where the study sponsors are also the manufacturers of the device (or substantially modify a manufactured device). When that study sponsor is lost, the manufacturing of the device ceases and, in addition, often the documentation related to the design and operation of that technology is lost. If the long-term user has a component that breaks (either implanted or external), there is no longer any technology available to replace that component. It is important to note that frequently, even the design details are lost, such that there would not even be a way to find a new manufacturer of the device. ***This issue is much more critical, in most cases, than finding sufficient finances; even if a fully sufficient supply of financing were available, there is no longer any technology available for purchase.*** Creating and maintaining a supply of technology for availability to support users over the long-term (e.g. for many decades) faces many hurdles. Implantable technology often has a limited shelf life. Sterilized packaging likely expires within a few years and re-sterilization may not be an option (and requires addressing the Regulatory Allowance issue first). Batteries within the implanted or even external devices will eventually expire. Further, the software utilized in these devices for operation and programming becomes outdated and difficult, if not impossible, to duplicate. As with the Regulatory Allowance issue, if technology availability is not assured for the ensuing years and decades during which users desire to continue utilizing their technology, then having a solution to the financing problem does *not* result in a practical solution to the overall the problem. At GIVE-A-HAND.tech, we propose working with investigators to identify solutions to the technology availability problem. These solutions include 1) *banking inventory*, i.e. implementing long shelf-life strategies under regulatory approval, and 2) *identifying alternative technologies* in advance of the study. Alternative technologies include open-source technologies that would be maintained in perpetuity by the non-profit. The significant advantage of open-source technologies is that the design, manufacturing, and operational documentation cannot be lost to the public. Such approaches place the responsibility for long-term technology availability onto an external sustainable entity (e.g. a non-profit), rather than on the backs of individual investigators who have limited professional lifetimes and limited resources. ***NIH can facilitate this solution by continuing to support open-source technologies that have the possibility of long-term relevance to the field.***

3. Expertise Availability. In nearly all cases, the implementation and maintenance of implantable technology requires specialized expertise. This includes technical expertise related to the software and hardware (often the software, and sometimes the hardware, is built in-house with unique features), as well as surgical expertise related to device installation and replacement. In some cases, nursing expertise or occupational / physical therapy expertise is also needed. During the course of a study, these individuals are funded to actively enable the success of each individual user. However, once the study ends, how is that expertise

maintained? The NIH Resource suggests that “Those responsible for planning and conducting the trial are encouraged to identify other individuals outside the research team with expertise in maintaining the device that can provide post-trial care in the absence of the research team.” Yet NIH provides no funding for such a hand-off and we are not aware of any source of funding that would support the ongoing availability of these experts. If studies end and experts are no longer supported, they will find other jobs and other careers and their expertise may be lost. Note that, to some extent, expertise is “encoded” in the IDE protocols and related technical documents such as the surgeon and user manuals and troubleshooting guides. Thus, if the Regulatory Allowance issue is solved, this may help significantly in the maintenance of expertise. This can be especially true if the regulatory documents are made open-source along with the technical design documents (see point “c” below).

4. Financing. The NIH Resource identifies multiple potential avenues for obtaining resources, none of which includes proposing that NIH provide *any resources at all*. Unfortunately, most of the identified avenues for providing financial resources in the “NIH Resource...” are impractical. For example, one option is “Whether the device manufacturer/sponsor has made a commitment to cover post-trial costs.” This seems to ignore the fact that, in most cases, the reason a technology has been abandoned is because the manufacturer/sponsor is no longer able to stay in business. A commitment to cover post-trial costs from a manufacturer who has gone out of business is hardly a viable plan for financial support. Further, as we have stated above, addressing finances is only useful *after the top three issues have been addressed*. For example, having some kind of long-term support insurance would seem like a possible solution, assuming such insurance exists. However, even if the insurance company were to provide a payout, how would the money be used to gain Regulatory Allowance, Technology Availability, and Expertise Availability? Insurance companies are only set up to disburse funds, not develop implantable device programs. Here again, GIVE-A-HAND.tech proposes to address the top three issues and then help users, investigators, companies, and the entire field, find the means to obtain the necessary financial resources to maintain long-term use of individual implantable technologies.

Tangible Ways in Which NIH Could Offer Real Resources for Post-Trial Support. Despite the assertion in the NIH Resource that “NIH award funds cannot be used after the award period has ended”, this does not mean that NIH has no mechanism for providing financial support toward this issue. There are multiple approaches that NIH could take in providing tangible financial and practical support to the field in order to enable others to directly support individuals with implantable devices after the end of a funded study. We identify five approaches in the paragraphs that follow.

a. *Encourage research into the long-term effects and impacts of implantable devices.* There are many scientifically-relevant questions regarding long-term implants, particularly those implants with active electronics. These questions include: physiological issues, such as the body’s response over time to the presence of these devices; long-term failure modes and analysis of failure mechanisms; psychological and societal impact of devices; issues of aging with an implanted device; and long-term effectiveness of these systems in providing function and alleviating disease. NIH could develop a specific program supporting these areas of research which would allow researchers to obtain resources to continue studies, evaluate long-term effects, and continue support.

b. *Encourage studies related to the ethics of device abandonment.* There is a significant knowledge gap regarding implantable devices in long-term use and their impact on the individual. Even fundamental issues, such as the magnitude of the problem and the specific needs of the individuals involved, are largely unknown. NIH could fund studies that focus on

these issues, possibly in partnership with other funding agencies and consumer advocacy groups.

c. *Expand the support of open-source implantable hardware.* The importance of open-source hardware to the long-term support problem is the assurance of long-term availability of technology. Obviously, there are no guarantees of long-term availability, but we do know that *proprietary* technology is always time-limited due to the fact that: 1) companies go out of business and take their technology with them into the abyss, or 2) companies change to a new product and bury the old system. Companies do not generally invest in older technologies that are no longer producing profits. Open-source hardware has the benefit of not being able to be “buried” by any private interests. Further, open-source hardware that finds broad use in the research community is much more likely to be sustained by that research community into the future. The NIH SPARC program led the way in supporting this approach with the HORNET program. NIH can encourage the further development of these programs by 1) issuing new RFPs for continued expansion of the concept and 2) by providing incentives for researchers to use open-source technologies in their research and contribute to their expansion. For example, the use of, or contribution to, open-source hardware and software could be a scorable criterion for certain proposals.

d. *Support individual researchers and interested entities in interactions with the FDA regarding long-term support.* NIH can take the lead in establishing open discussions between device researchers and the FDA regarding appropriate regulatory requirements for long-term support of individuals with implantable devices. At present, the IDE process is designed to support studies that are evaluating the safety and efficacy of a particular technology. By contrast, long-term support is rarely concerned with efficacy and would have different considerations concerning safety (e.g. short-term safety of the technology has already been demonstrated). Long-term support may also be more concerned with how to troubleshoot and repair technologies – issues that do not have a specific research hypothesis associated with them.

e. *Partner with emerging entities who are seeking to provide solutions to the long-term support problem.* This includes evaluating existing (or proposed) programs and communicating these alternatives to the research community. For example, NIH could identify specific pre-approved approaches for long-term support that would partially or fully satisfy the “Post-Trial Transition Plan for Participants” section of proposals with clinical trials.

In summary, the initial draft of the “NIH Resource...” fails to sufficiently describe the problem of long-term support for implantable device trials, and falls short of providing researchers with any tangible “resources” related to that support. However, we feel that there is significant room to improve the document as a guide. Further, as we have identified, there are many different ways in which NIH could provide real resources to address this problem. We respectfully submit our comments and appreciate the opportunity to address this important problem.

Respectfully,
The GIVE-A-HAND.tech Board of Directors
Kevin Kilgore, President
Anne Bryden, Secretary
Brian Smith, Treasurer
Nathan Makowski, At Large
Website: give-a-hand.tech
Email Contact: Support@give-a-hand.tech

5. J. Galen Buckwalter, PhD

I am responding: On behalf of myself

Name: J. Galen Buckwalter, PhD

Name of Organization: N/A

Type of Organization: Not Applicable

Role: Other

Role - Other: Participant/Scientist

Domain of research most important to you or your organization: Neuroethics

Date Submitted: 5/13/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

Resource 1 correctly identifies the ethical complexity of implantable device trials but stops short of establishing enforceable protections. As written, it permits the transfer of long-term medical, financial, and continuity risks onto participants, despite these risks arising directly from research participation. For high-risk, potentially irreversible interventions, these elements should be elevated from optional considerations to required standards.”

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 1: Plan/Options for Device Explantation or Remaining In Situ

Strengths

Recognizes dual pathways (explant vs. retention)

Incorporates participant preference

Encourages individualized decision-making

Core Problems

Autonomy not binding: Participant preference may be overridden without clear thresholds

No protection against coercion: Retention/explantation may be implicitly conditioned

Static consent model: No requirement for ongoing or post-trial re-consent

No ethical default: Fails to establish when retention vs. explantation should be presumed

Bottom Line

Treats device disposition as a clinical/logistical choice, not a matter of ongoing bodily autonomy and consent.

Element 2: Risks and Potential Benefits

Strengths

Identifies key risks: surgical, chronic implantation, loss of benefit, loss of support

Core Problems

Loss of benefit minimized: Not treated as a clinically meaningful harm

Dependency ignored: No recognition of neural, behavioral, or psychological reliance

Systemic risks understated: Manufacturer withdrawal framed as contingency, not structural risk

No decision thresholds: No guidance for comparing explantation vs. retention risks

Bottom Line

Risks are enumerated but not operationalized, leaving participants exposed to poorly bounded uncertainty.

Element 3: Anticipated Participants' Needs

Strengths

Broad scope: clinical, technical, psychosocial, regulatory

Core Problems

Descriptive, not predictive: No requirement for scenario-based planning

Psychosocial needs underdeveloped: Not tied to required services or monitoring

Healthcare system gaps minimized: Limited attention to provider inexperience and access barriers

No prioritization: Critical vs. non-critical needs not distinguished

Bottom Line

Identifies needs but does not ensure realistic planning or prioritization.

Element 4: Plans for Meeting Former Participants' Needs

Strengths

Addresses both retained and explanted participants

Recognizes need for continuity of expertise and care

Core Problems

No enforceable obligations: "Plans" may exist without guarantees

Continuity is aspirational: No requirement for institutional responsibility beyond individuals

Access uncertainty: No guarantee of hardware, software, or technical support

Weak transition planning: No fallback if standard care options are unavailable

Bottom Line

Creates plans without accountability, leaving continuity of care uncertain.

Element 5: Financial Plan

Strengths

Transparently acknowledges cost burden and insurance uncertainty

Core Problems

Cost shifting normalized: Participants may bear long-term costs

No minimum coverage standard: No requirement for essential protections

No secured funding requirement: Plans may be speculative

Lifecycle gap: No obligation to cover long-term maintenance, complications, or explantation

Bottom Line

Represents a systematic ethical failure—financial risk is externalized to participants.

Element 6: Oversight of Long-Term Care Plan

Strengths

Recognizes need for monitoring and responsible party

Core Problems

No enforcement mechanism: No consequences for failure

Undefined duration: Oversight not aligned with long-term implant realities

Lack of independence: Oversight may remain within conflicted entities

No participant recourse: No grievance or escalation pathways

Bottom Line

Oversight is nominal, not functional—lacks enforceability and durability.

Best Practice Considerations

Strengths

Ethically progressive principles:

Retain device if beneficial

Respect participant wishes

Encourage continued care

Core Problems

Non-binding: Can be ignored without justification

No ethical floor: No minimum acceptable standard

Internal inconsistency: Recommends care while acknowledging it may not exist

No prioritization: Essential vs. aspirational practices not distinguished

Bottom Line

Ethically sound but structurally toothless.

Cross-Cutting Failures

1. Voluntary Framework Problem

Entire document framed as optional guidance

Inadequate for high-risk, irreversible interventions

2. Temporal Mismatch

Trials are time-limited

Participant risks are long-term or lifelong

Framework remains trial-centric

3. Burden Misallocation

Participants bear:

medical risk

financial burden

continuity risk

Institutions retain:

limited, discretionary responsibility

Closing Position

Resource 1 identifies the correct ethical terrain but fails to establish enforceable protections. In its current form, it permits the transfer of long-term risks—medical, financial, and structural—onto participants. For implantable device trials, these elements should be elevated from optional considerations to required minimum standards aligned with the principles of respect for persons, beneficence, and justice.

1.3 Hurdles or barriers to broad use of this resource by the research community

1. Lack of Enforceability (“Voluntary Guidance” Problem)

The document explicitly states it is voluntary and not regulatory guidance

Investigators and institutions are **not required to comply, even if gaps are obvious

In practice, busy research teams default to:

- * IRB minimum requirements

- * sponsor constraints

- * Anything beyond that—especially complex post-trial obligations—gets deprioritized

This resource likely becomes:

a reference document, not a decision driver

Adoption is inconsistent and selective, especially in resource-constrained settings

Bottom line

If it’s optional, it will be applied unevenly—and often ignored where it matters most.

2. Resource and Funding Constraints (Structural Feasibility Problem)

The resource calls for:

- * long-term care planning
- * device maintenance
- * continuity of expertise

At the same time, it acknowledges:

NIH funding cannot extend beyond the award period
Insurance coverage is uncertain

Investigators lack:

- * funding mechanisms
- * institutional support
- * contractual leverage with manufacturers

Even well-intentioned teams cannot operationalize:

- * long-term maintenance
- * guaranteed care pathways

Leads to aspirational plans rather than executable ones.

Bottom line

The resource asks for long-term responsibility without providing a viable way to fund or sustain it.

3. Misalignment of Incentives Across Stakeholders (Accountability Problem)

Responsibility is described as “shared” among:

- * investigators
- * institutions
- * sponsors
- * manufacturers

Shared responsibility often means diffused accountability.

Each party has incentives to limit long-term obligations:

investigators → grant-limited timelines
institutions → liability exposure
manufacturers → commercial risk
sponsors → cost containment

No single entity is:

- * clearly responsible
- * contractually obligated

* Critical needs (e.g., maintenance, explanation, follow-up care) fall into **gaps between stakeholders**

Bottom line

Adoption is limited because the resource is optional, unfunded, and structurally unaccountable.

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

Resource 2—*Informed Consent for Research Using Investigational Implantable Devices*—represents a meaningful and timely effort to improve the quality, clarity, and scope of informed consent in a domain where traditional consent models have been insufficient. Its primary utility lies in its ability to "surface and standardize discussion of issues that have historically been under-communicated", particularly those related to post-trial uncertainty, long-term device maintenance, and the practical realities of living with an investigational implant beyond the study period. By encouraging plain language, structured disclosure, and explicit discussion of downstream risks, the resource meaningfully enhances transparency and participant understanding.

From a usability standpoint, the document is well-designed for research teams. The inclusion of modular "points to consider" alongside adaptable sample language allows investigators and IRBs to incorporate relevant sections into consent forms efficiently. Its organization around standard consent components (procedures, risks, benefits, costs, etc.) facilitates integration into existing workflows without requiring a complete redesign of institutional templates. Additionally, its emphasis on readability and participant comprehension aligns with best practices and is likely to improve the consistency and completeness of consent documents across studies.

However, the utility of Resource 2 is ultimately constrained by its scope and positioning as a disclosure tool rather than a protective framework. While it improves what participants are told, it does not meaningfully alter what participants can expect in terms of support, rights, or safeguards. Investigators can fully comply with the resource while still asking participants to accept substantial, foreseeable risks—such as loss of device support, limited access to expertise, or significant financial burden—without any obligation to mitigate those risks. In this sense, the resource risks functioning as a mechanism for enhanced risk disclosure without corresponding risk management.

There are also practical limits to usability in high-complexity contexts. Even when clearly written, the volume and sophistication of information required—particularly around long-term contingencies—may exceed what participants can realistically process or act upon in a typical consent interaction. This is especially true for implantable device trials, where risks are longitudinal, uncertain, and dependent on future institutional and market conditions. As a result, the usability of the document for participants is

uneven: while it improves clarity, it does not resolve the deeper challenge that many of the most important risks are structural and not meaningfully within the participant's control.

Finally, the effectiveness of Resource 2 is tightly coupled to the strength of the underlying post-trial care planning (as outlined in Resource 1). Where such plans are robust and well-resourced, Resource 2 can serve as a powerful communication tool. Where they are weak, speculative, or unfunded, the consent process may accurately describe uncertainty but cannot compensate for it. This creates a situation in which high-quality consent language may coexist with inadequate participant protections, limiting the real-world impact of the resource.

In sum, Resource 2 is highly usable and valuable as a standardization and transparency tool, and it will likely improve the quality of informed consent documents across the research community. Its utility, however, is bounded by the absence of enforceable protections: it enables participants to better understand the risks they are assuming, but does not ensure those risks are acceptable, mitigated, or fairly distributed. For implantable device research, particularly in high-risk or irreversible contexts, its full potential will only be realized if paired with stronger requirements for post-trial care, financial protection, and long-term accountability.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Cross-Cutting Requirement (Critical)

Across all sections, Resource 2 should explicitly require:

1. Definition of Neural Data

Raw signals

Processed signals

Decoded outputs

Derived inferences

2. Ownership / Control Framework

Ownership vs. license vs. custodianship

Participant rights (if any)

3. Secondary Use Transparency

AI training

Commercial development

Data sharing

4. Limits of Withdrawal

Clear, specific, unavoidable constraints

Bottom-Line Position

Neural data is qualitatively different from other biomedical data: it is persistent, potentially identifying,

and capable of revealing highly sensitive information. Resource 2 must move beyond general privacy language and explicitly address ownership, control, reuse, and long-term risk of neural data across all consent components.

2.3 Hurdles or barriers to broad use of this resource by the research community

1. Legal Risk Aversion → Safe Harbor + Required Core Language**

Barrier

Institutions resist fully transparent consent language because:

- * it exposes uncertainty (e.g., loss of support, cost burden)
- * it may increase perceived liability

Leads to diluted or avoided use of Resource 2.

Solution

Establish a regulatory safe harbor (via Office for Human Research Protections / U.S. Food and Drug Administration) where good-faith use of Resource 2 language does not increase liability exposure

Require non-editable core consent modules, including:

- * post-trial uncertainty
- * financial exposure
- * neural data ownership, reuse, and limits of withdrawal

Bottom line

Protect disclosure legally → institutions will actually use it.

2. Operational Complexity → Modular Tools + Pre-Approved Language

Barrier

Resource 2 is:

- * complex
- * time-intensive
- * requires expertise most teams lack

Leads to partial or superficial implementation.

Solution

NIH provides:

- * plug-and-play consent builder (modular sections)
- * IRB-approved language library

Include a standard neural data stewardship module:

- * tiered/modular consent
- * data sharing
- * AI/commercial use
- * revocation rights

Bottom line

Make it easy to implement → adoption scales.

3. Credibility Gap (Disclosure Without Support) → Tie Consent to Enforceable Plans

Barrier

Researchers must disclose risks they cannot mitigate:

- * no guaranteed long-term care
- * uncertain device support
- * unclear data governance

Leads to vague language and weak consent.

Solution

Require no disclosure without a plan:

- * If a risk is disclosed → a credible mitigation or support plan must exist

Link Resource 2 to:

- * mandatory post-trial care standards (Resource 1)
- * binding data governance plans, including:
 - * neural data ownership/control
 - * sharing restrictions
 - * withdrawal/revocation limits

Bottom line

Align what is disclosed with what is actually delivered.

Synthesis

Adoption of Resource 2 depends on making it legally safe, operationally simple, and credibly aligned with real protections—especially for neural data ownership, use, and control.

2.4 Other feedback relevant to this resource

N/A

Upload a File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/Neural-Data-Stewardship-1-1.docx>

Description: This is a very preliminary draft of a Neural Data Stewardship model of consent for neural data. The hope is it furthers the ongoing discussion of the ethical treatment of neural data.

Neural Data Stewardship (Participant-Centered Model)

What is “Neural Data”?

In this study, we will collect “neural data,” which includes:

- signals recorded from your nervous system (e.g., brain or nerve activity),
- processed versions of those signals, and
- information inferred from those signals (e.g., intended movement, communication, or patterns of activity).

Neural data may be unique to you, difficult to fully de-identify, and may reveal sensitive information about your health, behavior, or patterns of thinking.

Our Stewardship Commitment

We use a stewardship model, which means:

- You are the source and primary stakeholder of your neural data.
 - The research team acts as a steward (caretaker), not an unrestricted owner.
 - We will use your data only in ways you permit, with ongoing opportunities for you to review and change those permissions.
-

Your Choices (Modular Consent)

You can choose which potential uses of your neural data you may want to explore. If any opportunities for future use of your data are brought to our attention, we will contact you to give you the information you need to decide if you want to participate. Separate Consent is needed for any use of your data beyond the current study.

Please check each box that you would consider becoming involved in were any such opportunities become available. You may change these choices at any time.

Please initial your choices:

- ☐ **Use for this study** (required to participate)
- ☐ **Future academic research** (by this or other universities or non-profit institutions)
- ☐ **Technology development** (including collaboration with industry partners)
- ☐ **Commercial use** (development of products or services for sale)
- ☐ **Data sharing with other qualified researchers**
- ☐ **Use in artificial intelligence / machine learning development**

You may decline any optional category without affecting your participation in this study.

Ongoing Control (Participant Dashboard)

We will provide you with access to a participant data portal (“dashboard”), where you can:

- review how your data are being used,
- update your consent choices,
- request restrictions on future use, and
- submit questions or concerns.

If electronic access is not available to you, you may exercise these rights by contacting the study team.

Right to Withdraw and Revoke Data Use

You may withdraw from the study at any time.

If you withdraw, you may also request that:

- no new data be collected, and
- previously collected data no longer be used in future research.

Important limitations:

- Data already used in completed analyses, publications, or regulatory submissions cannot be removed.
- Data already shared with other researchers or incorporated into large datasets may not be fully retrievable or deletable.
- We will make reasonable, good-faith efforts to stop future use and withdraw your data from active datasets where possible.

We will explain clearly what actions were taken in response to your request.

Privacy and Risks

We take steps to protect your data, including secure storage and controlled access. However:

- Neural data may be uniquely identifying. That is neural data may contain information that could only come from you

- There is some degree of risk of unauthorized access or re-identification
 - Future technologies may increase the ability to interpret or link data back to you
-

Future Use and Re-Contact

- We will ask for your permission before using your data in new ways.
 - In some cases (e.g., large datasets you previously consented to), re-contact may not be possible.
-

Commercial Use and Benefit Sharing

Your neural data may contribute to technologies that have commercial value.

If substantial commercial value is created directly from datasets that include your data, the institution will consider mechanisms for participant-aligned benefit sharing, consistent with applicable laws and policies.

Right to Transparency and Audit

You have the right to:

- request information about how your data have been used,
- receive a summary of categories of data sharing, and
- request review of whether your data use aligns with your consent choices.

We will provide this information in a clear and understandable format.

Data Storage and Duration

Your neural data may be stored for many years or indefinitely for research purposes.

Even if your device is removed or stops working, previously collected data may continue to be used, subject to your consent choices and any withdrawal requests.

Oversight and Accountability

Use of your data is overseen by:

- the research team,
- institutional review boards (IRBs), and
- institutional data governance and privacy policies.
- you

Contact for questions or concerns:

- Study team: [insert contact]
 - Data privacy / governance office: [insert contact]
-

Summary

By participating, you are allowing us to steward your neural data under a model that emphasizes:

- your ongoing control and choice,
- transparency in data use, and
- responsible, accountable handling of your information over time.

6. Melissa Reeves

I am responding: On behalf of myself

Name: Melissa Reeves

Name of Organization: N/A

Type of Organization: Government Agency

Role: Investigator/Researcher

Domain of research most important to you or your organization: Rare ophthalmic disease

Date Submitted: 5/14/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

I think this is a very good resource that could easily be used by the community.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

I think the main concern would be regarding long-term care for implantable devices. The follow-up for the device (if left in place) should be for a defined time and performed by the study team. I would recommend working in a post-primary study plan as a part of the initial grant (or other funding mechanism) proposal to ensure funding is available to the study team throughout the primary study and post-follow-up. Since the technology may be unique and not supported (either in device or software) by the community, the funding team should be prepared to provide follow-up device care to participants post initial study and include those data points as a part of the study. For instance, if the study team included a post-primary study 5-year follow-up, they could collect data on any device malfunction, battery loss, physical complications, or any other unforeseen circumstances on an annual basis. If after 1 or 2 years, the devices are no longer useful (providing any measurable influence on the participant), the device could be removed, and the participant would be finished with the study. Any remaining funds that are not used in the post-primary study could be returned or reallocated to the study in other ways (data analysis or data sharing) if written into the original proposal. An official post-primary study period could also allow time for the device to become FDA-approved, which would impact the participant directly in terms of insurance coverage and follow-up by a PCP.

1.3 Hurdles or barriers to broad use of this resource by the research community

N/A

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

N/A

2.3 Hurdles or barriers to broad use of this resource by the research community

N/A

2.4 Other feedback relevant to this resource

N/A

7. Sara Goering

I am responding: On behalf of myself

Name: Sara Goering

Name of Organization: UW Neuroethics Research Group

Type of Organization: Other

Type of Organization - Other: Research group within academic institution

Role: Bioethicist

Domain of research most important to you or your organization: ethics of implantable neurotechnology

Date Submitted: 5/21/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

N/A

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

N/A

1.3 Hurdles or barriers to broad use of this resource by the research community

N/A

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

N/A

2.3 Hurdles or barriers to broad use of this resource by the research community

N/A

2.4 Other feedback relevant to this resource

N/A

Upload a File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/Comments-on-NIH-Draft-Resources-to-Support-Implantable-Device-Trials.pdf>

Description: Our brief comments are collected in the attached PDF.

Comments on NIH Draft Resources to Support Implantable Device Trials - Due **May 25, 2026**.

1. We appreciate the effort to ensure that all investigators working on implantable devices are thinking through long-term care planning for the participants, regarding the full range of options from explantation to full continued use (with the likely need for follow-up maintenance associated with very specific expertise).

2. We thought it might make sense to include attention to two additional issues:

a. Issues of participant capacity changing over the course of the research (or after the study), and what should happen in those cases. This might be a restoration of capacity through the intervention, or a loss of capacity, due to progressive disease.

b. Issues of data privacy and ownership (in resource 2). In our own work with participants, we have found that some people are quite interested in having access to their own data, and some are concerned about who else will have access to their data. Not including this issue in that section felt like an oversight.

3. We appreciate the difficulty of trying to cover a wide range of different kinds of implantable device studies. We did wonder, though, if the intentional hands-off approach (e.g., these are guidelines that are entirely voluntary, and may not apply), combined with the longer list of duties related to providing post-trial care and planning, might have the (perhaps unintended effect?) of nudging researchers to set a short explantation date and aim to stick to it. Another way of putting this point is that while the documents call out factors that ought to be considered, there aren't many teeth in them. It's more a list of what should be considered, rather than a recommendation for what should be provided.

a. The best practice considerations section seems like the place this should happen. The first bullet suggests offering a participant the option of keeping the device "unless there is an ethical, medical, regulatory, legal and/or scientific justification otherwise" (maybe a strong or compelling ... reason otherwise)? We'd like to see the default put more strongly on keeping the device.

b. Similarly, later in that section, it says "Within pre-specified limits, medically indicated device related care should be provided or access to such care facilitated" but it doesn't make recommendations for what those pre-specified limits should be. Should there be at least one battery change? Battery changes for life?

c. We also felt like a move away from more legalistic language (e.g., in the start of the Sample Language Components, resource 2, it says "After this study ends, *we can't promise* that you will be able to obtain replacement parts for [x device]. We also can't promise that you will be able to see a doctor that knows how to maintain or remove this device.") toward language that is more positive and reassuring (e.g., "After this study ends, *we will make a good faith effort to ensure* that you are able to obtain replacement parts for [x device], even though that may not always be possible.")

4. We have few minor questions/suggestions:

- a. Maybe offer some examples of other kinds of implantable devices (given that the examples are primarily from implantable neural devices). Options: implantable cardiac defibrillators, pacemakers, insulin pumps, stentroids?
- b. Try to distinguish between kinds of care (clinical, support more generally, financial?) to consider. Sometimes care is defined as support, sometimes the document refers to “care and support.”
- c. Similarly, sometimes “benefit” is used very generally, and sometimes only for clinical benefit, therapeutic benefit, or personal benefit.
- d. The first bullet of Resource 1’s Element 1 has a parenthetical that doesn’t really follow (what’s in parentheses is not really an example of a decision making process). For the second bullet point, we’d add “and what options are available for explantation outside the original timeline.”
- e. In Resource 2, under “long-term practical considerations” the initial paragraph says “Investigators may consider providing this information via a section of the consent form (as demonstrated here) or by covering the information listed below in other sections of the consent form.” (We’re not sure how those are distinct options.)

8. American Brain Coalition

I am responding: On behalf of an organization

Name: Katie Sale

Name of Organization: American Brain Coalition

Type of Organization: Other

Type of Organization - Other: ABC is an umbrella organization representing the nation's leading professional neurological, psychological, psychiatric associations and patient organizations, clinicians, researchers, academia, industry, and government agencies.

Role: Organizational Official

Domain of research most important to you or your organization: Neuroscience

Date Submitted: 5/21/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

As an organization that represents many different brain and CNS conditions with several in leadership people who live with implantable devices, those approved to be on the market and those received under clinical trial, I cannot understate the importance of this resource. This is a first-of-its-kind resource to help investigators convey to prospective clinical trial participants the potential benefits, risks, and long-term care needs associated with implantable device trials. It is essential for researchers conducting implantable device trials to share the complexity of post-trial explantation, post-trial care, and device maintenance to ensure trial participation is determined based on a firm and complete understanding by the participant of all possible consequences of the study. Investigators and institutions should not only make the information covered by this resource available to prospective trial participants, but they should also ensure that participants read and comprehend the subject matter. Importantly, this resource allows researchers to proceed in the way that best fits their needs while ensuring that certain elements specific to implant trials are addressed. The document would be rendered even more useful if it were paired with structured templates to aid in the creation of post-trial care plans for participants. Beyond the current resource, it may also be beneficial to provide an additional approach by which the trial participant is offered a market-available alternative to the device following the trial that would help meet their individual health needs.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

- Element 1- Plan/Options for Device Explanation or Remaining In Situ
- o This element should also include discussion of potential future explantation-i.e. what if explantation is not planned for, but becomes necessary down the road. The document should discuss how an individual would recognize needs associated with their implanted device and the steps they should take with the institution or product sponsor to address unanticipated concerns.

- Element 2- Risks and Potential Benefits
 - o This element should also address communications planning for determining any changes to protocol should they become necessary during the life of the implanted device.
 - o This element also requires the additional discussion of chronic or long-term health impacts that may develop over time and are separate and distinct from acute surgical risks in trial, as well as third-party risk that may arise from other proximate devices or equipment that the participant may encounter.
- Element 3- Anticipated Participants' Needs
 - o This element should include discussion of what happens if explantation becomes required if the device is not cleared or approved by the FDA. If the device is not initially explanted, nor is it approved by the FDA, how does the team assess future safety of the device and how will the participant manage the device, particularly in the future if there are no qualified experts to help with device maintenance or care.
 - o This element could also be improved with the additional of discussion of potential participant advisory processes or shared decision-making tools beyond the investigator.
 - o Beyond care and support related to the implant, this element should address how the implant may affect other care that the participant may need (e.g., whether the participant is eligible to receive other implants in the future, if the device is not magnetic resonance (MR) conditional, how this may affect the participant's overall healthcare).
 - o In addition, this section does not address the needs of legally authorized representatives (LARs) or caregivers who may be involved in device management for participants who lack capacity. In pediatric trials and in trials involving participants with neurodegenerative or psychiatric conditions, caregiver needs are substantive and should be anticipated in the plan.
 - o There is also a lack of information on how to accommodate participants with geographic needs. Participants who travel significant distances for trial participation may face particular hardships accessing post-trial care if that care is only available at the enrolling institution. Investigators should be prompted to address how participants in remote or underserved communities will access device-related care after the trial.
- Element 4- Plans for Meeting Former Participants' Anticipated Needs
 - o This element should be explicit about what to do in the event of an acute health care need associated with the device, including infection. For instance, are there health care facilities local to the participant that are most equipped to respond to acute concerns associated with implanted devices? Additionally, the element should recommend that investigators and sponsors clearly identify the party responsible for coordinating post-trial care.
 - o This element should also include outlines for a formal transition of care of an implanted device from the investigator team after the trial. This includes resources the participant can share with their primary care physician or other providers. Participants should be made aware of how the implanted device may impact their access to health care, including regarding insurance coverage or other payment needs.
 - o This element should also include plans for participant contact if safety information about the device changes after the trial, for example, in the event of a safety recall or if new data emerges from additional studies. This includes contact information in the event the participant contact information changes in the future.
- Element 5- Financial Plan
 - o This is a critically important element given the growing cost of health care in the U.S. It is

essential to ensure that trial participants are not saddled with large bills for post-trial care after volunteering to take part in potentially risky research that could foster a significant benefit for the population. While this element does a good job of laying out the considerations, including whether the device manufacturer/sponsor will cover post-trial costs and whether trial specific insurance will be available, if the trial lacks financial resources for post-trial care that factor must be explicitly explained to potential trial participants.

- o This element also does not address potential financial implications for participants access to insurance coverage after the trial. Investigators should be prompted to address that eventuality.
- o Another option that could benefit prospective participants would be financial counseling to determine the financial risks and potential out of pocket costs involved with trial participation, what may be needed from the participant, and whether the participant can meet the future needs. No potential participant should be turned away from a trial because of inability to afford out of pocket costs related to post-trial care of the device.,
- o While it is currently the case that NIH award funds cannot be used after the award period has ended, NIH should consider allowing investigators to submit a financial plan as part of their grant submission for funds to be set aside by the institution to be allocated to post trial care of participants. By design, implant trials may present long-term needs and this should be considered.
 - Element 6- Oversight of Long-Term Care Plan for Implantable Device Studies
- o This should include a plan for continuous oversight of long-term care in the event that staff/experts transition away from the study and/or the institution that conducted the study.
- o This element should also address the overlap between long-term care plan oversight and any post market surveillance requirements set by FDA after device approval. These oversight functions should be coordinated.

1.3 Hurdles or barriers to broad use of this resource by the research community

- Resources to help investigators adapt the recommendations from this document into other formats, including additional languages, or for use by individuals with disabilities, could aid the implementation by the research community.
- Social workers or others with expertise in navigating uncertain health care scenarios with individuals could be an asset in implementing this as well. This document could include information on making such resources available to trial participants if there is funding available to do so (i.e. through the manufacturer or sponsor).
- This document recommends that investigators consider developing a post-trial care plan “if such a plan is required by the NIH Institute, Center, or Office,” but the document does not clarify whether NIH will require post-trial care plans as a condition of funding for implantable device trials.

1.4 Other feedback relevant to this resource

- o The financial dimensions of post-trial device retention extend beyond direct maintenance or explantation costs and should be understood within the broader context of health care access and equity. The continued presence of an investigational implantable device — whether active or inactive — may impose clinically significant constraints on a former participant's eligibility for standard medical and surgical interventions unrelated to the original trial. For example, participants retaining devices in anatomically sensitive locations may be precluded from otherwise indicated surgical procedures, and those with devices that are not magnetic resonance imaging (MRI) conditional or compatible may face meaningful limitations in access to routine and advanced diagnostic imaging. These constraints represent

a form of compounded burden in which former participants may have diminished access to standard healthcare resources available to the general population, with consequences that are likely to be most acute for individuals in underserved communities, those with limited insurance coverage, or those managing concurrent chronic conditions. Post-trial care plans should therefore explicitly address not only costs directly attributable to the investigational device but also the downstream effects of device retention on participants' broader healthcare access and eligibility.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

- This resource will be an important document for both investigators and trial participants alike. There are a lot of factors, including risks and potential benefits, that go into the decision to participate in a clinical trial. Those factors are multiplied when the trial involves the implantation of an investigational device. Prospective participants must have a full understanding of the post-trial needs and potential long-term consequences of implantation of a device that is still being studied. Since informed consent is already required, this resource will help aid investigators and their teams in conveying the necessary information for study participants to be able to provide informed consent.
- The sample language provided in this resource is immensely helpful.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

- Component 1- Introduction/Purpose
 - o No Comment
- Component 2- Procedures
 - o No Comment
- Component 3- Long-Term Practical Considerations
 - o In addition to general information about care and maintenance of a device in the long term, this document should include additional, more thorough, examples about how a trial participant should seek care in the post-trial period. This could include how to recognize device malfunction and options concerning explantation should it become necessary.
- Component 4- Potential Risks
 - o This section is critical. All potential risks, both common and uncommon and for every level of severity, must be thoughtfully explained to prospective trial participants. Special care and attention should be given to the explanation of post-trial risks, particularly for devices that are not explanted. It is critical that any trial participant has a full understanding of risks that may arise once they are no longer under the care of the investigators so that they can make a thoughtful decision as to whether they can address these risks as they arise and successfully manage their individual health.
- Component 5- Potential Benefits
 - o No Comment
- Component 6- Alternatives
 - o An additional alternative worth including would be entrance into a follow-on long-term study, which would provide additional data on the device.

- Component 7- Cost
 - o While cost should not be a barrier to participation in investigational research, care associated with some studies may necessitate billing an individual's insurance and/or out-of-pocket costs may arise. This component is critically important to ensure that trial participants are not burdened with unexpected costly expenses either during the trial or down the road. This component could also include language about financial resources for participants should they exist.
 - o It would also be helpful to provide an estimated costs related to care and maintenance of the device if it remains implanted post trial.
- Component 8- Compensation for Research-Related Injury
 - o No Comment
- Component 9- Withdrawal
 - o No Comment
- Component 10- Questions
 - o No Comment

2.3 Hurdles or barriers to broad use of this resource by the research community

- This is an important document that will aid investigators in recruiting knowledgeable trial participants who understand both the benefits and risks of study before volunteering.

2.4 Other feedback relevant to this resource

N/A

9. National Center for Health Research

I am responding: On behalf of an organization

Name: Akashleena Mallick

Name of Organization: National Center for Health Research

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Domain of research most important to you or your organization: N/A

Date Submitted: 5/22/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

The draft resource appropriately acknowledges the importance of post-trial planning for participants with an investigational implantable device, and that planning will need to vary based on factors such as device type, intended duration of implantation, anticipated need for device removal, level of technical support required, and expected long-term participant needs. However, implantable devices increasingly function within broader technological ecosystems involving software platforms, remote monitoring systems, proprietary replacement components, and specialized clinical expertise. As a result, participants' post-trial needs may extend beyond management of the device itself.

The resource provides useful considerations for investigators, IRBs, sponsors, and research teams. Since the framework is intentionally broad to apply across different device types, clinical settings, and study designs, it would be helpful for the resource to explicitly identify additional foreseeable scenarios. These should include, for example, situations in which participants relocate, transition between health systems, lose insurance coverage, or require care from clinicians unfamiliar with the investigational device. The resource should provide explicit guidance regarding continuity of specialized expertise and accountability when investigators change institutions, research teams dissolve, or participants require care outside the original study setting. Post-trial responsibilities may need to extend beyond management of the implanted device itself and include continuity of expertise, sustained technical support, long-term data protection, and planning for evolving uses of technology (Hendriks et al., 2023). Broader discussions of post-trial obligations have similarly emphasized that responsibilities extend beyond access to an intervention and include ensuring appropriate transition to ongoing care and support services (Cho et al., 2018). Medical device evaluation frameworks have recognized that important safety, usability, and performance considerations may emerge over time and at different stages of a device's use and dissemination (Sedrakyan et al., 2016). Incorporating specific examples that address these considerations would strengthen consistency and improve the practical utility of the resource.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 1: Plan/Options for Device Explantation or Remaining In Situ: For studies in which device

removal is planned or becomes necessary because of safety concerns, lack of effectiveness, device failure, or end of device life, specifying a timeline alone is insufficient. Long-term experiences with implantable devices suggest that when devices or device components remain in the body for many years, they can affect future MRI use, complicate future medical procedures, and result in too many implanted components remaining in the body over time, in addition to concerns already outlined in the draft, such as infections, replacement procedures, and subsequent interventions (Andreae et al., 2025). Plans should specify how participants will be monitored and managed if explantation is delayed or if devices remain implanted beyond the originally anticipated period, including who will monitor the participant, what clinical or device-related findings would trigger reassessment, and how responsibility will be transferred if care moves outside the original study setting. The resource should also include standardized post-trial documentation for participants and future healthcare providers, including device identification information, details of any components left in the body (e.g., leads, batteries, electrodes), MRI safety status or restrictions, and device-related contact information, particularly when the device or parts of the device remain implanted after study completion.

Element 2: Risks and Potential Benefits: The risk discussion should more explicitly address broader considerations that affect participants after study completion beyond the procedural and device-related risks already described in the draft. Participants can experience psychological effects, changes in self-perception, or device dependence, particularly when devices provide meaningful functional or therapeutic benefit or if devices are discontinued, not approved, recalled, or no longer available after study completion (Hendriks et al., 2019). For devices incorporating software components, analyses of software-related recalls have shown that software defects can affect device function and patient safety, with some issues becoming apparent only after implementation in real-world settings (Ronquillo & Zuckerman, 2017). Participants should also understand that some implantable devices function as platform technologies with applications across multiple diseases and indications. Risks and benefits observed in prior uses of these technologies do not directly apply to the current study population and can introduce additional uncertainty regarding expected outcomes.

Element 3: Anticipated Participants' Needs: The resource should emphasize practical participant needs that emerge over time. For example, participants may require assistance coordinating care across multiple providers and healthcare systems, particularly when specialized expertise for the investigational device is not easily available. These issues are especially important for an investigational device because there will be few health professionals familiar with it prior to it going to market, and even fewer if the product is never approved or cleared. Practical considerations are also important, such as transport for follow-up care, caregiver responsibilities, accessibility or language needs, influence participants' ability to receive appropriate support. Participants may also experience psychosocial effects living with an investigational implanted device. While the draft appropriately highlights age-specific considerations, such as pediatric populations, additional consideration should be given to demographic representation across age groups, race, and ethnicity to better reflect the populations likely to use these devices in real-world settings and anticipate potential differences in post-trial needs across subgroups.

Element 4: Plans for Meeting Former Participants' Needs

The resource should clearly address when and how investigators, institutions, sponsors/manufacturers, or other relevant stakeholders should re-contact former participants and respond to post-trial events

that require action. For example, plans should specify how participants will be informed of newly identified safety concerns, device recalls, updated monitoring recommendations, or clinically relevant findings that emerge after study completion. Plans should also describe the expected actions following such events, including additional evaluation, follow-up, or changes in device management.

Element 5: Financial Plan: The financial plan section does a good job of outlining potential sources of support, but it focuses on possible funding arrangements rather than providing a framework for accountability across stakeholders, especially when the funding of the study ends or support structures change. While we understand that NIH may not consider this type of accountability to be an issue for the agency to address, accountability should be addressed by the federal agency that is involved in the investigational device clinical trials, whether the NIH, FDA, or any other agency. Study participants should be made aware of these issues prior to agreeing to participate in the clinical trial of an implanted device.

Therefore, the resource should explicitly clarify responsibility for costs associated with adverse device events or complications occurring during or after the trial period. Prior discussions of implanted device research have highlighted concerns of device abandonment and uncertainty around responsibility for ongoing maintenance and support after studies end (Lázaro-Muñoz et al.). Broader discussions of post-trial responsibilities have similarly emphasized that if financial responsibilities are not clearly stated as part of the informed consent process, they can shift burdens onto participants and exacerbate inequities in access to ongoing care (Iunes et al., 2019). Some examples of more explicit guidance regarding stakeholder responsibilities are as follows:

- Sponsors/manufacturers should support device-specific needs, such as replacement components, software updates, technical support, and management of device failures directly related to the investigational device, during and after the trial.
- Research institutions or study sponsors should be responsible for trial-related monitoring and care occurring within defined post-trial periods.
- Insurers and public payors, including CMS where applicable should support clinically necessary routine medical care or emergency evaluations once devices transition into standard clinical management.
- Dedicated contingency mechanisms should be available, such as reserve or escrow funding models for anticipated long-term needs and circumstances if planned funding or manufacturer support ends.

Element 6: Oversight of Long-Term Care Plans: The resource should address participant attrition and loss to follow-up within long-term oversight planning, since disengagement may limit identification of delayed complications and unmet post-trial needs. Oversight plans should include strategies to support continued engagement, coverage and access to care. Resource 1 [DZ1.1] should also include patient experiences and patient-reported outcomes, because they provide important information regarding functionality, quality of life, and concerns that may not be captured through traditional clinical endpoints.

1.3 Hurdles or barriers to broad use of this resource by the research community

The voluntary nature of the resource is a potential barrier to broad use. Long-term planning requirements may vary substantially across institutions, creating inconsistency in implementation.

Limited funding, uncertainty regarding financial responsibility, and limited infrastructure for extended follow-up can also reduce adoption or the effectiveness of the resource.

1.4 Other feedback relevant to this resource

Investigational implantable device trials differ from many other forms of research because participants may continue living with the effects and responsibilities of the intervention for years after study completion, including after the device has been modified or is no longer on the market. Post-trial responsibilities should therefore be considered fundamental components of study design rather than optional considerations.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

While the resource provides a strong foundation on informed consent using a component-based structure and sample plain language, several sections need operational examples reflecting real-world use. In some areas, the sample language is so broad that it does not fully capture practical issues related to long-term management, evolving risks, and financial or care responsibilities that participants may encounter after implantation.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1 (Introduction/Purpose): The consent language should more clearly explain why a device is considered investigational, including whether it is entirely new, being studied for a new indication, or being used in a new patient population. Participants should understand whether the device has FDA authorization for any use and how the current study differs from those uses. For devices based on prior technologies, the consent should also describe the supporting evidence and important evidence gaps, particularly when human data are limited, to help participants understand the level of uncertainty associated with the investigational device.

Component 2 (Procedures): The procedures section should include use of visual aids where appropriate, since implantation procedures and device configurations are difficult to understand through text alone. Examples should include diagrams or short explanatory videos showing device location, implantation procedures, internal versus external components, and the expected recovery process. Such materials improve participant understanding of the overall treatment pathway and procedural expectations.

Component 3 (Long-Term Practical Considerations): The resource places substantial emphasis on post-trial considerations, but many of these practical issues are relevant throughout study participation and during long-term device use. Participants should receive clear, accessible take-home materials at enrollment and throughout the study, not only at study completion, summarizing device maintenance, restrictions, information needed for future healthcare encounters, travel considerations, and instructions for circumstances such as relocation or transition to new healthcare providers.

Component 4 (Potential Risks): The section does not adequately address uncertainty itself as a risk that

participants should understand during informed consent. The consent language should explicitly acknowledge that some risks may emerge only after prolonged use or broader implementation outside research settings. Where relevant, examples should also include risks related to privacy or cybersecurity and the potential impact of future loss of manufacturer support, as these affect device management and long-term care. Patients deserve to know what is known and not known about possible short-term and long-term risks and benefits.

Component 5 (Potential Benefits): The section does not sufficiently distinguish potential participant benefit from broader scientific or societal benefit. Participants should understand that implantation of a device does not necessarily result in direct clinical benefit and that benefits observed in prior studies, related technologies, or different patient populations may not apply to the current study population. The consent language should also clearly communicate uncertainty regarding the magnitude of potential benefit, particularly for investigational devices with limited or with no long-term evidence.

Component 6 (Alternatives): The section does not adequately explain how alternatives differ from study participation in ways that may influence decision-making. Because of the greater uncertainties of the risks and benefits of an implanted device, the consent language should include concise information on major differences between alternatives and the investigational approach, such as expected procedures, follow-up requirements, reversibility, long-term commitments, and potential risks or burdens, rather than only listing available options.

Component 7 (Cost): Consistent with the concerns we raised for Resource 1, this section does not adequately address assignment of responsibility for costs that may arise during long-term use of implanted devices. General statements that “some or all costs covered by health insurance or pay out of pocket” or “you or your insurer will need to cover the costs associated with keeping the device working or removing or replacing the device” do not provide sufficient information for participants to make an informed decision, and could be misleading because patients may be reassured by something that is said to them orally but is not in the written consent document. At the least, this wording results in confusion or uncertainty about the financial implications of study participation. Participants’ understanding of financial responsibilities should not depend on their interpretation of a vague statement about who becomes responsible if sponsor support ends, insurance coverage changes, or costs arise after formal study participation has ended.

Component 8 (Compensation for Research-Related Injury): Consistent with concerns raised in Resource 1 and in Component 7 of Resource 2 regarding financial responsibility and post-trial care, the sample language presents potential compensation pathways but does not specify the scope, duration, and assignment of responsibility for device-related injuries or complications. Participants should receive clear information regarding what injuries are covered, who is financially responsible, whether coverage extends to delayed complications after formal study participation ends, and how institutions will help participants navigate unforeseen situations involving out-of-pocket expenses, insurance denials, or coverage limitations.

Component 9 (Withdrawal): This section should clearly distinguish withdrawal from study versus discontinuation or removal of the implanted device. Participants should understand that leaving the

study may not necessarily mean that the device can or should be removed and that continued monitoring, maintenance, or clinical care may still be needed. The consent language should also clarify what support participants can expect if they withdraw from the study while continuing to live with the device.

2.3 Hurdles or barriers to broad use of this resource by the research community

Potential barriers include lengthy or ambiguous consent forms and variability across institutions. However, we are especially concerned that researchers will be reluctant to explicitly explain the uncertainties of the benefits of the device and of issues of financial responsibility, because it could reduce the willingness of patients to volunteer to participate. Unfortunately, the alternative is to have vaguely worded consent forms that result in study participants being misled about the likely benefits and financial implications of participating in the study. That in turn would leave participants and their families in uncertain and stressful situations that compromise long-term health and well-being and delay access to urgently needed care, and challenges communicating complex device-related concepts in plain language.

2.4 Other feedback relevant to this resource

Maintaining plain language, short sentences, visual aids, and approaches that promote participant understanding should remain central to the integrity of the resource. Participants should be supported in understanding not only study participation itself, but also the long-term implications of living with an investigational implanted device.

Description: References: 1. Sedrakyan, A., Campbell, B., Merino, J. G., Kuntz, R., Hirst, A., & McCulloch, P. (2016). IDEAL-D: a rational framework for evaluating and regulating the use of medical devices. *Bmj*, 353. 2. Hendriks, S., Hsu, N., Beckel-Mitchener, A. C., Ngai, J., & Grady, C. (2023). Continuing trial responsibilities for implantable neural devices. *Neuron*, 111(20), 3143-3149. 3. Cho, H. L., Danis, M., & Grady, C. (2018). Post-trial responsibilities beyond post-trial access. *The Lancet*, 391(10129), 1478-1479. 4. Andrae, A., Breitenstein, A., & Piccini, J. P. (2025). Long-term management of leadless pacemakers. *European Heart Journal Supplements*, 27(Supplement_2), ii26-ii38. 5. Ronquillo, J. G., & Zuckerman, D. M. (2017). Software-related recalls of health information technology and other medical devices: Implications for FDA regulation of digital health. *The Milbank Quarterly*, 95(3), 535-553. 6. Lozano, A. M., Lipsman, N., Bergman, H., Brown, P., Chabardes, S., Chang, J. W., ... & Krauss, J. K. (2019). Deep brain stimulation: current challenges and future directions. *Nature Reviews Neurology*, 15(3), 148-160. 7. <https://www.mayoclinic.org/tests-procedures/deep-brain-stimulation/about/pac-20384562> 8. Lázaro-Muñoz, G., Pham, M. T., Muñoz, K. A., Kostick-Quenet, K., Sanchez, C. E., Torgerson, L., ... & Zuk, P. (2022). Post-trial access in implanted neural device research: Device maintenance, abandonment, and cost. *Brain Stimulation*, 15(5), 1029-1036. 9. Iunes, R., Uribe, M. V., Torres, J. B., Garcia, M. M., Alvares-Teodoro, J., de Assis Acurcio, F., & Junior, A. A. G. (2019). Who should pay for the continuity of post-trial health care treatments?. *International Journal for Equity in Health*, 18(1), 26.

10. N/A

I am responding: On behalf of myself

Name: N/A

Name of Organization: N/A

Type of Organization: Academic Institution

Role: Investigator/Researcher

Domain of research most important to you or your organization: Neuroengineering, Neuroprosthetics

Date Submitted: 5/22/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

N/A

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 5 - There needs to be a way of reserving funds after the end of an award that paid for implants to cover explant. Some implants have expected durations longer than the typical 5-year NIH award (or realistically the 3-4 remaining years of an award once the implant happens). For other implants the duration of functionality may be unknown. Currently at the end of an award any funds reserved for explant surgery must be spent on something else or returned to the NIH if the participant is not read for explant.

1.3 Hurdles or barriers to broad use of this resource by the research community

N/A

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

N/A

2.3 Hurdles or barriers to broad use of this resource by the research community

N/A

2.4 Other feedback relevant to this resource

N/A

11. Implantable Brain-Computer Interface Collaborative Community (ibci-cc.org)

I am responding: On behalf of an organization

Name: Jessica Kelemen, MBA; Komal Kampasi, PhD

Name of Organization: Implantable Brain-Computer Interface Collaborative Community (ibci-cc.org)

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Collaborative Community, including academic researchers, medical device manufacturers, people with lived experience of neurologic disease or injury, patient support foundations, care partners, ethicists, and employees of federal agencies engaged in oversight or funding of clinical trial research and translation, engaged in a chartered precompetitive space.

Domain of research most important to you or your organization: Implantable Brain-Computer Interfaces

Date Submitted: 5/22/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

- We thank the NIH for its careful consideration of this complex topic. The resource addresses an important and timely gap as implantable brain-computer interface (iBCI) clinical trials advance in the development and testing of devices for communication and/or mobility for people with severe speech or motor impairments resulting from neurologic disease or injury. The resource offers a clear model for addressing multiple domains, making it easier for researchers to consider, and peer reviewers to assess, whether each domain has been addressed.
- Use of this resource is explicitly stated as voluntary. If one intent of the resource is to encourage NIH study section peer reviewers to consider the extent to which these domains are described in the Protection of Human Subjects or Long-term Care Plan section of grant applications, or if it is believed that this resource will be incorporated in whole or in part to future grant application instructions, we recommend that this be stated explicitly. Without this framing, voluntary uptake may be uneven and concentrated among institutions and researchers already engaged in best practices.
- The document identifies key gaps, but only limited guidance on feasible solutions other than extensive disclosure of risks to research participants. While disclosure is important, it is not sufficient on its own. Ethical post-trial care and support must be meaningfully ensured. As written, the burden appears to be on researchers and research institutions to bridge gaps and find solutions. NIH can play a more active role in enabling solutions, whether through building explicit post-trial care obligations into grant budgeting requirements, connecting awardees to existing mechanisms, and facilitating access to manufacturer device access programs. Beyond stating the fundamental challenge that study funds cannot be used to support post-trial activities after the grant ends, this resource would have additional

impact if accompanied by specific, actionable suggestions that NIH award recipients could adopt to financially support post-trial activities. The problem may be unsolved, but there is an opportunity here to offer concrete recommendations. Multiple references to the participant's own health insurance underscore the personal risk, and a brief reference is made to "trial specific insurance". Can more be added here to guide researchers toward solutions beyond the helpful disclosures recommended in the resource?

- As noted above, this resource may support NIH review panels by offering a structured framework to assess the adequacy of post-trial plans. At the same time, the guidance should avoid framing post-trial responsibilities in aspirational terms without acknowledging the need for feasible funding pathways, as this could place expectations on investigators and institutions that are not practically achievable.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 1- Plan/Options for Device Explanation or Remaining In Situ

Comments:

- It may be helpful to address who holds decision-making responsibility under circumstances such as when a manufacturer of a device being used in NIH-funded research ceases operations. Please consider including reference to how NIH can better support researchers in these situations, including access to funding or resources to ensure continuity of participant support if a manufacturer dissolves.
- While Element 2 partially addresses this concern, Element 1 can provide clearer guidance for cases where planned explant becomes unethical because the device is continuing to provide a meaningful benefit to the participant, or where explant poses greater risk than leaving the device implanted.
- This Element could benefit from expanding the discussion beyond explantation vs device remaining in-situ to also consider functional status of the device (active vs. deactivated). Even when the device remains physically implanted, decisions about deactivation are not purely technical and may require explicit participant consent. Deactivation can have meaningful clinical, functional, and psychological implications, and should be approached as a distinct decision point with appropriate ethical and regulatory consideration.

Element 2- Risks and Potential Benefits

Comments:

- Explicit mention of risks related to partial explantation could be added, as partial explantations carry distinct risk and decision-making considerations. For e.g., "1) explanting the device, and 2) leaving the device in place." could be replaced by, "1) fully explanting the device, 2) partially explanting the device, and 3) leaving the full device in place."
- Cybersecurity risks associated with wirelessly connected implanted devices could be more explicitly named as a post-trial risk category, particularly if remote telemetry and software update interfaces remain active after trial closure.
- Risks/benefits can be perceived differently prior to enrolling in a trial compared to after having access to the device. If a participant is receiving an ongoing benefit from an implanted device, they may be less willing to consent to explantation. We suggest adding a statement that encourages researchers to anticipate this shift in participants' perspective.

Element 3- Anticipated Participants' Needs

Comments:

- In addition to the mention of specific expertise needed for technical and clinical management support post-trial, some devices used after trial conclusion may require caregiver or family support, particularly for participants with severe motor or communication impairments. Similarly, psychological/psychiatric support may be needed based on the participant's experiences with the device, including the participant's perspectives on the device's impact on body ownership and integration.
- Study teams should ensure that participants have access to contact information available for long-term follow-up in case needs arise due to devices that are left implanted. To support continuity, providing multiple contacts including institutional resources, device manufacturers, and where appropriate, NIH-affiliated resources.

Element 4- Plans for Meeting Former Participants' Anticipated Needs

Comments:

- BCIs depend upon software or firmware that may require highly specialized calibration and troubleshooting expertise, for there is no "standard of care" in absence of clear commercial equivalents. Discuss strategies for firmware and software archiving obligations and general guidance on knowledge transfer protocols (e.g., to users, care partners, institutional staff) to help ensure that devices do not become non-functional due to software end-of-life after trial completion or when a team dissolves or critical stakeholders depart.
- The post-trial care plan should describe how cybersecurity will be sustained after trial closure, including who is responsible for monitoring and addressing newly discovered vulnerabilities, how long security support will be provided, and how participants will be notified of issues that affect their device. A clearly communicated end-of-security-support timeline allows participants to plan, similar to end-of-life disclosures for commercial medical devices.

Element 5- Financial Plan

Comments:

- Since NIH funding cannot be typically used for explantation once the award period has ended, it would be extremely beneficial for NIH to discuss mechanisms to make it possible to allocate funds to future explant/follow-up care such as bridge funding, supplements, escrow-like arrangements, or other models that would allow resources to be budgeted and/or reserved during the active award period for post-trial needs arising later.
- This section could also explicitly address whether any remuneration to participants is contingent on willingness to undergo post-trial explantation given that IDE sponsors or sponsor-investigators may have independent commercial interest in device retrieval (e.g., for histological analysis or hardware recovery) or other scientific interest. If the research is incentivizing the explant based on the value of the scientific knowledge gained or reduction of risk, the incentivization should be at noncoercive levels.
- Without a clearer NIH commitment to supporting post-trial access costs through specific, actionable funding structures, many of the care continuity suggestions outlined across this document may remain aspirational rather than achievable in practice. The draft Resource is anchored largely on this section, and achieves the important goal of raising awareness and inspiring institutions and researchers to contemplate creative solutions. Nevertheless, fulfillment of complex post-trial needs of research participants ultimately requires identified funding for staff, equipment, and processes.
- The financial plan can explicitly account for ongoing cybersecurity-related costs that persist after

trial closure such as security monitoring, software maintenance, and incident response capacity as these represent recurring operational obligations rather than one-time expenditures. If NIH funds cannot cover these costs after award close, the plan can perhaps identify an alternative responsible party and its source of funding.

Element 6- Oversight of Long-Term Care Plan for Implantable Device Studies

Comments:

- This section hinges upon establishing the specific responsible party for assuring compliance with the Long-Term Care Plan. It is likely that multiple parties (e.g., the academic institution AND the device manufacturer) will play a key role in executing a Long-Term Care Plan. A contingency plan should be included in the event of unavailability of any of the parties (due, for example, to dissolution of a company, move of a Principal Investigator to a new institution).
- Oversight should designate a responsible party for monitoring and responding to post-trial cyber-security incidents affecting the device, including communicating with affected former participants in the event of a critical vulnerability. A continuity plan should ensure that this function is maintained in the event of organizational changes, sponsor dissolution, or principal investigator departure.

Best Practice Considerations

Comments:

- It would be useful to ask researchers to anticipate and manage potential conflicts of interest where device manufacturers' or other IDE Sponsors' preferences may influence a participant's decision to keep or explant the device.
- The first bullet of this section refers to a "favorable risk to benefit profile". This assessment is likely best made through a shared decision-making process between the investigator and participant. The participant's personal assessment of benefit may evolve over the course of the trial, and it may differ from the assessment made by other trial participants. It would be helpful to clarify who best determines the presence of a favorable risk to benefit profile.
- Security-by-design principles should extend to post-trial continuity. Devices intended for long-term implantation should be engineered to remain secure and functional even if the infrastructure of some responsible parties (e.g., device manufacturer) is decommissioned. Devices would ideally maintain the ability to be used independently of active manufacturer support and to be safely and securely disabled at end of device life; these capabilities should be considered during device design rather than addressed reactively after trial closure.

1.3 Hurdles or barriers to broad use of this resource by the research community

- Clarification on recommended interface with IRB review processes or NIH funding conditions could help establish clearer expectations for the research community and increase adoption.
- Regardless of organizational scale or resource availability, all investigators should be expected to address post-trial care obligations and be transparent with participants about any limitations in what can be provided. The Resource will be a valuable guide for investigators seeking to design clinical trials of implanted devices that offer participants clear guidance and support regarding all post-trial considerations.

1.4 Other feedback relevant to this resource

- The cost of a device explant after the end of the trial period, while large or untenable to an

individual research participant, and highly problematic for complex, resource-constrained institutions, is likely well within the budget range of the trial at the time of grant proposal and award. A key issue is thus not the unavailability of funds for the explant, but the inability to retain, reserve, or place these funds in escrow for potential use beyond the study period. While policy changes (or, perhaps, legislation) is of course beyond the scope of this Resource, the NIH should create a section of this Resource that, at the very least, describes methods – where existing or theoretical - by which financial support for the many excellent suggestions in this Resource might be achieved.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

- The resource fills a meaningful gap by providing modular consent language tailored to implantable device trials. The modular "[If the...]" structure is practical for multi-site or multi-device trials. An accompanying streamlined decision tree could improve usability and readability.
- The modular consent language will help grant writers to attend to key issues, and grant reviewers to identify where the issues are addressed.
- The Resource should make clear that disclosing areas of uncertainty is not itself an adequate ethical solution. For example, informing participants that post-trial support may not be available does not discharge the research enterprise (inclusive of both funders and researchers) of responsibility for foreseeable needs created by investigational implantation.
- The resource could be strengthened by acknowledging that informed consent for implantable device trials is not a single documentation event but an ongoing, iterative process with participants revisiting and reaffirming their understanding as the trial progresses and device status changes, or post-trial scenarios evolve.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1- Introduction/Purpose

Comments:

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-

Component 2- Procedures

Comments:

- The section covers implantation and explantation well at a general level. Some implanted devices, including implantable neural interfaces, may require participants to spend considerable time engaged in research sessions dedicated to device programming, decoder retraining, and electrode mapping procedures. These should be described as expectations distinct from the surgical event. Relatedly, first-in-human (FIH) and early feasibility studies (EFS) involve hypothesis testing, iterative software development, and discovery of device characteristics. Some trials will also ask participants to engage in research primarily focused on fundamental science, with the hope that what is learned can lead to further device or neural interface system refinement or improvement. These time commitments,

and the goals of the research sessions, should be described.

- The section can benefit from sample language that is more extensive for the explantation, such as “Your research team recommends that [we remove the device/leave the device implanted in you]. Having this device remain inside of you has the following risks...”
- Explantation-specific risks such as pain, bleeding, scarring, or tissue adherence from device removal should be explicitly addressed in the sample language, as these may differ meaningfully from risks associated with the original implantation procedure.

Component 3- Long-Term Practical Considerations

Comments:

- Sample language and related points to consider should be added to address device inactivation, separate from both retention and explantation, and whether participant consent is required (under what circumstances). These considerations may meaningfully influence a participant's decision to enroll.
- The section should state that device function could decline, or the device might cease to function, if software support/updates cannot be provided.
- The section should mention that care needs for some devices may require assistance from care partners.

Component 4- Potential Risks

Comments:

- Risks related to data collected by the device, and device data shared with others, should be mentioned.
- Sample risks related to loss of therapeutic benefit should be included, particularly for BCIs where participants may develop functional dependence on the device and an explantation could result in meaningful setbacks in quality-of-life.
- Sample risks related to eligibility for future trials should be included, as the presence of a chronically implanted investigational device may disqualify participants from enrolling in subsequent studies.
- Cybersecurity risks should be listed as a distinct risk category in the sample language, and the consent should distinguish between read-only telemetry interfaces and write-capable interfaces. The latter introduces a categorically different risk, because a successful compromise could influence device behavior in ways that affect the participant’s body or cognition. This distinction is particularly important for neural interface devices.

Component 5- Potential Benefits

Comments: This section should more carefully consider the constant evolution in the understanding of “potential benefit” during the course of a device study. There is a long-standing practice of under-reporting potential direct benefit to device study enrollment. This is rooted in a desire to recruit participants who are willing to enroll even if, per the sample language, “you may not benefit... [because] in the future other people may benefit”. However, this is not mutually exclusive with the sample statement, “You may benefit if you join this study”. The Resource should make clear whether both statements can reasonably appear in an informed consent form.

Component 6- Alternatives

Comments:

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-

Component 7- Cost

Comments:

- Currently the document is focused primarily on disclosure. The NIH could offer guidance for minimum levels of support that should be offered to cover post-trial obligations.

Component 8- Compensation for Research-Related Injury

Comments:

-

Component 9- Withdrawal

Comments:

- This section should address disposition of device-transmitted data, cryptographic credentials, and any neural/biometric data collected or shared during the trial. Participants should be informed whether transmitted data will be retained or deleted, and what residual data flows (if any) continue if the device remains implanted after withdrawal.
-

Component 10- Questions

Comments:

- This section can prompt investigators to establish a distinct reporting channel for participants or care partners to flag unusual device behavior or in-built safety alarms, with guidance that such reports will be triaged as potential safety events rather than general participant inquiries. This ensures that a participant or caregiver who notices unusual device behavior has a clear, low-friction path to report it, which is critical for the post-trial period when access to clinicians familiar with the study may be reduced.

2.3 Hurdles or barriers to broad use of this resource by the research community

- Securing financial support for sufficient post-trial care is going to be a challenge. While it may require policy or legislative change, allowing funds for post-trial care to be allocated during the award period but spent later would address a key shortcoming of current NIH-funded implantable device research. Insurance options or resources that researchers can use to solicit funds from other sources would also be helpful. In its current form, the resource asks investigators to promise planning for contingencies that there are essentially no funds available to support.

2.4 Other feedback relevant to this resource

- The resource should provide guidance on IRB reporting and use of data after a study participant exits from the study (due to withdrawing from the study or study closure). Are there continuing obligations for reporting adverse events to the IRB? Can data collected during tech support visits (when a participant continues to use the system, but is no longer in an active trial) be used in peer-reviewed publications?
- When discussing post-trial interactions, it would be helpful for the Resource to encourage

researchers to anticipate the need for altering device settings to facilitate continued function when the circumstances of a (former) participant/user change (e.g., as a result of disease progression.)

- While cybersecurity is not a primary focus of either resource, a brief cross-reference to existing regulatory and standards guidance would help orient researchers, including academic investigators, to available frameworks. Relevant references include FDA's Section 524B premarket cybersecurity requirements and the 2023 FDA premarket cybersecurity guidance would be helpful. IEC 81001-5-1 (health software security lifecycle) a directly applicable international standard that could be referenced as a best-practice framework for sponsors building post-trial security plans.

12. Thomas B Freeman, MD and Dorothy E Vawter, PhD

I am responding: On behalf of myself

Name: Thomas B Freeman, MD and Dorothy E Vawter, PhD

Name of Organization: Department of of Neurosurgery and Brain Repair, University of South Florida
College of Medicine; Minnesota Center for Health Care Ethics

Type of Organization: Academic Institution

Role: Healthcare Provider

Domain of research most important to you or your organization: Surgical research study designs

Date Submitted: 5/22/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

N/A

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

N/A

1.3 Hurdles or barriers to broad use of this resource by the research community

N/A

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

N/A

2.3 Hurdles or barriers to broad use of this resource by the research community

N/A

2.4 Other feedback relevant to this resource

N/A

Upload a File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/Comments-re-NIH-implantable-device-guidance-TB-DV-5.22.2026.pdf>

Description: Comments re NIH implantable device guidance

Date: May 22, 2026

TO: NIH Office of Science Policy

FOM: TB Freeman, MD and DE Vawter, PHD

RE: Comments re NIH Implantable Device Guidance 5.22.2026

The following are our observations regarding this commendable draft guidance on implantable device research.

We recommend 1) clarifying concepts such as “post-trial” and “former participant” and 2) in accord with the title of the guidance, acknowledging and addressing a broader range of ethical issues involving implantable device trials.

It is important to acknowledge the ambiguity of terms such as “post-trial” and “the end of the trial” and we recommend that trialists define these terms in the context of particular trials. These terms often mean different things in different trials. Moreover, they can mean different things to a study’s participants and to the researchers. Failure to clarify what is meant by the “end of a trial” can lead to confusion, especially in studies in which the device remains in place. Without an explicit definition, a participant rightfully may wonder whether the trial ends when he/she reached the primary endpoint, when all participants reached the primary endpoint, when the trial data on safety and efficacy has been analyzed and disclosed so study participants are able to make informed decisions about post-trial options, etc. For example, when participants are informed that at the “end of the controlled trial” they will/may receive the active intervention in an open label extension or they will be followed up for an additional period of time, it is important to explicitly state whether the open label extension or the follow-up is part of the trial or is a post-trial activity. The answer affects both the researchers’ obligations to the participants as well as the participants’ expectations of the researchers and trial sponsors.

Offering the active intervention to participants in the control group before completing the trial for all participants and analyzing the safety and efficacy data makes it impossible to disclose the risks and benefits of “post-trial” options. These issues concerning the “end of a trial” are relevant to assessing the ethical acceptability of whether and when to offer study participants access to long-term follow-up, access to the active intervention in an open-label extension, to turn the device ON, and when the implant may or should be removed. They compound considerations regarding whether the device is retrievable or not, the type and amount of data available, whether the device is intended to slow disease progression, the time it takes to analyze the safety and efficacy data, etc. Long delays in data collection and analysis may exclude a participant with a progressive disease from accessing the active intervention as they may no longer satisfy inclusion criteria. Details

regarding the end of a trial and potential post-trial options add to the complexity of disclosure and informed consent process plans. An open label extension conducted prior to data analysis is essentially a redundant open label trial without any of the benefits of a controlled trial.

There are ethical and safety issues regarding explanting devices in addition to those mentioned in the guidance. Explanting at the completion of participant's primary endpoint is ethically suspect on numerous grounds. First, it denies the participant knowledge of possible efficacy and risks that can only be known after the data has been analyzed for the entire trial. Second, even if the device is ineffective, the removal of this ineffective device may pose greater risks than leaving it in place. Third, clinical trial risks may be novel including future loss of corporate support for an alpha device. If removed as part of the protocol any adverse events would be covered by the trial vs. by the subject or the subject's insurance in the future. Fourth, mandating explant as part of the study protocol is insufficient. The risks and benefits of removal must be fully justified and explained. An informed consent obtained at the beginning of a trial regarding a mandatory explant after completion of the primary endpoint by the subject is not valid. It is not current, it lacks information about potential efficacy derived from knowledge gained by the trial, lacks consideration of current alternatives as well as a comparison of risks and benefits of removal vs. leaving in place, and it disrespects the participant and the participant's autonomy.

Defining the start of an implantable device trial can also have ethical import. It is customary, though not universal, that implantable device trials begin before devices are implanted. This is, in fact, the only way to conduct a trial with an intention-to-treat analysis of safety and efficacy as well as surgical variability. Some implantable device trials, however, randomize after a successful implant has been performed, eliminating subjects with off-target placement, and those with SAEs. Delaying randomization and the start of an implantable device trial until after a successful implant obfuscates the risks of implanting the device and minimizes the role of the implant operation (including the percentage of unsuccessful operations) in the analysis of the intervention's safety and efficacy. Future treating physicians and future patients therefore will lack true understanding of the overall risks as well as success rate for a *de novo* patient receiving the device. Guidance regarding the start of implantable device trials would be an important contribution to the field.

Other ethical issues to address include sham controlled implantable device trials. Many such trials are lesion-controlled, in which everyone receives the device but those randomized to the control arm do not have their devices activated. It is important to justify the choice of this trial design. Does it satisfy the obligations to minimize risks to study

participants consistent with sound study design? Are there alternative designs that pose lower risk? Has the use of a lower risk imitation operation been considered? Is it adequate to blind researchers and participants?

Thank you for your consideration.

13. Members of the MetroHealth Center for Rehabilitation Research

I am responding: On behalf of an organization

Name: Nathan Makowski, Megan Moynahan, Anne Bryden, Michael Fu, Cynthia Kubu, Tina Vrabec, Anthony Dimarco, Krzysztof Kowalski

Name of Organization: Members of the MetroHealth Center for Rehabilitation Research

Type of Organization: Healthcare Institution

Role: Investigator/Researcher

Domain of research most important to you or your organization: N/A

Date Submitted: 5/25/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

N/A

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

See attached

1.3 Hurdles or barriers to broad use of this resource by the research community

See attached

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

See attached

2.3 Hurdles or barriers to broad use of this resource by the research community

See attached

2.4 Other feedback relevant to this resource

N/A

Upload a File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/NIH-Long-term-support-RFI-5.23.26.pdf>

Description: Summary response to the listed questions

We appreciate that NIH is considering the challenge of post-trial support for implant recipients.

The guidance appears limited to topics that are already required by the FDA and an IRB for a consent form. However, in our experience providing long-term support for participants over several decades, there are a range of practical challenges that investigators face as they navigate the practicalities of providing long-term support, for which NIH guidance and support could be provided.

Our experience has identified several key elements that are required in order to provide long-term support, including 1) regulatory maintenance, 2) technology availability, 3) expertise availability, 4) and financial support.

1) Regulatory maintenance: In order to provide long-term support so that implant recipients can *legally* have their systems maintained (e.g. fixing external components, updating stimulation patterns, or replacing implanted components) requires active IDE and IRB protocols permitting interactions with implant recipients from a regulatory perspective. Furthermore, if a research team is working with a company under a company-sponsored IDE, this requires having a mechanism in place proactively that allows for the IDE and protocol to transfer to people who want to facilitate long-term support. Otherwise, a potential scenario is that if a company does a pivotal trial based on a researcher's technology that has been modified, the original researcher would not have access to the following: 1) contact information for implant recipients so that there is a way to even let people know that there are individuals who want to support their ongoing use and 2) IDE and relevant documentation to allow for legal interactions between the people providing and receiving long-term support. A new type of investigator-sponsored IDE is needed for researchers to provide long-term support of research participants, where knowledge of the underlying technology may not be fully known or supportable by the IDE-holder. NIH can play a role in coordinating this requirement with the FDA.

2) Technology availability: Assuming that regulatory mechanisms are in place, the investigator team also requires access to technology. This includes hardware, software and associated hardware for programming, and technical documentation. Maintaining inventory on a shelf is often identified as a solution, but for active implantable medical devices this also requires ongoing maintenance of sterility and raises questions about battery life for some devices. If inventory is not available, it means manufacturing new components which either requires using the original manufacturer or securing approval for a new manufacturer. Beyond inventory, it also means maintaining legacy computer systems with software necessary to program implanted systems. Without technical documentation, it is unrealistic to expect a generally knowledgeable individual to be able to repair external components without significant reverse engineering to understand what needs to be fixed and how to do so. Challenges arise when a company has updated a device, conducted a trial, and no longer supports a system, so that even the original research team that developed the concept is left unable to repair systems without additional information. NIH can play a role in supporting open-source documentation about the technology, to permit transfer of knowledge to other willing entities.

3) Expertise availability: In addition to the above, successful long-term support requires having knowledgeable individuals who are capable of repairing external components, programming legacy implants, or in the most involved cases explanting and replacing implanted components. This means keeping a research team intact and/or transferring knowledge about older systems when team members leave or retire as implant recipients may use a system for the rest of their life. A wide variety of knowledge bases are required ranging from clinical to technical. Training other teams to function as a second site for a clinical trial is a substantial amount of work and training people to be independent in long-term care requires even more preparation and documentation. NIH can play a role in supporting open-source documentation for surgical implant techniques and medical management of long-term participants.

4) Financial support: All of the activities and personnel described above require some form of financing to maintain the regulatory approvals, technology availability, and expertise. Funding research is the lifeblood of NIH, and the challenges described here all lend themselves to possible creative funding mechanisms for researchers. Within the funding mechanisms themselves, the NIH peer review process needs to respect the value of long-term follow-up data as a unique contribution to science. In many cases, people who sign up for research involving an implanted device hope to either gain benefit from the device and/or contribute to science, thereby benefitting future patients like themselves. When studies end, or companies go out of business, or devices fail, these participants continue to accrue all the risks of having a permanent implant without experiencing any of the health or potential additional scientific benefits (provided the participant continues to provide informed consent in any future studies). Ongoing long-term access to implanted devices also provides an opportunity to use information gleaned during the clinical trial to potentially convert non-responders to

responders which maximizes benefit. At a minimum, allowing these participants to continue to contribute to science by supporting the research teams that provide follow-up care, is a step NIH can take now that would be much more impactful than the current proposed guidance.

In summary, in addition to the proposed guidance for consent forms and research protocols, the following actions by NIH would be valuable: 1) supporting long-term research studies of people with existing devices, 2) supporting the use of open-source hardware/software to facilitate long-term access to technology and regulatory documentation, 3) working with the FDA to simplify the process for teams to provide long-term support to enable people to have the option to continue benefiting from a system, and 4) supporting empirical neuroethics research that identifies the scope of the problem and practical solutions to address these challenges.

14. Cleveland Clinic

I am responding: On behalf of an organization

Name: blair barnharthinkle

Name of Organization: Cleveland Clinic

Type of Organization: Healthcare Institution

Role: Organizational Official

Domain of research most important to you or your organization: N/A

Date Submitted: 5/25/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

Attached please find a comment letter with all of our feedback.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified
N/A

1.3 Hurdles or barriers to broad use of this resource by the research community
N/A

1.4 Other feedback relevant to this resource
N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource
N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language
N/A

2.3 Hurdles or barriers to broad use of this resource by the research community
N/A

2.4 Other feedback relevant to this resource
N/A

Upload a File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/5_22_2026-NIH-RFI_IMPLANTABLE-DEVICE-TRIALS.pdf

Description: Attached please find a comment letter with all of our feedback.



Serpil C. Erzurum, M.D
Chief Research and Academic Officer

May 22, 2026

NIH
Office of Science Policy
6705 Rockledge Drive
Suite 630
Bethesda, MD 20892

Re: Request for Information on Draft NIH Resources to Support Implantable Device Trials

Submitted Via: <https://osp.od.nih.gov/comment-form-draft-nih-resources-to-support-implantable-device-trials/>

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching, and research. With a footprint in Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 23 hospitals, including a main campus near downtown Cleveland with more than 6,700 staffed beds, including a main campus near downtown Cleveland and 15 Northeast Ohio regional hospitals, as well as 300 outpatient locations. Cleveland Clinic employs over 6,600 physicians and researchers, and 17,600 nurses and 4,300 advance practice providers. Last year, our system had 15.9 million patient encounters including 14.4 million outpatient visits and 343,000 hospital admissions and observations. Below is our feedback on the Draft NIH Resources to Support Implantable Device Trials document.

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive and Investigational Implantable Device

1. Utility and useability of this resource

The resource demonstrates high quality and comprehensive coverage, making it highly valuable for investigators and stakeholders. Its implementation will require clear guidance, including a post-trial plan template that aligns with NIH expectations for effective utilization. Investigators may encounter challenges such as confusion about device retention, but a well-designed template can bridge these gaps and support operationalization of best practices.

2. For each section of the resource, gaps or additional concepts that should be included or clarified

To further enhance the resource and ensure comprehensive coverage, several additional concepts should be clarified for each section. The resource should clarify if data collection continues beyond the trial, under what consent, and with what oversight, addressing privacy and practical risks. First, explicit guidance regarding post-trial data transmission is needed. Investigators should understand how to securely transmit and store data after the study concludes, including protocols for de-

identifying sensitive information and timelines for data transfer. Clear instructions on who is responsible for overseeing data management post-trial will help minimize confusion.

Second, the relationship between the device and the user after the study warrants more attention. The resource should specify whether participants retain devices, return them, or have them deactivated, as well as outline procedures for ongoing support or monitoring if necessary. The resource would benefit by asking investigators to contemplate whether any of the considerations for meeting anticipated needs or financial plans change if the participant withdraws from the study. This clarity will aid investigators in communicating next steps to participants.

Third, considerations for device failure and removal, such as handling an implanted defibrillator malfunction, should be thoroughly addressed. The resource should recommend protocols for identifying device failures, criteria for removal, and coordination with clinical teams to ensure patient safety. Including step-by-step guidance for emergency situations will support operational readiness.

Lastly, mechanisms for alerting investigators and stakeholders to conditions that may lead to device failure should be incorporated. The resource should outline systems for real-time monitoring, automated alerts, and escalation procedures, ensuring prompt response to potential issues. By addressing these gaps, the resource will provide a more robust framework for post-trial device management and support best practices across all stages of implementation.

NIH could further support implementation by providing a standardized post-trial planning template and accompanying checklist(s) of minimum elements investigators should address across domains (e.g., device disposition, clinical follow-up responsibilities, participant contact pathways, data types and flows, storage and access controls, retention and transfer timelines, and post-trial risk management considerations). This approach would promote consistency while allowing flexibility for institutional policies and study context. Sponsors/manufacturers should, in turn, be responsible for providing the device- and system-specific technical and operational details required to complete these elements (e.g., device data outputs, transmission methods, monitoring capabilities and limitations, known failure modes, deactivation or return procedures, and support infrastructure), enabling investigators to operationalize NIH expectations accurately and communicate clearly with participants.

3. Hurdles or barriers to broad use of this resource by the research community.

Operationalization of this resource could pose hurdles for broad adoption within the research community. Investigators may face challenges translating the comprehensive guidance into practical workflows, particularly if local infrastructure or institutional policies differ from those assumed by the resource. Additionally, ensuring consistent implementation across diverse study settings may require significant training and adaptation, which could slow uptake and limit the resource's effectiveness in standardizing best practices.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

1. Utility and useability of this resource

When developing informed consent materials for research involving investigational implantable devices, it is essential to strike a balance between providing comprehensive information and avoiding overwhelming or alarming patients with excessive detail. Consent templates are valuable tools for

standardizing language and ensuring key issues are addressed, but their effectiveness depends on clarity, conciseness, and a risk-based approach that prioritizes the most critical information.

To support investigators and IRB members, we recommend a concise consent template that highlights the most important points. Key considerations include:

- **Device Management Post-Trial:** Clearly explain what happens to the device after the study concludes, such as whether it will be retained, returned, or deactivated, and outline any ongoing monitoring or support procedures.
- **Data Transmission and Security:** Provide high-level information about how study-related data will be transmitted, stored, and de-identified, including who is responsible for data management and relevant timelines.
- **Risks of Device Failure or Removal:** Describe the main risks associated with device malfunction or removal, focusing on realistic scenarios and emergency protocols, without listing every improbable event.
- **Monitoring and Alerts:** Inform participants about mechanisms in place for real-time monitoring and automated alerts, emphasizing safety and prompt response to potential issues.

Sample language for consent might include: “After the study, you may be asked to return or deactivate the device, depending on your situation. Your data will be securely transmitted and stored, with identifying information removed whenever possible. Although rare, there is a risk the device may malfunction; if this occurs, you will be supported by our clinical team. We monitor devices closely and will notify you promptly if any concerns arise.”

Templates should be brief and focus on the most relevant risks and procedures, avoiding exhaustive lists of unlikely scenarios that could unnecessarily alarm participants. By adopting a high-level, risk-based approach and maintaining balanced, robust consent language, investigators can ensure patients are well-informed without being overwhelmed, supporting ethical research and best practices in post-trial device management.

2. For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

The current informed consent materials are quite lengthy, which may make it difficult for both investigators and participants to efficiently navigate and absorb the most critical information. The volume of detail, while comprehensive, could risk overwhelming participants and complicating the study team's workflow.

To address this, we strongly urge the development of a succinct FAQ sheet. An FAQ can serve as a practical companion to the main consent documents by highlighting essential information, clarifying common concerns, and streamlining the consent discussion. This approach can promote consistency, ensure that the most frequently asked questions are addressed up front, and empower teams to deliver clear, participant-centered communication without unnecessary repetition or detail.

Integrating an FAQ sheet would not only enhance the efficiency of the consent process but also reduce the cognitive burden on participants and make it easier for study teams to remember and deliver key materials at the appropriate time. We recommend that the FAQ be concise, easy to

reference, and provided alongside the core consent documents as a flexible tool—supporting, but not replacing, the informed consent process itself.

3. Hurdles or barriers to broad use of this resource by the research community

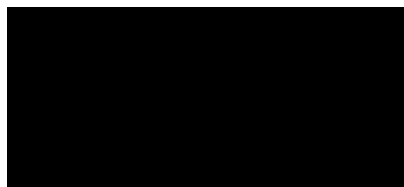
Despite the advantages of concise consent templates and FAQ sheets, several barriers may hinder their widespread adoption by the research community. One significant challenge is the potential length of these resources; when templates or FAQs become too detailed, investigators may request that the entire document be included, leading to confusion about which sections are relevant for a particular study. Administrative staff may struggle to determine which information applies to their protocol, increasing the risk of miscommunication and procedural delays.

Clinical interpretation presents another hurdle. Coordinators or nurses who lack experience with implanted device clinical trials may find device-related information difficult to understand, especially when the resource contains technical details about management, monitoring, or risks. This complexity can place additional burden on IRB members, who may need to streamline content to ensure it is accessible and appropriately tailored for study participants

Another fundamental barrier to broad adoption is the responsibility for providing device-specific information. Much of the relevant content, including post-trial management, potential risks, and technical details, should ideally originate from the device sponsor and be included in the Instructions for Use (IFU) documentation. If investigators are not the inventors or manufacturers, they may lack access to critical details necessary for informed consent. Without clear regulatory requirements compelling sponsors to supply comprehensive information, investigators and study teams are left to navigate gaps on their own, which can further complicate and prolong the consent process. Ensuring that sponsors proactively provide this information is essential for high-quality, participant-centered communication and ethical research practice.

Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of our feedback. Should you need any further information, please contact me.

Sincerely,



Serpil C. Erzurum, M.D
Alfred Lerner Memorial Chair in Innovative Biomedical Research
Cleveland Clinic Chief Research and Academic Officer

15. The Michael J. Fox Foundation for Parkinson's Research

I am responding: On behalf of an organization

Name: Mason Zeagler

Name of Organization: The Michael J. Fox Foundation for Parkinson's Research

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Domain of research most important to you or your organization: Parkinson's disease

Date Submitted: 5/25/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

The Michael J. Fox Foundation for Parkinson's Research appreciates the opportunity to comment on NIH's draft resource, Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device. We support NIH's effort to encourage proactive, participant-centered planning for implantable device trials.

This resource is useful and timely for Parkinson's disease research, particularly for studies involving deep brain stimulation and other implanted neuromodulation technologies. We agree with NIH that post trial planning should occur before study enrollment and should address anticipated care needs, financial responsibility, continuity of care, and long-term oversight.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 3: Anticipated Participants' Needs

We support NIH's inclusion of anticipated physical, clinical, technical, and psychosocial needs. We recommend that NIH more explicitly encourage study teams to consider care partner and logistical needs as part of this element.

For many implantable device trials, especially DBS-related studies, care partners may need to accompany participants to surgery, discharge, perioperative visits, programming visits, follow-up visits, or urgent evaluations. These needs may include transportation, lodging, parking, meals, missed work, caregiving coverage at home, and help during recovery. These are not minor details; for some participants and families, they determine whether participation is feasible.

We also support NIH's inclusion of psychosocial needs and recommend that the final resource make clear that uncertainty itself can be burdensome. Many people with Parkinson's disease experience anxiety as part of the disease experience, and uncertainty about surgery, device management, post-trial care, insurance coverage, or whom to contact if something goes wrong may add avoidable distress.

Planning should therefore address communication and support needs, not only clinical procedures.

Element 4: Plans for Meeting Former Participants' Anticipated Needs

We agree with NIH's emphasis on continuity of care when a participant retains an investigational device or requires explantation after the trial. To make this more usable, we recommend NIH encourage study teams to describe the handoff plan in clear terms: what information the participant will receive, what information will be shared with treating clinicians, what device documentation will be provided, and who remains available for device-related questions after the study ends.

Element 5: Financial Plan

We strongly support NIH's inclusion of a financial plan and appreciate that the draft resource recognizes that health insurance coverage is not guaranteed and that some participants may lack insurance entirely. We recommend making this issue more explicit so that study teams describe how the financial plan will apply to participants who are uninsured, underinsured, or experience coverage denials during or after the study.

We also recommend that NIH provide an optional participant-facing financial responsibility table. The table could identify major cost categories and specify whether each cost is covered by the study, billed to insurance, covered by the institution, covered by the sponsor or manufacturer, covered by trial-specific insurance, reimbursed to the participant, or potentially owed by the participant.

Relevant categories could include implantation, explantation, programming, battery replacement, replacement parts, software updates, maintenance, device-related complications, emergency care, post-trial clinical care, travel, lodging, parking, and care partner support.

Element 6: Oversight of Long-Term Care Plan

We support that NIH encourage study teams to identify a durable institutional contact mechanism, not only an individual PI or coordinator. Participants may need support years after enrollment, and staff turnover is common. A standing institutional office would help participants reconnect with the appropriate clinical or research personnel after a study ends.

Best Practice Considerations

We recommend adding patients, care partners, and patient organization reviews as a best practice. Patient organizations with condition specific expertise can help study teams identify community level concerns and recurring barriers, while patients and care partners can assess whether the plan is understandable and realistic from a lived experience perspective.

These reviewers can help identify real-world barriers, including travel feasibility, recovery expectations, visit burden, insurance confusion, care partner availability, anxiety related to uncertainty, and whether the post-trial care plan is useful for participants and families.

1.3 Hurdles or barriers to broad use of this resource by the research community

The main barrier is that the resource may be viewed as aspirational unless study teams have tools to apply it. NIH could improve uptake by providing optional templates, including a post-trial care checklist, a model financial responsibility table, and example language for participants.

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

The Michael J. Fox Foundation for Parkinson's Research strongly supports NIH's draft informed consent resource.

Implantable device trials require a high clarity because the consequences of participation may extend beyond the study period. Participants may need to understand not only study procedures and risks, but also what happens if the device remains in place, is removed, becomes nonfunctional, requires maintenance, causes complications, affects future care, or creates future costs.

For people with Parkinson's disease considering DBS or other implantable device research, these issues intersect with symptom management, mobility, medication timing, care partner support, and anxiety about disease progression and future care.

We appreciate NIH's emphasis on plain-language informed consent materials, with the recommendation that materials be written at an 8th grade reading level. In our work when reviewing participant-facing materials, we similarly recommend plain language, clear definitions, short sentences, and formatting that helps participants and care partners understand what participation will mean.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1: Introduction/Purpose

We support NIH's recommendation that the introduction clearly explain the study purpose and the investigational device. We recommend NIH encourage study teams to be especially clear when the study involves a familiar technology, such as DBS, being used in an investigational way. Participants may hear a familiar term and assume the device, procedure, software, or indication is standard clinical care.

Component 2: Procedures

We recommend NIH encourage study teams to describe care partner expectations and logistics as part of the procedure burden. For example, for DBS-related studies, a care partner may be needed for surgery, discharge, recovery, transportation, programming, follow-up, or urgent visits. If care partner involvement is required or necessary, this should be stated clearly in the consent process. In MJFF's work supporting

study teams for patient centric research practices, we often recommend that study teams proactively arrange and reimburse reasonable care partner expenses, including travel, lodging, parking, meals, and related logistics. Participants and care partners should understand these arrangements before enrollment.

Component 3: Long-Term Practical Considerations

We strongly support NIH's inclusion of long-term practical considerations. We recommend NIH encourage a short participant-facing "what this means for you" summary as a companion sheet. The purpose would not be to duplicate the full consent form, but to highlight the most decision-relevant practical issues: what device is being implanted, whether it may remain in place, what care may be needed after the study, what costs may arise, what future medical care could be affected, what happens if the participant withdraws, and who to contact.

Component 6: Alternatives

We support NIH's inclusion of alternatives to participation. For studies of device-based interventions, we recommend NIH encourage study teams to distinguish between clinical care alternatives and research alternatives. Participants should understand whether approved or clinically available options exist, whether they may be eligible for those options outside the study, and whether joining the study could affect access to future procedures, trials, or standard care.

Component 7: Cost

We support NIH's cost section and agree with its emphasis on financial consequences, post-trial liability, insurance uncertainty, future insurance changes, and participant responsibility when no post-trial arrangements have been made. We recommend NIH provide tools that make the cost information easier for participants to understand.

Component 8: Compensation for Research-Related Injury

We support NIH's inclusion of compensation for research-related injury, including post-trial injuries related to the device. We recommend NIH encourage study teams to distinguish clearly between compensation or treatment for research-related injury, reimbursement for study-related expenses, and participant payment or incentives. Participants may reasonably hear "compensation" and assume it includes reimbursement or payment for time, when the section may actually refer only to research-related injury.

Component 9: Withdrawal

We support NIH's recommendation that withdrawal language explains what happens if a participant withdraws. We recommend NIH also encourage study teams to explain financial responsibility after withdrawal. If a participant withdraws but the device remains implanted, the consent process should

explain who pays for maintenance, monitoring, emergency care, explantation, or transition to clinical care.

2.3 Hurdles or barriers to broad use of this resource by the research community

A major barrier is making sure informed consent materials are understandable and useful to participants and care partners, not just complete. Consent forms are often long and technically complex. We agree with NIH's recommendation that consent materials should be written in plain language at approximately an 8th grade reading level, and we recommend that study teams work with patients, care partners, and patient organizations when developing or reviewing consent materials.

2.4 Other feedback relevant to this resource

We recommend NIH explicitly encourage patient, care partner, and patient organization input in developing and reviewing consent materials for implantable device trials. Patient organizations with condition-specific expertise can help identify common concerns across the community, while patients and care partners can assess whether the materials are understandable, relevant, and usable for decision-making.

In sum, MJFF supports NIH's draft informed consent resource. We recommend retaining the current emphasis on plain language, post-trial care, cost transparency, mental health effects, and durable contacts, while adding practical implementation tools such as financial responsibility tables, one-page participant summaries, and review by patients, care partners, and patient organizations.

16. Erika Versalovic, Asad Beck, Amanda R. Merner, Helen S. Mayberg, Tommy J. Wilson, Sahand Babapoor-Farrokhran, Joan A. Camprodon, Cristina Cusin, Martijn Figee, Robert M. Richardson, Patricio Riva-Posse, Joseph J. Fins, Gabriel Lázaro-Muñoz

I am responding: On behalf of myself

Name: Erika Versalovic, Asad Beck, Amanda R. Merner, Helen S. Mayberg, Tommy J. Wilson, Sahand Babapoor-Farrokhran, Joan A. Camprodon, Cristina Cusin, Martijn Figee, Robert M. Richardson, Patricio Riva-Posse, Joseph J. Fins, Gabriel Lázaro-Muñoz

Name of Organization: N/A

Type of Organization: Healthcare Institution

Role: Investigator/Researcher

Domain of research most important to you or your organization: clinical neuromodulation and neuroethics

Date Submitted: 5/25/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

As researchers who work and study the development and translation of investigational neural devices, we strongly support NIH's initiative to establish resources for post-trial support planning for investigational implantable device studies. The resources effectively outline the importance of and steps necessary to properly transition support of trial participants after the trials' end. Within this comment, we speak to the ways we have seen these support needs arise within neural device trials in particular. Throughout our comment, 'neural device trials' refers to clinical trials that involve devices implanted within the brain, including brain-computer interfaces, deep brain stimulation systems, visual implants, and neural prostheses. While many of our comments may be applicable to other forms of implantable devices (e.g., implantable drug delivery systems, cardiovascular implants), these may require unique considerations outside the scope of our comments. With this in mind, we offer the following observations:

To improve utility, we ask for clarification regarding how, if at all, these plans will shape grant evaluation. Furthermore, we encourage the NIH to establish a dialogue with the Centers for Medicare & Medicaid Services to ensure insurance coverage for NIH trial participants who have treatment-resistant conditions but receive symptom relief from the investigational implantable device. Evidence of clinical benefit of the investigational device on an otherwise treatment-resistant condition should be enough to consider this device "medically necessary" for that participant, in this narrow context. Furthermore, economic evidence suggests that health insurance providers save money by covering experimental implantable

devices that are working compared to spending on treatments that have already been shown not to work for patient with treatment-resistant conditions.

We suggest adding context to the statement that “clinical trials have discrete endpoints” This statement is not consistent with the experience of participants and researchers have both reported that trial endpoints can feel ambiguous to trial participants due to their ongoing relationships with study clinician-researchers. In our work, we have found the phrasings of ‘long-term support’ or ‘continued support’ (rather than ‘post-trial support’) to better align with the ways these investigational devices are experienced by trial participants themselves.

We suggest inverting the order of Element 1 and Element 2 to improve its utility, as mapping potential risks and benefits is a prerequisite to outlining the plan/options for device retention or explantation after the trial’s end. The enumeration of risks and potential benefits of the device remaining In Situ vs explanted should guide the post-trial options researchers propose, rather than the latter shaping the former.

Additionally, to improve the useability of this resource, we recommend the incorporation of ‘quick reference’ visuals such as a flowchart or tables with example language to improve the readability and navigability of this rich resource. A visual organizer with bulleted summaries and examples of each element would greatly help with navigability.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Our recommendations for these sections are as follows:

Element 1. Plan/Options for Device Explanation or Remaining In Situ

1.1: To harmonize the description of the elements with the ‘Best Practice Recommendations,’ we urge NIH to emphasize the need for a higher burden of justification for trial policies that plan for explantation of all trial participants at a trial’s end. We agree with the importance of providing post-trial device management plans and that explantation at a trial’s end may be an appropriate recommendation in cases where (1) there is a mutual decision to have it explanted; (2) there is no individual-level benefit the patient may receive from the device; and (3) keeping the device implanted could exclude them from other clinical trials (e.g., having an implant being an automatic exclusion criteria). However, in cases when the device could provide continued benefit or is helping to manage a condition that has not responded to available treatments, the default post-trial plan should not be explantation (unless for safety considerations and participant agreement). Consistent with this, explantation should not be a requirement for consenting to participate in a neural device trial if the device may be the only effective intervention available for the participant. Potential participants may feel coerced to participate in trials even if they do not agree with the explantation of the device, given the lack of any remaining available intervention options.

1.2: A participant always has the option to withdraw from a study or refuse a surgical procedure; thus, even if the participant consented to participate in a trial with a device removal requirement, the participant will always have the right to refuse the explantation of the device. Thus, research teams’ plans should account for participants who do not end up explanting, even when that may be the

intention at the trial's start. To reflect the resource's Best Practice Recommendations, we also suggest changing the order in which explantation and remaining In Situ are presented as options within Element 1.

1.3: We recommend expanding the In Situ options presented to include pathways where the device (1) remains In Situ and maintenance is ensured for a period of time or through insurance coverage, if available; (2) remains In Situ and turned off; or (3) remains In Situ and functional and the patient has to make arrangements for maintenance. The current verbiage that presents the two options as being explanted or remaining implanted implies a binary that could limit investigators' post-trial considerations.

Element 2. Risks and Potential Benefits:

2.1: In response to the accounts provided by trial participants in our work examining post-trial care, we urge the resource to acknowledge the extent of harm that may result from explantation of a therapeutically beneficial investigational implant at the trial's end or a lack of maintenance to enable continued use. The current phrasing of "Additionally, losing a therapeutic benefit if the device is explanted could also be considered a negative outcome for the participant" fails to capture the magnitude of potential harms that can come from loss of access or maintenance of the device. For those in deep brain stimulation trials, for example, explantation or insufficient maintenance can risk returning participants to a state of suffering high symptom burden with no other effective treatment options available (as eligibility criteria for implantable device trials often require participants whose condition is 'treatment resistant' to approved therapies). Further, in addition to 'losing a therapeutic benefit,' there can sometimes be an exacerbation of symptoms through 'rebound effects' in which symptoms return worse than before the trial.

2.2: We suggest adding device-company related risks within this element. Research teams should consider the scenarios that could arise if the company goes out of business, decides to change the design of the investigational device, stops pursuing approval or research on the device, or sells the intellectual property from the trial. Researchers should consider how they will minimize risks related to obsolescence such as firmware going out of date or parts becoming difficult to obtain. In addition, there are biological risks associated with device degradation and associated immune responses.

2.3: We suggest incorporating consideration of IT security risks. Researchers should consider how patient privacy and security will be ensured over time as data breaches or out of date devices could expose patients to unnecessary risks from bad actors. Ongoing data stewardship practices (e.g., whether there will be ongoing data collection, location of storage, responsibility for maintaining security) should be part of post-trial planning.

2.4: We offer that providing a taxonomy of types of risk and benefits may help research teams map the range of potential risks and benefits. One way this taxonomy could read is:

"Types of risks and benefits could include:

Medical (e.g., surgical complications, infection, symptom burden)

Technological (e.g., data privacy and security, access to programming/updates, obsolescence if company goes out of business)

Psychosocial (e.g., bodily integrity, impact on day-to-day activities or quality of life)”

Element 3. Anticipated Participants’ Needs.

3.1: We encourage NIH to expand upon the parenthetical mention of psycho-social needs. We suggest elevating that mention from the parenthetical towards the bottom to being foregrounded earlier in this section with examples to illustrate these types of needs such as peer support, transportation and lodging assistance for appointments, additional assistance in cases there is an accompanying support partner, and mental health resources for the post-trial transition.

3.2: We suggest the addition of how life post-trial may require additional support for patients’ other medical providers. For example, after a patient participates in a deep brain stimulation trial, the patient’s local psychiatrist or neurologist may require additional informational resources for ongoing clinical management.

3.3: Here, and across resource sections, we emphasize the importance of communicating these anticipated needs to participants directly, and support partners when relevant. Adding language in this section asking researchers to explain how they will ensure these anticipated needs are communicated to participants will help ensure post-trial plans translate to patient resources.

Element 4. Plans for Meeting Former Participants’ Anticipated Needs.

4.1: To increase accessibility for all trial participants, we encourage the resource to account for the social factors that shape individual participants’ needs such as physical distance from the trial site, access to transportation, or ability to take time off for additional appointments. One could revise the current sentence “Consider plans across the scenarios outlined above” to instead read: “Consider plans across the scenarios above, attending to social factors that may shape the kind of support different participants may need in those scenarios (e.g., residing in a rural setting, lacking transportation or other resources).”

4.2: We suggest adding consideration of the specialized clinical support participants who retain devices may need after the trial. In our work with neural device trials (i.e., experimental deep brain stimulation for psychiatric indications such as depression, obsessive-compulsive disorder), former trial participants describe the increased difficulties they have faced finding clinicians who feel comfortable managing psychiatric care for a patient who has been in a neural implant trial. This resource would benefit from discussion of the need for support resources when participants’ broader healthcare needs may shift due to having participated in a neural device trial.

4.3: Here, and across sections of this resource, we encourage planning for how these forms of support will be communicated to participants, and, when relevant, support partners. As mentioned in 2.3.2,

there should be mention of how these resources will be communicated to participants themselves to improve transparency and increase accountability. Researchers should consider reconsenting patients at regular intervals to affirm the plans for long term care.

4.4: To strengthen consideration of possible future scenarios within post-trial planning, we suggest adding the need for research teams to plan for the possible scenario of a device company's dissolution or device part obsolescence. Post-trial planning requires consideration of scenarios in which the accessibility of device parts or device knowledge access shifts due to the changes within the device development market.

Element 5. Financial Plan.

5.1: To increase accessibility for all trial participants, we encourage the resource to account for the social factors that shape individual participants' needs such as physical distance from the trial site, access to transportation, or ability to take time off for additional appointments. One could revise the current sentence "Consider plans across the scenarios outlined above" to instead read: "Consider plans across the scenarios above, attending to social factors that may shape the kind of support different participants may need in those scenarios (e.g., residing in a rural setting, lacking transportation or other resources)."

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5.3: Here, and across sections of this resource, we encourage planning for how these forms of support will be communicated to participants, and, when relevant, support partners. As mentioned in 2.3.2, there should be mention of how these resources will be communicated to participants themselves to improve transparency and increase accountability. Researchers should consider reconsenting patients at regular intervals to affirm the plans for long term care.

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Element 6. Oversight of Long-Term Care Plan.

6.1: To improve accountability and effectiveness of post-trial care planning oversight, we suggest the resource should mention who will serve as an ongoing point of contact(s) for participants. In our research interviews with participants in neural device trials (i.e., deep brain stimulation), many

mentioned the need for a phone number they can call as questions arise after the trial, and the need for those calls to be reliably answered by a knowledgeable person. In initial consent process, contact information for the surgeon's office and device company should be provided. At the trial's close, contact information of appropriate experts should be provided for future device-related questions participants may have. Those responsible for post-trial plan oversight must be accessible by trial participants to improve accountability and aid in participants' long-term navigation of device-specific benefits and risks.

1.3 Hurdles or barriers to broad use of this resource by the research community

To broaden the applicability of this resource, we suggest the NIH include a more diverse range of device examples and more clearly define the policy's scope. In the current draft, the only examples given are cases of deep brain stimulation devices. To improve uptake of this resource by the broader implantable device research community, we recommend incorporating other device examples that would fall within this policy (e.g., intrathecal 'pain' pumps, brain-computer interfaces) as well as clarifying devices that would not fall under this policy (e.g., investigational cardiac devices) and whether post-trial support is available for individual participants receiving benefit from the device even when the trial itself 'failed.'

We suggest NIH provide examples for each post-trial care plan element. As post-trial planning is nascent within some research areas, the current resource format may be too broad — a shortcoming that could be addressed through providing post-trial plan examples. We encourage NIH provide multiple examples within each element that speak to the range of implantable device trials and align with the 'Best Practice Recommendations.'

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

Given that participants may have difficulty retaining information related to post-trial care, we recommend restructuring the informed consent process to be an iterative process that is responsive to participant needs and understanding. Participants often enroll in neural devices trials because their conditions have proven to be unresponsive to preexisting treatments or medication; consequently, these participants typically present with high symptom burden upon entry to clinical trials. At the same time, information conveyed during the consent process covers a broad range of topics, often containing technical detail. These two factors together can lead to low retention of information communicated during the consent process. We suggest an addendum to the Key Points section emphasizing the need for consent information to be regularly revisited and adapted to participants' understanding and needs as they evolve over time. While different disorders/devices will have different endpoints and thus necessitate case-specific consent statements, an example of how this key point may read is:

"Depending on the patient population and trial context, participants may not retain information shared during the informed consent process. Informed consent should be viewed as a longitudinal and iterative process that is revisited throughout the trial, particularly as participants respond to the device and as research teams prepare participants for the post-trial transition."

This change would necessitate updating language throughout the document to reflect this change to a more dynamic and responsive informed consent process. For example, in the ‘General Points to Consider’ section, the beginning of the fourth bullet point should read, “Prior to initiating the study, investigators should develop a post-trial care plans that are communicated to research participants and includes: ...”

Further, we recommend the below changes in wording:

Rewording “However, investigators may consider the importance of highlighting” to “However, investigators should consider the importance of highlighting.”

Adding to “...long-term post-trial care plan, including a designated responsible party” so it reads “...long-term post-trial care plan, including a designated responsible party and patient contact.”

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1. Introduction/Purpose.

1.1 We recommend adding language regarding communicating trial timeline, exit plans, and transitional support to participants. Given the length of neural device trials (typically exceeding 6 months), participants often do not know when the clinical trial ends and, once it has ended, who to contact for post-trial concerns. This component should add language emphasizing the importance of providing transitional support resources at trial end (e.g., stepwise plan for transitioning to off-label clinical use if the device provides continued therapeutic benefit) — rather than solely during initial enrollment. This would work in tandem with broader change to the informed consent process to be more responsive to participant needs throughout the study.

1.2 We encourage the use of more accessible language, as well as visual representations, during the consent process. A recent study found that 54% of adults read below a sixth grade reading level. Given that the target populations are managing treatment-resistant conditions — some including disrupted executive function — participants are likely to be under greater cognitive load and therefore have less capacity to process information provided during the consent process. To ensure increased accessibility and comprehension, we suggest amending the recommended reading level from 8th grade to 6th grade, as well as encouraging visual representations, when possible (e.g., for the device, study design, risks and benefits), to aid in visualizing and clarifying often very technical detail. A helpful approach would be to provide the patient with a video introduction to the study, that goes over and illustrates the consent forms. Researchers may continue to use and provide copies of the often text-heavy consent forms and use strategies to assist comprehension, but research suggests that patients often miss important information (e.g., post-trial management plans) during the consent process or have difficulty understanding the study design. Thus, it is important to change how consent is approached in these settings to be one that centers participant understanding and not just disclosure.

Component 2. Procedures.

2.1: We recommend adding language regarding (double-)blind study procedures and associated expectations. Should the neural device trial involve separating participants into experimental vs. placebo groups, it is important participants have adequate understanding of these procedures.

2.2: In bullet point three (regarding relevant details for the procedure), we suggest the additional mention of anticipated social support needed. For instance, whether the trial requires the identification of a support partner to accompany them to/from the study site.

2.3: Relatedly, given that proximity to the clinical site will vary between participant, we recommend disclosing anticipated travel and lodging cost considerations, including physical locations in which the procedures will take place as well as any travel-related planning and expenses. This addition would improve considerations for socioeconomic differences (e.g., lower-income, more rural participants).

2.4: If data will be captured and sent to the clinical site for analysis, we recommend adding considerations regarding data security and privacy. This may include language regarding who would have access to the data during the clinical trial, what steps are in place to ensure data security, and whether the participant has access to their data during, or post-trial. Many participants are not aware that, if the neural device trial relies on public funding (e.g., NIH BRAIN), the data collected from their implanted investigational device is required to be publicly shared and thereby potentially accessed by commercial entities without additional expressed permission of the participant. Instead, most participants believe that the data collected from their implanted device remains only within academic research team circles. Sample language address this could include:

“The device collects information about your brain activity. This brain data will be [kept by/shared with] [name parties]. After the study ends, your brain data will be [kept/deleted/made anonymous]. You [will/will not] be able to see or delete your brain data.”

2.5: We additionally recommend adding considerations regarding disclosures of partnerships with industry/commercial entities, as well as whether data collected from participants will be used in development of commercial devices. While many participants in neural devices trials express the desire for data collected from their implanted investigational device to be used to advance science and innovation, they simultaneously express concerns regarding use of said data for commercial purposes.

2.6: Given these devices typically rely on a data analysis/signal processing algorithm, we recommend adding language addressing algorithmic transparency regarding the device. Sample language could include:

“The device in this study has a computer program that reads signals from your brain and that can change how the device works on its own, without your doctor making the change.”

2.7: To ensure participants know they have a right to device removal at any point, we recommend changing “You may choose to have the device removed at the end of the study” to read “You may choose to have the device removed at any point, during or after, the study.”

Component 3. Long-Term Practical Considerations.

3.1: As mentioned in previous points, we recommend this aspect of informed consent should be one that is regularly revisited during and especially at the end of the study. For instance, this would involve adding the language,

“Additionally, the information could be provided in the form of a fact sheet, for easy reference. This information should be reviewed and presented again at the conclusion of the study to maximize participant comprehension and preparedness for the transition to the post-trial phase.”

3.2: We recommend highlighting the importance of working with the participant to individualize the post-trial care plan. Given that participants’ understanding and needs continue to develop post-trial, working with the patient to anticipate needs and personalize the post-trial care plan would help ensure their unique circumstances are addressed (e.g., consistently available transportation for more rural patients). This element should be considered part of the initial IRB review process.

3.3: We greatly appreciate the mention of the importance of an ongoing post-trial point of contact for participants and request it be added to the sample language. For example, it could read “We will give you an information card that includes basic details about the device and a point of contact for post-trial care questions or issues related to the device.” This information could alternatively take the form of an online resource that would ensure information would not be lost and could be easily updated in the future.

3.4: We encourage the addition of language offering participants the option to connect to a network of peers. Because enrolling in a neural device trial leads to unique (and, for some, transformative) long-term changes in lifestyle, participants in past trials have found significant value in networking with others enrolled in the same or similar trials. Offering participants the option to be connected to others enrolled in the trial would provide access to a unique, longer-term social support network of peers, which would additionally aid in their navigating post-trial issues and concerns that may otherwise go unaddressed or misunderstood by those without lived experience. Mechanisms should be developed to allow for these exchanges with respect to participant confidentiality and the avoidance of the introduction of any bias through these interactions.

Component 4. Potential Risks.

4.1: Regarding implantation risks, we have the following suggestions:

Include considerations regarding physical aesthetics. The physical appearance of the device may lead to social discomfort and thereby cause the participant to discontinue its use to avoid unwanted attention or perceived stigma.

4.2: Regarding explantation risks, we have the following suggestions:

Rephrase physical/psychological risks to clinical/psychosocial risks. Currently, this section seemingly underestimates the degree of psychological risks that could come from explantation, primarily seen in the phrasing of psychological risk as “depression due to loss of benefit achieved through the device.” We suggest amending the two categories of risk from physical to clinical (e.g., infection, recurrence of symptoms) and from psychological to psychosocial (e.g., loss of benefits that enabled engagement in meaningful activities).

4.3: Regarding risks related to having an implanted device, we have the following suggestions:

Include risk of potential hardware or software malfunction. This may include cable failures, lead migrations, or faulty hardware — any of which could lead to unforeseen changes in device efficacy or even patient injury.

Include considerations regarding possible loss of device support. This would include bankruptcy of device manufacturer, insufficient battery availability, or obsolete hardware/software. Sample language could include:

"This device needs software to work. Like a smartphone or computer, the software may need updates. After the study, the study team [will/may not] be able to give you these updates, which could compromise the security of the device. If the company that made the device goes out of business, it may not be possible to get updates or parts. We have [describe any plans, or state that no plans exist]."

4.4: We recommend adding language capturing possible changes in behavior — or ways of thinking, feeling, or acting — during and after implantation. Prior studies have shown that implantable neural devices have the potential to induce changes in an individual’s way of thinking, feeling, or behaving (e.g., emotion regulation, sense of self, feelings of autonomy or control). This is due in part to their efficacy at managing refractory conditions (e.g., depression, OCD), but also due to the (often necessary) titration of drugs following activation of an implantable device or to the stimulation leading to side effects such as hypomania. While these changes could be seen as desirable, participants should be made aware of these potential changes during the consent process. Sample language could include:

“This implantable neural device may influence aspects of your mood, cognition, or behavior. The research team will be monitoring these changes during the study. Consult with the research team if you, your family, or friends notice changes they view as concerning or changes that may lead to harmful or dangerous behavior. The research team can discuss what changes are most often reported among patients with [condition]. If the device is removed or stops working, you may notice another change. We will [describe monitoring plan] and [describe available support].”

Component 5. Benefits.

5.1: Because of how deeply personal investigational implantable devices are, participants often express interest in the data and results generated by their participation, even if they do not directly benefit from such results. We encourage the addition of language clarifying how findings gleaned from the neural device trial(s) may be shared with participants.

Component 7. Cost.

7.1: Related to procedure-related considerations regarding travel, we recommend including language regarding non-clinical costs participants may incur for research-related appointments (e.g., transportation, parking, hotel). The form should clearly state whether these costs will be covered by the study, whether participants will be reimbursed for study-related costs, or whether patients are expected to pay for these costs themselves.

7.2: We greatly appreciate the inclusion of post-trial considerations regarding insurance coverage in the sample language, and we recommend adding language regarding willingness to work with participant insurer to the considerations as well. This section should also address the fact that, regardless of whether the device is providing benefit, health insurance providers can deny coverage of the device as it would be considered an investigational device, and even government-sourced insurance may fail to cover procedure-related costs.

7.3: Here, and when financial aspects of the implantable device are mentioned throughout these resources, we recommend adding clarification of how long (or within what limits) each aspect of device-related care coverage will be provided.

Component 8. Compensation for Research-Related Injury.

8.1: Participants who benefit from an implantable investigational device, but have the device explanted or who are not able to maintain their devices functional, may experience rebound effects or worsening of symptoms. We suggest the inclusion of language clarifying whether care costs associated with such post-explantation, or lack of maintenance-related symptoms, would be covered as research-related injury.

8.2: Further, the verbiage of “who is responsible” should clarify what type of responsibility to which it refers (e.g., financial, legal liability).

8.3: We also recommend the consideration of media-related risks as a potential research-related injury. This may be more or less applicable depending on the device used in the study (e.g., Neuralink vs. spinal cord stimulator); however, inclusion in device trials may expose participants to privacy-related harms due to potential intrusive attention by journalists

Component 9. Withdrawal.

9.1: We recommend including language clarifying that participants may elect/refuse to have the device explanted at any time (even if they previously consented to device explantation) and cannot be explanted against their wishes. This would ensure the consent process would be in line with various national and international regulatory guidelines and legislation.

9.2: Regarding withdrawal, we recommend including the contingency that the study is stopped by the

device company. As the sample language is currently worded, it reads “sponsor or an oversight group”; sponsor could refer to the funding agency or the manufacturer, leading to ambiguity. We recommend rephrasing at “the trial sponsor, an oversight group, or the device manufacturer.”

9.3: Regarding the withdrawal sample language, we encourage adding sample language for how voluntary withdrawal does or does not affect patient out-of-pocket costs, or other potential ramifications.

2.3 Hurdles or barriers to broad use of this resource by the research community

We applaud the inclusion of sample language within each section and suggest the further addition of example documentation of how Informed Consent form may look. This may also/additionally take the shape of an interactive online form in which investigators are given individual modules corresponding to each listed component (e.g., procedures, risks/benefits, cost) and can enter the study-specific details to help generate a post-trial plan/language for consent. This would have the accompanying benefit of potentially, on the participant-side, serving as a consent hub in which the procedures are outlined clearly in small modules (e.g., surgery, data collection, study design, stimulation, measures being collected, post-trial) allowing participants can revisit/review modules associated with the study at any time. This would also include contact information for the study team that is relevant to that aspect of the study.

2.4 Other feedback relevant to this resource

N/A

Upload a File: <https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/MGH-PublicComment-PostTrialResources.pdf>

Public Comment in Response to Request for Information on Draft NIH Resources to Support Implantable Device Trials

Authors: Erika Versalovic, Asad Beck, Amanda R. Merner, Helen S. Mayberg, Tommy J. Wilson, Sahand Babapoor-Farrokhran, Joan A. Camprodon, Cristina Cusin, Martijn Figee, Robert M. Richardson, Patricio Riva-Posse, Joseph J. Fins, Gabriel Lázaro-Muñoz

Type of Organization: Healthcare Institution

Domain of research most important to you or your organization: Clinical neuromodulation and neuroethics

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device.

1. Utility and useability of this resource

As researchers who work and study the development and translation of investigational neural devices, we strongly support NIH's initiative to establish resources for post-trial support planning for investigational implantable device studies. The resources effectively outline the importance of and steps necessary to properly transition support of trial participants after the trials' end. Within this comment, we speak to the ways we have seen these support needs arise within neural device trials in particular. Throughout our comment, 'neural device trials' refers to clinical trials that involve devices implanted within the brain, including brain-computer interfaces, deep brain stimulation systems, visual implants, and neural prostheses. While many of our comments may be applicable to other forms of implantable devices (e.g., implantable drug delivery systems, cardiovascular implants), these may require unique considerations outside the scope of our comments. With this in mind, we offer the following observations:

To improve utility, we ask for clarification regarding how, if at all, these plans will shape grant evaluation. Furthermore, we encourage the NIH to establish a dialogue with the Centers for Medicare & Medicaid Services to ensure insurance coverage for NIH trial participants who have treatment-resistant conditions but receive symptom relief from the investigational implantable device. Evidence of clinical benefit of the investigational device on an otherwise treatment-resistant condition should be enough to consider this device "medically necessary" for that participant, in this narrow context. Furthermore, economic evidence suggests that health insurance providers save money by covering experimental implantable devices that are working compared to spending on treatments that have already been shown not to work for patient with treatment-resistant conditions.

We suggest adding context to the statement that "clinical trials have discrete endpoints" This statement is not consistent with the experience of participants and researchers have both reported that trial endpoints can feel ambiguous to trial participants due to their ongoing relationships with study clinician-researchers. In our work, we have found the phrasings of 'long-term support' or 'continued support' (rather than 'post-trial support') to better align with the ways these investigational devices are experienced by trial participants themselves.

We suggest inverting the order of Element 1 and Element 2 to improve its utility, as mapping potential risks and benefits is a prerequisite to outlining the plan/options for device retention or explantation after the trial's end. The enumeration of risks and potential benefits of the device

remaining *In Situ* vs explanted should guide the post-trial options researchers propose, rather than the latter shaping the former.

Additionally, to improve the useability of this resource, **we recommend the incorporation of ‘quick reference’ visuals** such as a flowchart or tables with example language to improve the readability and navigability of this rich resource. A visual organizer with bulleted summaries and examples of each element would greatly help with navigability.

2. For each section of the resource, identify gaps or additional concepts that should be included or clarified.

Our recommendations for these sections are as follows:

Element 1. Plan/Options for Device Explanation or Remaining *In Situ*

- 1.1: To harmonize the description of the elements with the ‘Best Practice Recommendations,’ we **urge NIH to emphasize the need for a higher burden of justification for trial policies that plan for explantation of all trial participants** at a trial’s end. We agree with the importance of providing post-trial device management plans and that explantation at a trial’s end may be an appropriate recommendation in cases where (1) there is a mutual decision to have it explanted; (2) there is no individual-level benefit the patient may receive from the device; and (3) keeping the device implanted could exclude them from other clinical trials (e.g., having an implant being an automatic exclusion criteria). However, in cases when the device could provide continued benefit or is helping to manage a condition that has not responded to available treatments, the default post-trial plan should not be explantation (unless for safety considerations and participant agreement). Consistent with this, explantation should not be a requirement for consenting to participate in a neural device trial if the device may be the only effective intervention available for the participant. Potential participants may feel coerced to participate in trials even if they do not agree with the explantation of the device, given the lack of any remaining available intervention options.
- 1.2: A participant always has the option to withdraw from a study or refuse a surgical procedure; thus, **even if the participant consented to participate in a trial with a device removal requirement, the participant will always have the right to refuse the explantation of the device.** Thus, research teams’ plans should account for participants who do not end up explanting, even when that may be the intention at the trial’s start. To reflect the resource’s Best Practice Recommendations, we also suggest changing the order in which explantation and remaining *In Situ* are presented as options within Element 1.

- 1.3: **We recommend expanding the *In Situ* options presented** to include pathways where the device (1) remains *In Situ* and maintenance is ensured for a period of time or through insurance coverage, if available; (2) remains *In Situ* and turned off; or (3) remains *In Situ* and functional and the patient has to make arrangements for maintenance. The current verbiage that presents the two options as being explanted or remaining implanted implies a binary that could limit investigators' post-trial considerations.

Element 2. Risks and Potential Benefits:

- 2.1: In response to the accounts provided by trial participants in our work examining post-trial care, **we urge the resource to acknowledge the extent of harm that may result from explantation** of a therapeutically beneficial investigational implant at the trial's end or a lack of maintenance to enable continued use. The current phrasing of "Additionally, losing a therapeutic benefit if the device is explanted could also be considered a negative outcome for the participant" fails to capture the magnitude of potential harms that can come from loss of access or maintenance of the device. For those in deep brain stimulation trials, for example, explantation or insufficient maintenance can risk returning participants to a state of suffering high symptom burden with no other effective treatment options available (as eligibility criteria for implantable device trials often require participants whose condition is 'treatment resistant' to approved therapies). Further, in addition to 'losing a therapeutic benefit,' there can sometimes be an exacerbation of symptoms through 'rebound effects' in which symptoms return worse than before the trial.
- 2.2: **We suggest adding device-company related risks** within this element. Research teams should consider the scenarios that could arise if the company goes out of business, decides to change the design of the investigational device, stops pursuing approval or research on the device, or sells the intellectual property from the trial. Researchers should consider how they will minimize risks related to obsolescence such as firmware going out of date or parts becoming difficult to obtain. In addition, there are biological risks associated with device degradation and associated immune responses.
- 2.3: **We suggest incorporating consideration of IT security risks.** Researchers should consider how patient privacy and security will be ensured over time as data breaches or out of date devices could expose patients to unnecessary risks from bad actors. Ongoing data stewardship practices (e.g., whether there will be ongoing data collection, location of storage, responsibility for maintaining security) should be part of post-trial planning.
- 2.4: **We offer that providing a taxonomy of types of risk and benefits** may help research teams map the range of potential risks and benefits. One way this taxonomy could read is:

“Types of risks and benefits could include:

- Medical (e.g., surgical complications, infection, symptom burden)
- Technological (e.g., data privacy and security, access to programming/updates, obsolescence if company goes out of business)
- Psychosocial (e.g., bodily integrity, impact on day-to-day activities or quality of life)”

Element 3. Anticipated Participants’ Needs.

- **3.1: We encourage NIH to expand upon the parenthetical mention of psycho-social needs.** We suggest elevating that mention from the parenthetical towards the bottom to being foregrounded earlier in this section with examples to illustrate these types of needs such as peer support, transportation and lodging assistance for appointments, additional assistance in cases there is an accompanying support partner, and mental health resources for the post-trial transition.
- **3.2: We suggest the addition of how life post-trial may require additional support for patients’ other medical providers.** For example, after a patient participates in a deep brain stimulation trial, the patient’s local psychiatrist or neurologist may require additional informational resources for ongoing clinical management.
- **3.3: Here, and across resource sections, we emphasize the importance of communicating these anticipated needs to participants** directly, and support partners when relevant. Adding language in this section asking researchers to explain how they will ensure these anticipated needs are communicated to participants will help ensure post-trial plans translate to patient resources.

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- **4.1: To increase accessibility for all trial participants, we encourage the resource to account for the social factors that shape individual participants’ needs** such as physical distance from the trial site, access to transportation, or ability to take time off for additional appointments. One could revise the current sentence “Consider plans across the scenarios outlined above” to instead read: “Consider plans across the scenarios above, attending to social factors that may shape the kind of support different participants may need in those scenarios (e.g., residing in a rural setting, lacking transportation or other resources).”
- **4.2: We suggest adding consideration of the specialized clinical support participants who retain devices may need after the trial.** In our work with neural device trials (i.e.,

experimental deep brain stimulation for psychiatric indications such as depression, obsessive-compulsive disorder), former trial participants describe the increased difficulties they have faced finding clinicians who feel comfortable managing psychiatric care for a patient who has been in a neural implant trial. This resource would benefit from discussion of the need for support resources when participants' broader healthcare needs may shift due to having participated in a neural device trial.

- 4.3: Here, and across sections of this resource, **we encourage planning for how these forms of support will be communicated to participants**, and, when relevant, support partners. As mentioned in 2.3.2, there should be mention of how these resources will be communicated to participants themselves to improve transparency and increase accountability. Researchers should consider reconsenting patients at regular intervals to affirm the plans for long term care.
- 4.4: To strengthen consideration of possible future scenarios within post-trial planning, **we suggest adding the need for research teams to plan for the possible scenario of a device company's dissolution or device part obsolescence**. Post-trial planning requires consideration of scenarios in which the accessibility of device parts or device knowledge access shifts due to the changes within the device development market.

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Element 6. Oversight of Long-Term Care Plan.

- 6.1: To improve accountability and effectiveness of post-trial care planning oversight, **we suggest the resource should mention who will serve as an ongoing point of contact(s) for participants**. In our research interviews with participants in neural device trials (i.e., deep brain stimulation), many mentioned the need for a phone number they can call as questions arise after the trial, and the need for those calls to be reliably answered by a knowledgeable person. In initial consent process, contact information for the surgeon's office and device company should be provided. At the trial's close, contact information of appropriate experts should be provided for future device-related questions participants may have. Those responsible for post-trial plan oversight must be accessible by trial participants to improve accountability and aid in participants' long-term navigation of device-specific benefits and risks.

3. Hurdles or barriers to broad use of this resource by the research community

To broaden the applicability of this resource, **we suggest the NIH include a more diverse range of device examples and more clearly define the policy's scope**. In the current draft, the only examples given are cases of deep brain stimulation devices. To improve uptake of this resource by the broader implantable device research community, we recommend incorporating other device examples that would fall within this policy (e.g., intrathecal 'pain' pumps, brain-computer interfaces) as well as clarifying devices that would *not* fall under this policy (e.g., investigational cardiac devices) and whether post-trial support is available for individual participants receiving benefit from the device even when the trial itself 'failed.'

We suggest NIH provide examples for each post-trial care plan element. As post-trial planning is nascent within some research areas, the current resource format may be too broad — a shortcoming that could be addressed through providing post-trial plan examples. We encourage NIH provide multiple examples within each element that speak to the range of implantable device trials and align with the ‘Best Practice Recommendations.’

Comments related to Resource 2. Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource.

1. Utility and useability of this resource

Given that participants may have difficulty retaining information related to post-trial care, **we recommend restructuring the informed consent process to be an iterative process that is responsive to participant needs and understanding.** Participants often enroll in neural devices trials because their conditions have proven to be unresponsive to preexisting treatments or medication; consequently, these participants typically present with high symptom burden upon entry to clinical trials. At the same time, information conveyed during the consent process covers a broad range of topics, often containing technical detail. These two factors together can lead to low retention of information communicated during the consent process. We suggest an addendum to the Key Points section emphasizing the need for consent information to be regularly revisited and adapted to participants' understanding and needs as they evolve over time. While different disorders/devices will have different endpoints and thus necessitate case-specific consent statements, an example of how this key point may read is:

“Depending on the patient population and trial context, participants may not retain information shared during the informed consent process. Informed consent should be viewed as a longitudinal and iterative process that is revisited throughout the trial, particularly as participants respond to the device and as research teams prepare participants for the post-trial transition.”

This change would necessitate updating language throughout the document to reflect this change to a more dynamic and responsive informed consent process. For example, in the ‘General Points to Consider’ section, the beginning of the fourth bullet point should read, “Prior to initiating the study, investigators should develop a post-trial care plans *that are communicated to research participants* and includes: ...”

Further, we recommend the below changes in wording:

- Rewording “However, investigators *may* consider the importance of highlighting” to “However, investigators *should* consider the importance of highlighting.”
- Adding to “...long-term post-trial care plan, including a designated responsible party” so it reads “...long-term post-trial care plan, including a designated responsible party *and patient contact.*”

2. For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language.

Component 1. Introduction/Purpose.

- **1.1 We recommend adding language regarding communicating trial timeline, exit plans, and transitional support to participants.** Given the length of neural device trials (typically exceeding 6 months), participants often do not know when the clinical trial ends and, once it has ended, who to contact for post-trial concerns. This component should add language emphasizing the importance of providing transitional support resources at trial end (e.g., stepwise plan for transitioning to off-label clinical use if the device provides continued therapeutic benefit) — rather than solely during initial enrollment. This would work in tandem with broader change to the informed consent process to be more responsive to participant needs throughout the study.
- **1.2 We encourage the use of more accessible language, as well as visual representations, during the consent process.** A recent study found that 54% of adults read below a sixth grade reading level. Given that the target populations are managing treatment-resistant conditions — some including disrupted executive function — participants are likely to be under greater cognitive load and therefore have less capacity to process information provided during the consent process. To ensure increased accessibility and comprehension, we suggest amending the recommended reading level from 8th grade to 6th grade, as well as encouraging visual representations, when possible (e.g., for the device, study design, risks and benefits), to aid in visualizing and clarifying often very technical detail. A helpful approach would be to provide the patient with a video introduction to the study, that goes over and illustrates the consent forms. Researchers may continue to use and provide copies of the often text-heavy consent forms and use strategies to assist comprehension, but research suggests that patients often miss important information (e.g., post-trial management plans) during the consent process or have difficulty understanding the study design. Thus, it is important to change how consent is approached in these settings to be one that centers participant understanding and not just disclosure.

Component 2. Procedures.

- **2.1: We recommend adding language regarding (double-)blind study procedures and associated expectations.** Should the neural device trial involve separating participants

into experimental vs. placebo groups, it is important participants have adequate understanding of these procedures.

- 2.2: In bullet point three (regarding relevant details for the procedure), **we suggest the additional mention of anticipated social support needed**. For instance, whether the trial requires the identification of a support partner to accompany them to/from the study site.
- 2.3: Relatedly, given that proximity to the clinical site will vary between participant, **we recommend disclosing anticipated travel and lodging cost considerations**, including physical locations in which the procedures will take place as well as any travel-related planning and expenses. This addition would improve considerations for socioeconomic differences (e.g., lower-income, more rural participants).
- 2.4: If data will be captured and sent to the clinical site for analysis, **we recommend adding considerations regarding data security and privacy**. This may include language regarding who would have access to the data during the clinical trial, what steps are in place to ensure data security, and whether the participant has access to their data during, or post-trial. Many participants are not aware that, if the neural device trial relies on public funding (e.g., NIH BRAIN), the data collected from their implanted investigational device is required to be publicly shared and thereby potentially accessed by commercial entities without additional expressed permission of the participant. Instead, most participants believe that the data collected from their implanted device remains only within academic research team circles. Sample language address this could include:

“The device collects information about your brain activity. This brain data will be [kept by/shared with] [name parties]. After the study ends, your brain data will be [kept/deleted/made anonymous]. You [will/will not] be able to see or delete your brain data.”

- 2.5: We additionally **recommend adding considerations regarding disclosures of partnerships with industry/commercial entities, as well as whether data collected from participants will be used in development of commercial devices**. While many participants in neural devices trials express the desire for data collected from their implanted investigational device to be used to advance science and innovation, they simultaneously express concerns regarding use of said data for commercial purposes.
- 2.6: Given these devices typically rely on a data analysis/signal processing algorithm, **we recommend adding language addressing algorithmic transparency regarding the device**. Sample language could include:

"The device in this study has a computer program that reads signals from your brain and that can change how the device works on its own, without your doctor making the change."

- 2.7: To ensure participants know they have a right to device removal at any point, we recommend changing "You may choose to have the device removed at the end of the study" to read "You may choose to have the device removed at any point, during or after, the study."

Component 3. Long-Term Practical Considerations.

- 3.1: As mentioned in previous points, **we recommend this aspect of informed consent should be one that is regularly revisited during and especially at the end of the study.** For instance, this would involve adding the language,
 - "Additionally, the information could be provided in the form of a fact sheet, for easy reference. *This information should be reviewed and presented again at the conclusion of the study to maximize participant comprehension and preparedness for the transition to the post-trial phase.*"
- 3.2: **We recommend highlighting the importance of working with the participant to individualize the post-trial care plan.** Given that participants' understanding and needs continue to develop post-trial, working with the patient to anticipate needs and personalize the post-trial care plan would help ensure their unique circumstances are addressed (e.g., consistently available transportation for more rural patients). This element should be considered part of the initial IRB review process.
- 3.3: **We greatly appreciate the mention of the importance of an ongoing post-trial point of contact for participants and request it be added to the sample language.** For example, it could read "We will give you an information card that includes basic details about the device *and a point of contact for post-trial care questions or issues related to the device.*" This information could alternatively take the form of an online resource that would ensure information would not be lost and could be easily updated in the future.
- 3.4: **We encourage the addition of language offering participants the option to connect to a network of peers.** Because enrolling in a neural device trial leads to unique (and, for some, transformative) long-term changes in lifestyle, participants in past trials have found significant value in networking with others enrolled in the same or similar trials. Offering participants the option to be connected to others enrolled in the trial would provide access

to a unique, longer-term social support network of peers, which would additionally aid in their navigating post-trial issues and concerns that may otherwise go unaddressed or misunderstood by those without lived experience. Mechanisms should be developed to allow for these exchanges with respect to participant confidentiality and the avoidance of the introduction of any bias through these interactions.

Component 4. Potential Risks.

- 4.1: Regarding implantation risks, we have the following suggestions:
 - **Include considerations regarding physical aesthetics.** The physical appearance of the device may lead to social discomfort and thereby cause the participant to discontinue its use to avoid unwanted attention or perceived stigma.
- 4.2: Regarding explantation risks, we have the following suggestions:
 - **Rephrase physical/psychological risks to clinical/psychosocial risks.** Currently, this section seemingly underestimates the degree of psychological risks that could come from explantation, primarily seen in the phrasing of psychological risk as “depression due to loss of benefit achieved through the device.” We suggest amending the two categories of risk from physical to clinical (e.g., infection, recurrence of symptoms) and from psychological to psychosocial (e.g., loss of benefits that enabled engagement in meaningful activities).
- 4.3: Regarding risks related to having an implanted device, we have the following suggestions:
 - **Include risk of potential hardware or software malfunction.** This may include cable failures, lead migrations, or faulty hardware — any of which could lead to unforeseen changes in device efficacy or even patient injury.
 - **Include considerations regarding possible loss of device support.** This would include bankruptcy of device manufacturer, insufficient battery availability, or obsolete hardware/software. Sample language could include:
 - "This device needs software to work. Like a smartphone or computer, the software may need updates. After the study, the study team [will/may not] be able to give you these updates, which could compromise the security of the device. If the company that made the device goes out of business, it may

not be possible to get updates or parts. We have [describe any plans, or state that no plans exist].”

- **4.4: We recommend adding language capturing possible changes in behavior — or ways of thinking, feeling, or acting — during and after implantation.** Prior studies have shown that implantable neural devices have the potential to induce changes in an individual’s way of thinking, feeling, or behaving (e.g., emotion regulation, sense of self, feelings of autonomy or control). This is due in part to their efficacy at managing refractory conditions (e.g., depression, OCD), but also due to the (often necessary) titration of drugs following activation of an implantable device or to the stimulation leading to side effects such as hypomania. While these changes could be seen as desirable, participants should be made aware of these potential changes during the consent process. Sample language could include:

“This implantable neural device may influence aspects of your mood, cognition, or behavior. The research team will be monitoring these changes during the study. Consult with the research team if you, your family, or friends notice changes they view as concerning or changes that may lead to harmful or dangerous behavior. The research team can discuss what changes are most often reported among patients with [condition]. If the device is removed or stops working, you may notice another change. We will [describe monitoring plan] and [describe available support].”

Component 5. Benefits.

- **5.1:** Because of how deeply personal investigational implantable devices are, participants often express interest in the data and results generated by their participation, even if they do not directly benefit from such results. **We encourage the addition of language clarifying how findings gleaned from the neural device trial(s) may be shared with participants.**

Component 7. Cost.

- **7.1:** Related to procedure-related considerations regarding travel, **we recommend including language regarding non-clinical costs participants may incur for research-related appointments** (e.g., transportation, parking, hotel). The form should clearly state whether these costs will be covered by the study, whether participants will be reimbursed for study-related costs, or whether patients are expected to pay for these costs themselves.

- 7.2: We greatly appreciate the inclusion of post-trial considerations regarding insurance coverage in the sample language, and **we recommend adding language regarding willingness to work with participant insurer to the considerations as well.** This section should also address the fact that, regardless of whether the device is providing benefit, health insurance providers can deny coverage of the device as it would be considered an investigational device, and even government-sourced insurance may fail to cover procedure-related costs.
- 7.3: Here, and when financial aspects of the implantable device are mentioned throughout these resources, we recommend adding clarification of how long (or within what limits) each aspect of device-related care coverage will be provided.

Component 8. Compensation for Research-Related Injury.

- 8.1: Participants who benefit from an implantable investigational device, but have the device explanted or who are not able to maintain their devices functional, may experience rebound effects or worsening of symptoms. **We suggest the inclusion of language clarifying whether care costs associated with such post-explantation, or lack of maintenance-related symptoms, would be covered as research-related injury.**
- 8.2: Further, the verbiage of “who is responsible” should clarify what type of responsibility to which it refers (e.g., financial, legal liability).
- 8.3: We also **recommend the consideration of media-related risks** as a potential research-related injury. This may be more or less applicable depending on the device used in the study (e.g., Neuralink vs. spinal cord stimulator); however, inclusion in device trials may expose participants to privacy-related harms due to potential intrusive attention by journalists

Component 9. Withdrawal.

- 9.1: **We recommend including language clarifying that participants may elect/refuse to have the device explanted at any time (even if they previously consented to device explantation) and cannot be explanted against their wishes.** This would ensure the consent process would be in line with various national and international regulatory guidelines and legislation.
- 9.2: Regarding withdrawal, we recommend **including the contingency that the study is stopped by the device company.** As the sample language is currently worded, it reads

“sponsor or an oversight group”; sponsor could refer to the funding agency or the manufacturer, leading to ambiguity. We recommend rephrasing at “the trial sponsor, an oversight group, or the device manufacturer.”

- 9.3: Regarding the withdrawal sample language, we encourage adding sample language for **how voluntary withdrawal does or does not affect patient out-of-pocket costs**, or other potential ramifications.

3. Hurdles or barriers to broad use of this resource by the research community

We applaud the inclusion of sample language within each section and **suggest the further addition of example documentation** of how Informed Consent form may look. This may also/additionally take the shape of an interactive online form in which investigators are given individual modules corresponding to each listed component (e.g., procedures, risks/benefits, cost) and can enter the study-specific details to help generate a post-trial plan/language for consent. This would have the accompanying benefit of potentially, on the participant-side, serving as a consent hub in which the procedures are outlined clearly in small modules (e.g., surgery, data collection, study design, stimulation, measures being collected, post-trial) allowing participants can revisit/review modules associated with the study at any time. This would also include contact information for the study team that is relevant to that aspect of the study.

17. Motif Neurotech, Inc.

I am responding: On behalf of an organization

Name: Danny Barber

Name of Organization: Motif Neurotech, Inc.

Type of Organization: Commercial Entity (Biotech/Device/ Pharmaceutical Company/Small Business)

Role: Other

Role - Other: Legal

Domain of research most important to you or your organization: Neuromodulation

Date Submitted: 5/25/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

Overall, the resources provided useful non-exhaustive examples of hypothetical scenarios industry should be considering as they pursue their respective neurotechnological approaches. Given the diversity of these industry approaches, both in technological form factor and target patient population, each approach will have scenarios that are specific to that particular therapy modality, which may not apply at all to different neurotechnological approaches.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 5. Financial responsibility following sponsor insolvency.

The NIH should consider clarifying whether some form of predefined financial assurance mechanism is recommended or expected for higher-risk implant studies (e.g trial-specific insurance, escrow/reserve funding, institutional contingency agreements, or other limited post-trial financial protections). At minimum, some acknowledgment is needed that participants should not become medically stranded solely due to sponsor insolvency.

Element 3, 6. Clarification regarding scope and duration of sponsor obligations.

For early-stage companies, indefinite or open-ended obligations may not be financially feasible and discourage innovation. It may be helpful for NIH to clarify that post-trial obligations should be prospectively defined, proportionate to device risk, and include appropriate limitations. There should be differences in obligations depending on invasiveness and dependency on clinicians for the device to remain operative.

Element 3. Trial-specific insurance expectations.

The documents reference trial-specific insurance multiple times lay out what constitutes sufficient coverage. Clinical trial coverage should explicitly cover delayed complications, long-term implant maintenance, hardware failures occurring years later, and insolvency-related explantation for implants.

The NIH may wish to provide guidance on reasonable insurance expectations for implantable device studies.

Element 6. Long-Term Device Sustainability and Component Availability

The guidance appropriately discusses replacement parts, software updates, and technical support availability. The NIH should consider encouraging the Sponsor to carry a reserve inventory of critical replacement components to cover the lifespan of any implanted device, regardless of whether the implant is related to clinical research or commercial use.

Element 5. Coordination with FDA and CMS

The NIH may wish to coordinate with FDA and CMS (or consider another governmental funding source) regarding: explantation coverage pathways, management of investigational device complications, and reimbursement mechanisms for medically necessary post-trial care.

1.3 Hurdles or barriers to broad use of this resource by the research community

Because the neurotechnology industry uses many varied and medically unique approaches, each technology will have different and specific informed consent practice considerations, based on the specific medical procedures used in relation to the respective medical device. It would be challenging to adopt a uniform example set of informed consent guidance across technologies in the industry, given the specificity of these technologies. That said, industry should be encouraged to think conscientiously about these concepts, and adopt informed consent practices that reflect their technological approach and patient population.

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

The proposed informed consent language was useful to highlight broad conceptual considerations industry should be taking into account for their particular therapeutic approach. However, because the industry's approaches are so varied and highly distinct, it is hard to provide a one size fits all solution. Each technology will have different informed consent practices, based on the specific medical procedures used.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

N/A

2.3 Hurdles or barriers to broad use of this resource by the research community

It would be challenging to adopt a set of uniform informed consent practice examples across industry. That said, industry should be encouraged to think conscientiously about these concepts, and adopt best practices that reflect their technological approach.

2.4 Other feedback relevant to this resource

N/A

18. Monash Bioethics Centre

I am responding: On behalf of an organization

Name: Nathan Higgins

Name of Organization: Monash Bioethics Centre

Type of Organization: Not Applicable

Role: Bioethicist

Domain of research most important to you or your organization: Global bioethics, neuroethics, reproductive ethics, infectious disease ethics

Date Submitted: 5/25/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

Post-trial care and support is a complex ethical challenge for investigators conducting implantable device trials. We strongly support the development of guidance for those responsible for designing post-trial care plans. These comments were prepared by the authorship team on a recent consensus study that developed recommendations on post-trial care for implantable neural devices (devices implanted in or adjacent to the central or peripheral nervous system). Several collaborators on this project, including the lead and senior researchers, are based at the Monash Bioethics Centre, a WHO Collaborating Centre for Bioethics. Our comments are therefore informed by the discussions and final recommendations arising from that project, as published earlier this year (doi: 10.1186/s12910-026-01475-7). We have also published other empirical scholarly work on the topic of post-trial care in the area of implantable neural devices (see doi: 10.1136/bmjst-2024-000262).

Overall, we are pleased to find that the NIH is publishing guidance on post-trial care, and are generally supportive of the presentation of the post-trial care as Elements. The content and structure of this resource will be useful for investigators preparing post-trial care plans for the NIH Institute, Center or Office. While the Elements are clearly framed as considerations for implant trial investigators, it may be helpful to explicitly acknowledge that clinical investigation plans are typically developed through consultation with a range of stakeholders, including commercial trial sponsors, device manufacturers, IRBs, and host institutions. Investigators are seldom the sole contributors to study design or risk assessment, yet the current framing treats them as though they bear exclusive responsibility. Greater clarity on the respective roles of key actors would strengthen the guidance, particularly regarding responsibilities for risk identification and management. This would also better reflect how investigators rely on and collaborate with these stakeholders in meeting the post-trial care considerations outlined in the document.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Introduction:

Excerpt: “Clinical trials involving implanted investigational devices (“implant trials”) differ from other types of clinical trials in that the device may either remain in the body following the completion of the trial or require a surgical or other procedure to be removed.”

- We agree that this is an ethically significant feature of implantable device trials, however in practice the distinction drawn between leaving an implant in situ and fully removing it is not always clear-cut as is suggested here. Implantable devices may be only partially explanted, for example in deep brain stimulation (DBS) where the battery pack and lead extensions may be removed while the intracranial leads and electrodes remain implanted. Our research has shown that it is not uncommon for users to have the only intracranial leads left implanted to minimise surgical risk (via craniotomy).

Excerpt: “Post-trial care refers to “care related to research participation that is needed after the research study has ended.”

- If the term “care” is used, it is not clear whether this is intended to include forms of support beyond strictly clinical care / healthcare, such as financial assistance for device maintenance or repeat procedures. If the definition is limited to clinical care, then other forms of post-trial support may be excluded. The more inclusive concept of “post-trial support” could be considered as an alternative, as participants’ needs may extend beyond healthcare alone.

Element 1 - Plan/Options for Device Explantation or Remaining In Situ:

- We agree with the thematic organisation of considerations in this Element. We take a similar position on our study on post-trial care in implantable neural device trials: “Participants must be informed of whether device removal is planned as part of the trial protocol. If not, investigators must explain the conditions that might lead them to recommend device removal, including if and when the device can be fully or partially removed, and whether and for how long removal procedures will be funded by the trial” (Recommendation 1, Recommendations on post-trial responsibility in implantable neural device research: a multidisciplinary consensus study, doi: 10.1186/s12910-026-01475-7)

- In clinical trials that require explantation at the end of the study, participants may still experience pressure or coercion at the point of device removal even if they understood and agreed to these terms at the start of the trial. This ethical hazard is not currently acknowledged in this Element. Where a protocol involves optional surgical removal at study conclusion, or where removal is clinically recommended, investigators and IRBs must ensure that participants are not exposed to undue pressure to proceed with surgery. This is reflected in Recommendation 6 from our recent paper on implantable neural devices: “Importantly, if the trial protocol involves optional surgical removal of the device at its conclusion, or if device removal is clinically recommended for other reasons by investigators, IRBs and investigators must ensure that participants are not subjected to undue pressure to undergo surgical removal procedures” (Recommendation 6, Recommendations on post-trial responsibility in implantable neural device research: a multidisciplinary consensus study, doi: 10.1186/s12910-026-01475-7).

Element 2 - Risks and Potential Benefits:

- We agree that post-trial care plans should consider how these risks of harm, discomfort and adversity may arise after the trial has ended. We are glad to see that this resource acknowledges post-trial risks (beyond mere safety risks, adverse events related to the device) associated with long-term use of an investigational implant. As this Element recognises, these risks should be discussed by investigators with participants during informed consent in a way that they understand, and are supported to understand. In case it might be useful, in our paper we distinguish between two forms of post-trial risk: (1) Post-trial risks associated with the premature discontinuation of the clinical development of the device and (2) post-trial risks associated with how plans for trial exit are configured:

1. On risks from the discontinuation of the clinical development of the device: There are numerous scenarios that could lead to the early termination of clinical development for an implantable device, including sponsor bankruptcy, adverse events, or failure to secure reimbursement. Risks to participants arising from trial termination, or later discontinuation of device development by the manufacturer, should therefore be considered during study design and ethical review. We argue IRBs should work with trial investigators and sponsors during the review process to identify and assess risks associated with discontinuation. In our multidisciplinary study, IRB representatives on our expert panel emphasised that they do not have the resources or expertise to identify these risks alone. Investigators should work with IRBs to ensure that appropriate risk management and mitigation plans are in place should a trial be prematurely discontinued. At the level of institutional governance, legal agreements between parties should, where possible, establish clear lines of accountability for risk mitigation. These responsibilities should be transparent and form part of the HREC review process. Commitments from sponsors and device manufacturers will need to be secured in advance.

2. On risks of how participants are discharged (exit) from the trial, or are transitioned into post-trial care: Loss of access to the device or device-related support, or changes in how a participant is able to use the device, may result in harms that are neither well understood nor simple to monitor. As rightly acknowledged in the introductory paragraph to these resources, what constitutes ‘appropriate’ follow-up – beyond the cadence of visits to the trial site for safety monitoring – is less clear for implantable devices. We argue that investigators, sponsors, and HRECs should pay close attention to the less obvious psychological and social risks that participants may experience when leaving a trial or after follow-up ends, and ensure there are appropriate supports and safeguards in place to minimise these harms. See below an excerpt from our article describing a few risks based on the specific configuration of trial exit processes: “When participants exit these trials they may face potential psychological and social harms, as well as discomforts and burdens, that are more subtle and difficult to detect than the physical risks of continued device implantation or removal (24,26). For example, during the trial, participants attend regular study visits over several years, building close, collaborative, and empowering relationships with the research team (53,57,58). By contrast, post-trial follow-up may involve few or no site visits, with only ad hoc communication about safety or data collection over a limited period. Such arrangements may be appropriate for the purposes of safety and tolerability monitoring, but they can overlook potential feelings of isolation, loss of connection, and diminished sense of meaning that participants may experience after the trial has ended.” (Recommendation 6, Recommendations on post-trial responsibility in implantable neural device research: a multidisciplinary consensus study, doi: 10.1186/s12910-026-

01475-7).

Element 3 - Anticipated Participant's Needs:

- We agree that investigators should describe the care and support participants are expected to need, including the type and timing of care, the needs of particular participant groups (e.g., specific age cohorts), and the required clinical and technical expertise. One aspect that could be emphasised in this Element is the need for investigators to communicate clearly and transparently about what participants can reasonably expect. For example, investigators should clearly distinguish between post-trial care available through approved, reimbursable healthcare services and care that remains unapproved and is only accessible through enrolment in a new extension trial or a special access scheme.

- It is critical to discuss these matters during informed consent at the beginning of the trial. But participants should also be informed, throughout the trial and wherever appropriate, about relevant developments in the regulatory status or commercialisation strategy of the device. This is an ongoing responsibility throughout the trial. As we argue: "These updates could influence participants' prospects for continued use and their willingness to continue participating. If the trial device is in an advanced stage of development, participants should be reasonably informed of timelines for the device's regulatory approval and commercialisation..." Recommendation 1, Recommendations on post-trial responsibility in implantable neural device research: a multidisciplinary consensus study (doi: 10.1186/s12910-026-01475-7).

Excerpt: "Outline the expected need and timing of care and support most participants should expect ... as well as needs that a subset of participants are reasonably anticipated to experience (e.g., leads break, surgical complication during explantation)."

- The use of the word "needs" does not appear to be quite right in this sentence. The examples listed (i.e., battery replacements and follow-up explantation) seem more appropriately characterised as "risks" or "potential harms".

Excerpt: "Outline the specific expertise needed for technical and clinical management of participants post-trial".

- "Management" is perhaps not the most appropriate term here. It may be a suitable term in reference to the device or intervention, but not to participants (this term risks dehumanising research participants). "Support" would be more appropriate. Suggested rephrasing: "Technical expertise needed for the management of the device, and clinical expertise needed for the care and support of participants."

Final general comment on Element 3: We noticed a shift in the use of first- and third-person referents between Elements 1 and 3. Element 1 refers to "investigators" in the abstract (i.e., "Investigators ought to do x"), whereas Element 3 addresses the reader directly, as though they are a trial investigator. We would encourage the drafters of this resource to adopt a consistent approach throughout. In our view, the former style is more appropriate.

Element 4 - Plans For Meeting Former Participants' Anticipated Needs:

- The language used in this Element suggests that post-trial arrangements are determined before the trial and remain fixed throughout the trial, such that the investigator's role is simply to disclose these arrangements to participants during informed consent at the start of the trial. Contrary to this view, we argue that such plans should be flexible and responsive to both the capacities and willingness of clinical and research personnel to provide ongoing support, and to changes in participants' personal circumstances that may require adjustments to the nature or delivery of long-term support.

- Element 4 calls for "strategies" to be put in place to minimise risks related to explantation and plans follow-up. One strategy for risk minimisation that has not been mentioned is consulting research and clinical staff about expectations and capacities for long-term responsibilities of technical and clinical support. Part of this will involve ascertaining whether participants' primary treating provider is available and competent to continue providing support. Reliance on a lone or small number of trial investigators poses a risk to participants' ongoing care if these individuals become unavailable due to retirement, relocation, or other reasons. We articulate this concern in our paper: "For trial investigators with exclusive clinical or technical expertise to manage the device - many of whom may be passionate about seeing these participants continue to benefit - there may be no reimbursement for ongoing device-related procedures if these devices are not yet covered by health insurance, and the time commitment involved may limit the researchers' capacity for other clinical research projects or provision of clinical care to other patients. Academic clinical researchers may not obtain sustainable funding for ongoing research programs and may therefore no longer be able to offer support to previous participants. There may also be issues with liability and insurance coverage for these experts if they provide support to participants when they are no longer covered by clinical trial insurance, which may then lead to reluctance to provide any post-trial support. (Recommendation 7, Recommendations on post-trial responsibility in implantable neural device research: a multidisciplinary consensus study (doi: 10.1186/s12910-026-01475-7))

Element 5 - Financial Plan:

We agree that these matters should, wherever possible, be discussed with participants and, where appropriate, their families and carers. While we support the inclusion of these financial considerations, we suggest that two additional financial matters could be more explicitly addressed in this Element:

1. Compensation: Trial insurance and compensation agreements function to provide financial and operational protection against liability claims brought on by adverse or unforeseen events during the trial. As this Element notes, participants continuing to use devices that are 'unapproved' may lack coverage and protection after the trial ends despite facing ongoing and potentially serious risks related to the intervention. We argue there should also be clear and explicit communication to participants of the types of harms covered and duration of coverage during informed consent. Participants must have a genuine opportunity during informed consent to discuss the insurance protections available for device-related harms that may arise after the trial concludes. The existence and nature of these protections may be a critical factor in participants' decisions to enrol, especially in trials where participants are

consenting to receive potentially lifelong or irreversible implantable devices (adapted from Recommendation 9 in our paper).

2. Reimbursement for study-related costs: Although most of the personal cost of continued use paid by past participants will be associated with specialist healthcare services and device maintenance, sponsors, investigators, and HRECs should also consider how the costs of travel (and in some cases, accommodation) for regular outpatient visits can act as a barrier. The level of reimbursement for travel and accommodation deemed acceptable during the trial may disproportionately affect participants who are geographically isolated or socio-economically challenged once the trial concludes. Decisions about reimbursement should recognise that while excessive payment may unduly influence participation, the excessive emphasis of the risk of undue influence can result in insufficient participant reimbursement and can stand as a barrier to ongoing access (adapted from Recommendation 9 in our paper).

Best practice considerations:

Excerpt: “If an individual participant is experiencing ongoing and significant clinical benefits without evidence of a countermanding safety concern, they should be offered the opportunity to keep the device, even if the overall trial results do not support safety/effectiveness at a population level, unless there is an ethical, medical, regulatory, legal and/or scientific justification provided as to why the device cannot be kept.”

- It is difficult to conceive of a device-related safety concern at the level of the study population that would not be sufficiently serious to warrant device removal, even for participants who have derived individual benefit. If the text instead referred to “effectiveness” at the population level, this requirement may be easier to defend.

Excerpt: “Those responsible for planning and conducting the trial are encouraged to identify other individuals outside the research team with expertise in maintaining the device that can provide post-trial care in the absence of the research team.”

- We agree with this. One group that investigators should routinely consult in the implementation of post-trial care plans is participants’ primary treating clinicians. Establishing relationships with referring clinicians is critical for ensuring continuity of care. Wherever possible, they should be actively engaged throughout the trial, rather than merely informed of their patient’s participation (with the participant’s consent). Depending on the nature of the trial and intervention, these clinicians may also be equipped with appropriate clinical or technical competencies, commensurate with their training, to support aspects of participants’ ongoing care needs as part of a shared-care arrangement (adapted from Recommendation 3 in our paper).

- Some implantable devices are intended to remain implanted for the lifetime of the device. Investigators should therefore consider whether participants have adequate family, carer, and clinician support to meet the demands of the study, and whether that support can reasonably continue beyond the end of the trial. Investigators should also be prepared to identify and accommodate changes in participants’ care arrangements, particularly where foreseeable changes are raised during recruitment, such as the

declining capacity of an older family member to provide care or make decisions, or changes in a participant's General Practitioner or specialist. At the same time, it is important to recognise that while some participants may depend on caregivers or relatives for ongoing support, others may not require family or carer involvement during the trial (adapted from Recommendation 3 in our paper). As such, making this a strict eligibility criterion may not be appropriate.

1.3 Hurdles or barriers to broad use of this resource by the research community

N/A

1.4 Other feedback relevant to this resource

Additional consideration 1 - Access barriers to long-term support:

- Socioeconomic and geographic barriers place many approved implantable neural devices (e.g., DBS) out of reach for people who may benefit from them. For example, a potential participant may be excluded due to concerns about their ability to meet study demands or provide valid informed consent, including where linguistic, cultural, or ethnic differences, or fluctuating or reduced decisional capacity, are present. Others may never have the opportunity to hear about a trial because of geographic isolation or socioeconomic disadvantage.

- These access barriers are often understood primarily in terms of how they prevent otherwise eligible individuals from participating in research. However, they should also be considered in light of their disproportionate impact on participants' ability to continue accessing interventions after a trial concludes. Some individuals may be able to participate in a trial, but face significant barriers to continued access once the study ends. Anticipating these post-trial challenges, some prospective participants may decide not to enrol. From a recruitment perspective, concerns about participant loss to follow-up — and the implications this may have for long-term monitoring and data collection — may also inadvertently favour the recruitment of participants from more urban and economically advantaged areas. Post-trial care plans should therefore consider whether certain forms of disadvantage may result in some individuals being excluded from participation, or choosing not to participate, because they are unable to guarantee ongoing access to care or support beyond the trial.

Additional consideration 2 - Consultation with families, carers, and people with lived experience:

- Families, carers and clinicians should be consulted prior to the design of the trial, and ideally co-design the trial with researchers and those with lived experience of the condition, including by identifying what post-trial care needs there may be, what flexibility may be required, and what current resources there are for care. While study designs should not be configured to meet the post-trial hopes and expectations of individual participants, they should accommodate, or at least not needlessly obstruct, participants from pursuing post-trial goals — especially when these accommodations are relatively simple, not resource intensive, or can be incorporated into initial trial funding proposals (adapted from Recommendation 4 in our paper).

Additional consideration 3 - Appropriateness of discussions about healthcare vs. long-term support:

- Careful consideration should be given to who is most appropriate and qualified to hold discussions

about post-trial hopes and expectations. Discussions of participants' hopes and expectations regarding their post-trial healthcare arrangements should only occur with their primary treating clinicians, as this falls within their expertise and the scope of their role. Engaging in healthcare-related discussions with an investigator who is not clinically trained may introduce risks, particularly where they are not equipped to provide appropriate clinical advice or do not have complete information about the participant's health or healthcare. However, discussions of hopes and expectations that are limited in scope to the device and post-trial support — such as programming and calibration, software and hardware updates, or repeat medical procedures — may reasonably be explored by clinical trial personnel who are most knowledgeable about the likely outcomes and ongoing device-specific care to be offered. In some instances, there may be ambiguity as to whether certain post-trial hopes and expectations raised by participants are clinical in nature. Investigators must therefore judge whether post-trial support issues fall within their remit, should be referred to the participant's primary healthcare provider, or require coordinated input to determine appropriate post-trial arrangements.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

N/A

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1 - Introduction / Purpose:

Excerpt: "Include if the device may be retained beyond the study period]: We [do/do not] plan to remove the investigational device when the study ends. After this study ends, we can't promise that you will be able to obtain replacement parts for [investigational medical device]. We also can't promise that you will be able to see a doctor that knows how to maintain or remove this device."

- This excerpt appropriately seeks to communicate uncertainty surrounding post-trial access and support. However, phrasing the statement in this way may have two unintended effects. First, it places the onus on participants ("we can't promise you will be able to obtain..."). Second, the emphasis is almost entirely on what investigators cannot guarantee, rather than what they can reasonably commit to providing. It may therefore be helpful to balance these statements with clearer information about the forms of support that will be provided. For example, the BROADEN of Deep Brain Stimulation for Treatment Resistant Depression study specified that explantation surgery would be covered by the trial and that participants would receive a replacement battery (<https://clinicaltrials.gov/study/NCT00617162>).

Component 2 - Procedures:

Excerpt: "You may choose to have the device removed at the end of the study. Surgery is needed to remove the [device name] from your [body part]."

- Participants may reasonably wonder what happens if the device proves beneficial. This statement would be received as quite unusual in isolation. Given the likelihood of therapeutic optimism (different from therapeutic misconception) amongst participants in this area of research, many will hope they benefit and can continue using the device, and will wonder what support will be available, and whether the device will continue to function after the study concludes. For this reason, it may be more appropriate for this statement to follow a discussion of whether participants can continue using the device at the end of the study, and what ongoing care or support arrangements would apply.

Component 3 - Long-term Practical Considerations:

Expert: "Investigators should inform participants of the long-term considerations (i.e., applying both during the trial and post-trial) of having an investigational medical device implanted as these may be relevant to a prospective participant's decision whether to join the study. Investigators may consider providing this information via a section of the consent form (as demonstrated here) or by covering the information listed below in other sections of the consent form."

- This framing appears somewhat unidirectional, focusing primarily on the disclosure of information from investigators to participants. It may also be valuable to emphasise opportunities for participants to discuss their own hopes, expectations, and preferences regarding long-term device use and post-trial support. For example, participants may wish to know how long particular support options will remain available, who they can speak to about ongoing preferences or concerns, and how evolving needs or expectations over time will be addressed.

Component 4 - Potential risks:

- How is a "potential risk" different to a "risk"? Typically just "risks" and "potential benefits" are used in research ethics. This term may be confusing for users.
- "Aware of MH effects" - in order to identify and mitigate impacts on mental health and wellbeing of participants, important to consult and discuss these matters with participants.

Component 5 - Potential benefits:

- First-in-human clinical trials (of implantable devices) typically only look at safety and tolerability, not efficacy. Participants enrolled in these trials should be informed of this during informed consent, and reminded of this throughout the trial, so that their expectations of benefit and post-trial use are not mismanaged.

2.3 Hurdles or barriers to broad use of this resource by the research community

N/A

2.4 Other feedback relevant to this resource

N/A

Upload a File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/69/s12910-026-01475-7_reference-4.pdf

Description: We have uploaded a preprint of our manuscript on post-trial care in implantable neural device trials, which substantially informed this Comment.

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We are providing an unedited version of this manuscript to give early access to its findings. Before final publication, the manuscript will undergo further editing. Please note there may be errors present which affect the content, and all legal disclaimers apply.

If this paper is publishing under a Transparent Peer Review model then Peer Review reports will publish with the final article.

Title: **Recommendations on Post-trial Responsibility in Implantable Neural Device Research: A Multidisciplinary Consensus Study**

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Declarations

This submission is not part of a special issue.

Human Ethics and Consent to Participate declaration: This study was approved by the Monash University Human Research Ethics Committee (ID: 31526). This research was conducted in accordance with the Declaration of Helsinki and received approval from the appropriate institutional ethics committee. Documentation supporting this approval (or exemption, where applicable) is available to the Editor upon request. Informed consent was obtained from all participants. Consent covered all personally identifiable data. Consent to publication: All participant data has been deidentified, and all participants consented to the publication of their deidentified data. Clinical trial number: not applicable.

Nathan Higgins, John Gardner, and Adrian Carter formed part of the core team that drafted the provisional recommendations and designed and facilitated the workshops and final survey. The remaining authors were members of the expert panel that participated in the workshops and survey, and contributed substantively to the development and refinement of the recommendations and the drafting of the manuscript. We would like to acknowledge Deama Amr, Tracy Cameron, Katrina Hutchison, and Jackie Leach Scully as members of the expert panel for their role in the workshops and consensus survey. We also acknowledge Georgia Ioakimidis-MacDougall and Molly Johnston for advice on survey design and operationalising our approach to measuring consensus, and Liam Robertson for assistance with organising and facilitating the workshops. All authors have approved the manuscript and its submission. The manuscript has not been published or submitted elsewhere. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Abstract

The clinical development of implantable neural devices raises complex ethical questions about post-trial responsibilities to participants. Continued support for participants who continue to use investigational implantable neural devices requires ongoing specialist care, technical expertise, access to tertiary clinical infrastructure, and substantial financial resources to pay for the device and related procedures. However, continued access may not be possible if the trial shows no benefit, if financial barriers limit commercial viability, or if safety concerns lead to suspension or early termination. Specific ethical guidance on post-trial responsibility is urgently needed. To address this challenge within the Australian innovation context, we conducted a modified Delphi study with a multidisciplinary panel of 24 experts, including representatives from industry, bioethics, law, neurosurgery, clinical psychology/neuropsychology, clinical research, neural engineering, regulation and governance, and lived experience advocacy. The process involved two workshops and a survey, guided by established RAND/UCLA methods with context-specific modifications. Drawing on prior empirical research and regulatory review, the panel developed 11 consensus recommendations for responsible post-trial practices. All recommendations achieved high levels of agreement and were rated as highly important for addressing ethical risks in the Australian environment. These are the first jurisdiction-specific recommendations of their kind, and we anticipate they will substantially enhance ethical and practical standards for post-trial responsibility in implantable neural device research in Australia and internationally.

Keywords

Recommendations, post-trial responsibility, neuroethics, implantable devices, research ethics

Background

Neurotechnology innovation is creating promising opportunities to alleviate the global burden of neurological and psychiatric diseases (1). Annually, billions of dollars in private investment and public funding are being poured into the development of novel devices for treating these conditions (2).

This study focuses on implantable neural devices: a family of complex, specialised, multi-component medical devices mostly used to treat intractable and debilitating manifestations of disease. These devices function by modulating, monitoring and/or decoding, the activity of the central or peripheral nervous system. Paradigmatic implantable neural devices include deep brain stimulation (DBS) for treating movement disorders (e.g., Parkinson's disease) and severe psychiatric conditions (3,4); and brain-computer interfaces (BCIs) that enable direct communication between the brain and an external device by recording, decoding, and/or stimulating neural activity. Investigational BCI systems have been shown to restore movement and enable limited pixelated vision in blind individuals (5), as well as provide new means of communication and interacting with the world (6-9).

Clinical investigations of implantable neural devices often have study designs that include inpatient hospital stays for device-related surgeries and several years of outpatient follow-up for device monitoring (10-12). One underaddressed ethical consideration that arises from the nature of how these trials are designed is whether, and to what extent, participants enrolled in clinical trials of implantable neural devices should be supported to continue using the implantable device after the trial has ended (whether planned or prematurely). Commentators agree on a few key points. For example, there is general agreement that research participants – who accept considerable risks and burdens to participate in trials of implantable systems – must be informed about what arrangements for post-trial support will be in place, and must not be discharged from the trials without some follow up support (13-15).

However, there remains considerable uncertainty and debate over who should be responsible for providing, funding and governing post-trial support for users of investigational implants (16-18). Some have argued that participants implanted with devices are owed continued support because they accept high levels of risk and burdens to participate in the trial, and would be exposed to significant harm and distress if they were to lose devices that were benefitting them (19,20). But implantable neural devices are complex and expensive interventions that require a multidisciplinary care and specialist clinical services to support their use. Given the significant and long-term resource demands of providing ongoing support for participants who continue to use irreversible and potentially lifelong trial devices, there is still no consensus about the extent of support that should be required of key trial stakeholders, including investigators, sponsors, institutions, regulators, and insurers (18).

The need for ethical guidance on this issue is becoming increasingly urgent as clinical trials of implantable neural devices are growing in size and in number. Several high-profile start-ups – including Blackrock Neurotech, Neuralink, and Synchron – are competing to be the first to bring an implantable BCI system to market. These companies will soon begin recruiting patients for multi-site pivotal trials to generate data for regulatory approval. Against this backdrop of accelerating research and investment, there have been a number of concerning reports of participants experiencing psychological harm and distress as a result of losing access to investigational implantable devices after the trial (21-25). The harms caused to participants in these situations is only beginning to be investigated (26). Without specific ethical guidance on this issue, trial organisers will continue to navigate post-trial responsibility in an *ad hoc* manner or rely on outdated international frameworks that have changed minimally since the early 2000s (27-29).

One avenue for progress is multidisciplinary consensus on the core questions, concepts and normative foundations that define this problem.

We are not the first to recognise the importance of multi-stakeholder consensus on the problem of post-trial responsibility (14,27,30,31). A recent multidisciplinary exercise by van Stuijvenberg and colleagues outlined recommendations on the use of investigational implantable neural devices in clinical trials, including several recommendations on ethical post-trial support (32). These recommendations target researchers and research ethics committees as key trial stakeholders and they were shaped by existing international standards and regulations.

A critical challenge to developing actionable ethical guidance for study design and coordination is acknowledging the extent to which post-trial considerations are shaped by the trial's geographic or jurisdictional context of the clinical trial. While the challenge of accounting for these contextual factors has already elsewhere been recognised – to our knowledge, it has not been extensively addressed in the bioethics literature. For example, in a recent workshop on the post-trial use of implantable devices it was observed that “conversations became increasingly speculative when we considered the questions about the extent of care required, and which stakeholders are most responsible” (28), and that meaningful progress would require “a full complement of stakeholders at the table”. Similarly, a recent analysis of this issue by Goering and colleagues notes that defining the practical “what” and “how” of post-trial responsibilities is “a complex task that requires input from stakeholders across many different organizations and areas of expertise and needs to be contextualised” (18).

If left unresolved, the problem of post-trial responsibility poses significant risks to prospective trial participants and a threat to innovation in the field. We conducted a collaborative, multidisciplinary exercise focused on developing recommendations for post-trial responsibility in Australia. Australian biomedical innovation represents a distinctive jurisdictional and regulatory context: despite a relatively small population of 27 million in 2025, the country remains a global leader in biomedical research having notably commercialised the first cochlear

implant in the 1980s and developed the Stentrode and Minder BCI technologies in late 2010s (33–35). Though Australia has recognised difficulties translating and commercialising local biomedical innovations (36), the country is reputed for its world-leading universal healthcare system and favourable environment for first-in-human research supported by fast-track regulatory exemption processes and tax incentives (37). This consensus exercise was situated within a national context to facilitate analysis of this complex topic. As such, the particularities of the Australian system (which include universal healthcare and a favourable environment for first-in-human research, supported by fast-track regulatory exemption processes and tax incentives) must be then taken into account when translating the articles findings to other jurisdictions.

Methods

We employed a modified Delphi approach to develop consensus recommendations on post-trial responsibility. Delphi methods are well-established for building consensus on topics of interest via multiple rounds of group and individual feedback (38,39). Our study had three stages: two 2.5-hour multidisciplinary workshops and a follow-up survey. This study design is similar to the RAND/UCLA Delphi method widely used in health policy and research priority setting (40–42). The RAND/UCLA Appropriateness Method (RAM) integrates the best available evidence with expert clinical judgment to assess the appropriateness of medical procedures for specific patient scenarios (41). It involves a thorough literature review followed by an independent survey and a final structured group discussion. We made some adaptations to this method to better align with our aims. Most notably, participants were identifiable to one another in both workshops, which allowed for open and direct verbal discussion where disagreements could be clearly expressed and mutually understood. Similar modifications to the RAND / UCLA design have been employed elsewhere in studies that employ empirical bioethics methodologies (43).

Extensive research and preparatory work were conducted by the core team (NH, AC, JG), including an international survey of current practices in implantable neural device research (28) and in-depth semi-structured interviews with trial investigators. The workshop activities were designed and facilitated by NH, AC, JG and LR. This consensus exercise complied with the ACCORD Consensus Reporting Document, but was not pre-registered (44). This study was approved by Monash University Human Research Ethics Committee (ID: 31526).

Selection of panellists

A multidisciplinary expert panel ($n = 24$) was convened by invitation. Most panellists co-authored the final paper with the core team, and the contributions of remaining members can be found in the Acknowledgements. Several factors were considered in the selection of experts (see Table 1 for demographic data). We purposively invited experts working in Australian research or clinical practice, or with significant familiarity or professional experience in the Australian context. Disciplines represented included bioethics, law, health economics, neurosurgery, clinical psychology/neuropsychology, clinical research, neural engineering, clinical trial regulation and governance, industry, and lived experience advocacy. We also sought a diversity of expertise with various kinds of clinical research and device types (e.g., clinical neuromodulation research, lab-based BCI research). Although the panel included lived experience and disability advocates, it did not include any individuals with lived experience as a current or former user of an implantable neural device. We acknowledge this as a limitation of the exercise and discuss this further in the Discussion section. Despite repeated efforts, we were unable to recruit a representative from the Australian National Health and Medical Research Council (NHMRC) or the Therapeutic Goods Administration (TGA). However, contacts from both organisations were consulted on policy matters during the development of provisional recommendations and expressed interest in the study's findings.

Other factors considered in panel selection were gender balance, direct scholarly engagement with post-trial responsibility, and panellists' academic or professional standing in the field. It was also important that panellists were broadly familiar with state and federal Australian research policies and health regulations. In general terms, the Australian federal government regulates areas with national scope such as medicines, medical devices, data protection, and the use of "unapproved" therapeutic goods, whereas Australian states and territories are primarily responsible for health service delivery including the funding of public hospitals. To this end it was important that our panel have representation from a number of Australian states and territories (Table 1).

Table 1: Demographics of multidisciplinary panel

Participants (n = 24)	
Expertise	
Bioethics or philosophy	10
Law, regulation, trial governance and health economics	5
Industry	3
Clinical psychology/neuropsychology, clinical research	2
Neurosurgery, neurology, psychiatry	1
Bioengineering, neural engineering	1
Social science	1
Lived-experience, consumer advocacy	1
Gender	
Man	12
Woman	11
Prefer not to say	1
Organisational affiliation in Australia	
Victoria	12
New South Wales	6
Queensland	3
Tasmania	1
South Australia	1
Australian Capital Territory	1

Workshops

In preparation for the first workshop the core team sorted ethical issues on post-trial responsibility into five themes. These issues were identified

via an unpublished literature review and empirical studies by our group (28). These five themes were: respect for persons, harms and benefits of research participation, responsibilities for continued support, access to research and continued support, and governance and innovation. Each theme was comprised of a set of ethical issues and ethical risk factors. We followed Drolet and colleagues in defining “ethical issue” as “any situation that may compromise, in whole or in part, the respect of at least one moral value that is considered socially legitimate and should thus be respected” (45). We defined “ethical risk factor” as “a contextual factor that increases the likelihood of an ethical harm occurring, or changes its manifestation in some way” (e.g., the regulatory status of an investigational device in a jurisdiction)(46).

The objective of the first workshop discussion was to identify ethical issues and risk factors relevant to the Australian context by drawing from the five ethical themes. Panellists were divided into breakout groups facilitated by a moderator from the core team. First, the moderators presented and described *general* ethical issues and risk factors relevant to post-trial responsibility from each of the five themes. In the second step, panellists were asked to consider (1) whether, and to what extent, these general post-trial ethical issues constituted genuine concerns in the Australian context, and (2) whether there were any Australia-specific risk factors that might heighten their likelihood or severity or alter how they might manifest. In the final part of the workshop, panellists were invited to suggest ways to address specific ethical issues and risk factors in the Australian context.

The objective of the second workshop was to solicit feedback on a provisional set of recommendations. These provisional recommendations were developed from workshop 1 discussions and a review of relevant Australian state and federal regulations, national research ethics guidance, and international good clinical practice (GCP) standards. During the second workshop, panellists were invited to evaluate each recommendation according to ethical acceptability (i.e., the strength and

targets of normative prescriptions), impact and desirability in the Australian context, and potential barriers to and consequences of implementation. Provisional recommendations were then revised in light of these workshop discussions ahead of the final survey.

Consensus

After revising the provisional recommendations, a final consensus survey was completed by panellists. Panellists were again asked to evaluate each provisional recommendation for its ethical acceptability, impact and desirability in the Australian context, as well as the level of coherence between the recommendation summary and supporting rationale and explanation. Throughout the survey panellists were provided with relevant background on existing professional guidelines or regulations when the core team deemed them critical for evaluating the recommendation's feasibility in the Australian context. Consistent with the RAND/UCLA approach, the final survey allowed panellists to anonymously vote on each recommendation. Panellists were given the option of accepting the recommendation, accepting with minor amendments, or rejecting it and providing reasons for the rejection. Panellists also gave a rating of the importance of each recommendation for addressing post-trial ethical issues and risk factors in the Australian context.

Though not strictly a definition of consensus, we adopted an 80% acceptance threshold for consensus. This is consistent with other Delphi-style policy consensus studies in this area of the health sciences (47). Correspondence with panellists during manuscript preparation was allowed for minor refinements to the recommendations without substantially altering their strength or intended targets.

Results

Summary of recommendations and consensus findings

The workshops and survey yielded a final set of 11 recommendations (Table 2). Twelve provisional recommendations were drafted ahead of the second workshop. Two underwent significant amendments prior to the

final survey, and one recommendation did not progress after its ethical appropriateness was reconsidered in light of an improved understanding of Australian medical device regulation. Of the 24 panellists who attended the first workshop, six panellists did not complete the final survey. The core team (NH, AC, JG) also did not vote in the final survey, as they were directly involved in drafting the provisional recommendations. Accordingly, the consensus data reflect the views of 14 eligible panellists who completed the final survey (83% response rate).

None of the 11 provisional recommendations in the final survey fell below the 80% acceptance threshold. All recommendations underwent minor amendments in response to survey feedback. Eight recommendations received only “keep” votes from all survey respondents, whereas three (Recommendation 3, 4 and 8) received some votes to “discard”. Panellists who had voted to discard certain recommendations worked with the core team to make minor amendments until they were satisfied. Recommendations in their final form were then reviewed and approved by panel members who co-authored the manuscript. All recommendations also achieved a median importance rating of 4 (‘Very important’) or above on our 5-point importance scale.

Below we present the 11 recommendations and their rationales. It is worth iterating that workshop discussions were carried out on an understanding that the current Australian institutional, regulatory, and funding environment should remain roughly as it is; they were developed to be practically workable within these structures. To this end, we applied a set of criteria to guide their design, ensuring consistency in formatting and in how prescriptive statements were supported by evidence and assigned to responsible parties.

Where possible, parties responsible for meeting certain stated normative requirements (e.g., X should be done, Y must not be done) were explicitly referenced. New responsibilities were distinguished from those already required by ethical guidelines and professional standards. We have used

several terms to qualify the normative force of each recommendation. Where national research ethics guidance, regulations, or laws prescribe a standard practice, we often use “it is required” descriptively to refer to the relevant governance in Australia. We use “should” to recommend changes in practice that may not yet be reflected in standard practice in Australia, and “must” to signal areas where a practice is already enshrined in ethical or professional governance but requires strengthening or clearer specification of how it should be implemented.

Where there was dissensus about a recommendation, even among those who voted in the survey to ‘keep’ it (e.g., “keep, with revisions”), these areas of discussion were explored in the recommendation description. For recommendations where there remained disagreement amongst panel members, these are also discussed. For Recommendations 1 and 8 we present supporting figures that propose how the recommendation could be implemented in the Australian context.

Table 2: Summary of recommendations with panel consensus and importance ratings

Recommendation	Consensus score after survey (% voted to “keep”)	Median importance rating 1 - 5 (interquartile range)
1. Participants must be fully informed of plans for post-trial arrangements during informed consent processes.	100%	5 (0)
2. Supported approaches must be employed during informed consent processes to ensure plans for post-trial arrangements are communicated to participants according to their communication needs and capacities.	100%	4 (1)
3. With participant consent, their families, carers and clinicians should be engaged throughout the trial wherever	93%	4 (0)

appropriate, as key parties impacting post-trial care.		
4. Design of post-trial arrangements should be informed by those with lived experience of the condition or intervention, as well as their clinicians, family and carers, with participants' hopes and expectations about their post-trial device-related healthcare and quality of life explored and ascertained during informed consent and throughout the trial.	88%	4 (1)
5. Study design and ethical review processes should identify and assess risks of harm, discomfort, and adversity from the discontinuation of clinical development of devices.	100%	5 (1)
6. Study design and ethical review processes should identify, assess for and mitigate risks of harm, discomfort, and adversity as a result of how participants are discharged from the trial or are transitioned into post-trial care.	100%	5 (1)
7. Study design and ethical review processes should take into account how post-trial device-related support will be managed after the trial ends, and by whom.	100%	4 (1)
8. Barriers to prospective participants accessing clinical trials and post-trial support should be identified and addressed.	93%	4 (1)
9. Trial insurance and compensation agreements should stipulate whether and what post-trial participation-related harms are covered. This must be discussed with participants during informed consent, and investigators should be prepared to explain it or assist participants with finding answers to questions outside their competency.	100%	5 (1)
10. Reform to medical device and clinical trial regulation should consider post-trial risks of participant harm, discomfort, and adversity. Regulators should be prepared to work with commercial and non-	100%	5 (1)

commercial device developers in addressing post-trial challenges.		
11. Specific ethical guidelines and a framework of responsibility should be developed to inform the design, implementation and ethical review of post-trial arrangements.	100%	4 (1)

Table 3: Relevant standards and guidelines for clinical investigations of medical devices in Australia

Title of document	Abbreviation	Form of governance	Description
Therapeutic Goods (Medical Devices) Regulations 2002	TG Act	Federal legislation	The Therapeutic Goods (Medical Devices) Regulations 2002 establish the detailed regulatory requirements for the classification, conformity assessment, and ongoing monitoring of medical devices in Australia, specifying the procedures and evidentiary standards that devices must meet to be included in the Australian Register of Therapeutic Goods and remain compliant throughout their lifecycle.
The National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2025)*	NS	National research ethics guidance	Australia's key research ethics guidelines that sets out principles and requirements to ensure human research is conducted ethically, responsibly, and with respect for participants.
NHMRC Participant Information Sheet/Consent Form Template for Interventional Studies (2025)	PICF	National research ethics guidance	Template document that helps researchers clearly explain study procedures, risks, and rights, and obtain informed consent from participants in clinical or other interventional research.

International Organisation for Standardisation (ISO) 14155 – Clinical Investigation of Medical Devices for Human Subjects (2020)**	ISO 14155	International standard	Outlines good clinical practice requirements for the design, conduct, recording, and reporting of medical device trials in human participants to protect their safety and ensure reliable data.
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*The latest NHMRC guidance was published in 2025 and referenced in this article, but this guidance does not come into effect in Australia until 2026.

**As a practical note, because these guidelines are firewalled and not universally accessible, many researchers rely on adapted interpretations of ICH-GCP guidance.

Recommendations

1. Participants must be fully informed of plans for post-trial arrangements during informed consent processes.

Informed consent processes must include information about the purpose of the trial, the intervention, the study schedule, and the risks and potential burdens of participation. Trials of implantable neural devices often last several years, and changes in the participants' lifestyle or health status can occur during this time. Eligible participants often have progressive conditions and experience comorbidities that require ongoing lifestyle and healthcare adjustments.

When post-trial arrangements are discussed during the informed consent process, investigators must ensure that information about post-trial arrangements is fully disclosed, communicated clearly and transparently, and that participants and their families or support persons are given a genuine opportunity to consider these arrangements.¹ Participants should also be encouraged to involve their primary treating clinician/s, considering the potential impact on their current treatment and post-trial care requirements. There was broad agreement across our multidisciplinary panel that “fully” informing participants means providing them with as clear a view as possible of what to expect regarding their options for continued use of the device post-trial.

¹ Some information about reimbursements for approved medical devices may be publicly available through the Australian Register of Therapeutic Goods (ARTG), an online database maintained by the TGA that records therapeutic goods approved for supply in Australia and provides details about their regulatory status, safety, and intended use.

However, there remained some disagreement about which specific kinds of information in an implantable neural device trial must be disclosed to “fully” inform participants, and on whether a subjective or objective standard of informed consent should apply.

Panellists did however agree that disclosure of post-trial information should address which kinds of care provided during the trial will continue to be available after the trial, whether investigators, trial sponsors, or device manufacturers will be providing this support, and what responsibilities participants will have for their own continued care. Participants must be informed of whether device removal is planned as part of the trial protocol. If not, investigators must explain the conditions that might lead them to recommend device removal, including if and when the device can be fully or partially removed, and whether and for how long removal procedures will be funded by the trial. If participants are expected to have the option of continuing to use the device after the trial, they should be informed of the nature of follow-up procedures for maintenance and repair, and which elements of clinical care and technical support will be continued after the trial or will not be accessible to them outside the trial. Investigators should clearly delineate between elements of post-trial care that are accessible as approved, reimbursable healthcare services, and those that are ‘unapproved’ and only accessible via enrolment in a new trial or a special access scheme.

There can be lengthy delays between trial conclusion, regulatory approval, and reimbursement. It is important that participants are informed of relevant developments in the regulatory status of the trial device or changes in the funding of the trial or commercial strategy for the translation of the device². These updates could influence participants’ prospects for continued use and their willingness to continue participating. If the trial device is in an advanced stage of development, participants should be reasonably informed of timelines for the device’s regulatory approval and commercialisation to enable them to make

² NS, 2025, §2.2.8.

necessary preparations for their continued use of the device. In early-stage trials of investigational devices, it can be helpful to reduce the risk of therapeutic misconception (i.e., misconstruing research as clinical care) by emphasising that the purpose of the trial is to assess safety and tolerability, not to provide therapeutic benefit (see Recommendation 2 for more on supporting participant understanding) (Horng and Grady, 2003).

Panellists in our workshops acknowledged that current guidelines and standards already require disclosure of post-trial arrangements during consent. In Australia, national human research ethics guidance requires investigators to disclose (in oral and written form) information about the trial in a form and language participants can understand, and to inform participants throughout the trial of relevant developments that could influence their decision to continue participation³. There was agreement amongst our panel that these guidelines and standards could do more to assist investigators in knowing what must be explained, and how the longevity and associated surgical procedures for devices informs what should be emphasised in disclosure. Implantable devices that require surgical removal or may be intended to be lifelong raise disclosure considerations that should be given greater emphasis in national ethics guidance documents to assist investigators in designing ethical post-trial care arrangements and conducting informed consent processes (see Figure 1).

³ NS, 2025, §3.1.37

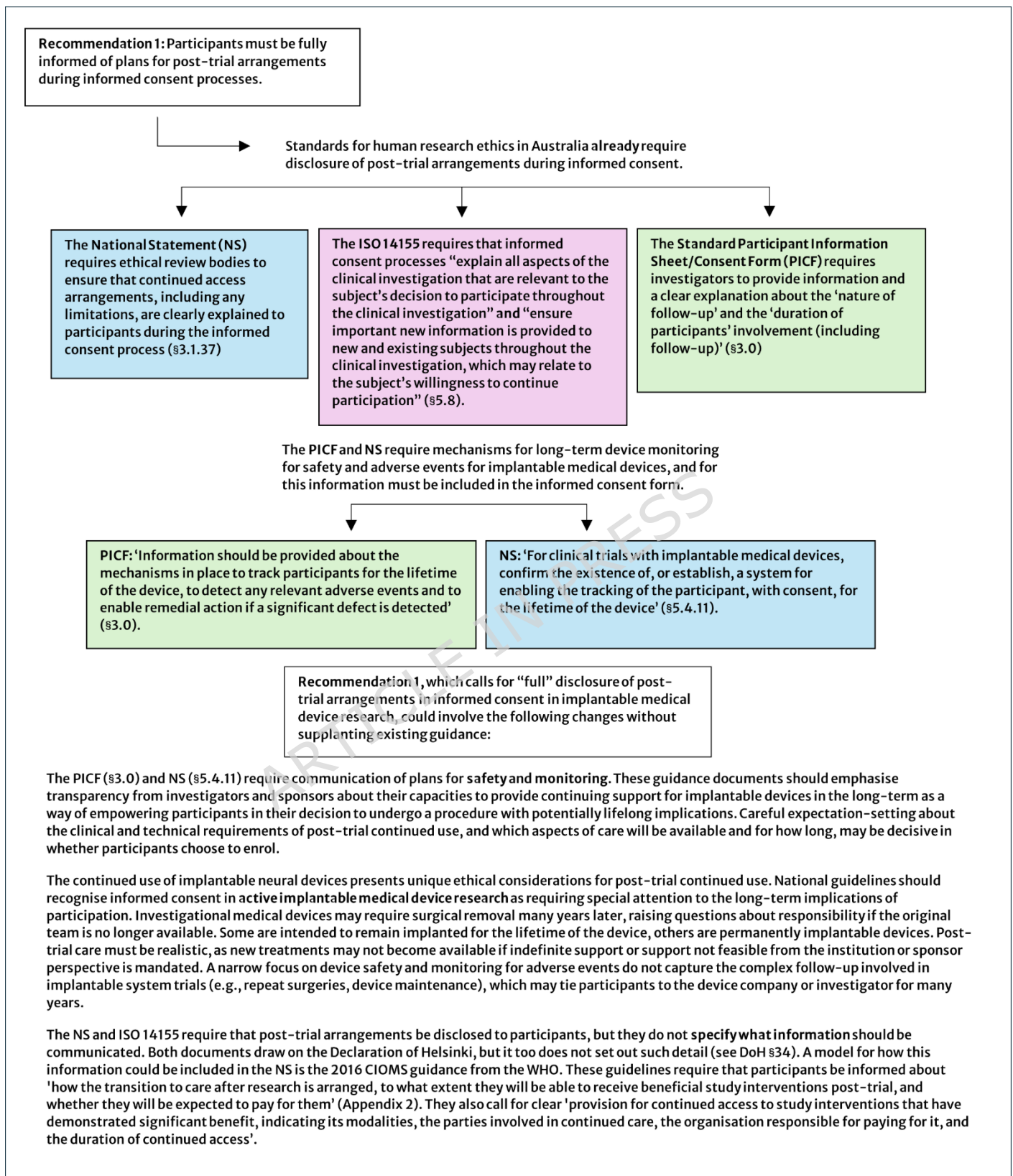


Figure 1: Implementation of first recommendation on disclosure of post-trial arrangements to participants during informed consent in Australia

2. Supported approaches must be employed during informed consent processes to ensure plans for post-trial arrangements are communicated to participants according to their communication needs and capacities.

Participation in a trial of an implantable neural device often brings novel experiences or situations, or levels or kinds of risk, that are unfamiliar or unknown at the time of trial consent, and as such can be challenging to comprehend. Some of these experiences, situations, or risks related to trial participation may arise only after the trial has ended (e.g., surgical device removal)(48). Setting expectations about these situations and experiences so that potential participants are able to appropriately consider them can be challenging under normal circumstances. This becomes even more difficult when prospective participants are desperately looking to improve their health condition with few or no other treatment options, or when cognitive impairments related to their health condition make it harder for them to understand information and weigh their options (49,50).

In Australia, it is best clinical practice to employ supported approaches during informed consent. Funders, regulators, and Human Research Ethics Committees (HRECs) must consider the need for informed consent supports during the design stage of research. National human ethics guidance requires that information must be presented in ways suitable to each participant⁴ and that any supports must be appropriate to each participant's needs and circumstances "taking into account the nature of the research and how these factors may interact".⁵ Several encounters are usually required for consent to be obtained.

Deciding to participate in an implantable device trial requires participants to imagine receiving an investigational, potentially lifelong implant with significant and uncertain risks. Investigators and HRECs must consider whether and how to support them to comprehend the long-

⁴ NS, 2025, §5.3.6

⁵ NS, 2025, §4.2.1

term implications of trial participation. Consultation with relevant patient and participant reference groups is necessary during the design and funding stages to ensure appropriate communication and informational supports are available to participants who need them (e.g., translating services, short videos, illustrations and written material with easy readability).⁶ Investigators, with ethical approval and the aid of the trial institution, should also explore opportunities to allow participants to meet with relevant consumer representatives, such as former trial participants or patients who have previously used similar devices. Alternatively, approved videos of individuals from these groups describing their experiences could be utilised as part of the consent process, with caution required to prevent them becoming testimonials. These conversations may be critical in supporting participants to set expectations, consider the long-term implications of trial participation, and ultimately decide whether an investigational implantable device is the right choice for them.

3. With participant consent, their families, carers and clinicians should be engaged throughout the trial wherever appropriate, as key parties impacting post-trial care.

Families and carers are often involved in participants' care during the trial, follow-up studies, and beyond. It is standard in Australian research to consult families and carers, wherever possible, as key knowledge-holders in a manner appropriate to each participant's circumstances.⁷ During the trial, families, carers and clinicians can provide valuable insights into the device's effects on participants' symptoms and quality of life. Families and carers may play an important role in helping participants adjust to the intervention, and they may also be impacted as participants respond to the intervention. Trial participation can reshape family dynamics, relieving caregiving burdens or enabling new relational roles (51-53).

⁶ NS, 2025, §4.5.33

⁷ NS, 2025, §4.5.29; PICF §1

Given that some devices are intended to be implanted for the lifetime of the device, investigators should consider not only whether participants have adequate family, carer and clinician support to meet the demands of the study, but also the longevity (or continuation of) that support beyond the end of the trial. Investigators should be prepared to identify and allow for changes in participants' care arrangements, particularly when foreseeable changes are raised by the participant during recruitment (e.g., the declining capacity of an older family member to provide care or make decisions, change in General Practitioner or specialist).

Investigators should be cautious that making robust family or carer support an inclusion criterion could exclude otherwise eligible individuals who lack such support, potentially disproportionately affecting marginalised or socially isolated groups. While some participants will depend on caregivers or relatives for ongoing support, others may not require their families or carer to be involved during the trial.

Investigators should also carefully consider the potential for family and carer involvement when designing the trial and informed consent processes. Although involved and better-informed families and carers will be able to better identify post-trial needs and support post-trial care, sharing information with them must be explicitly consented to by the participant. If the participant agrees to involve family members and carers in decision making, investigator teams should be prepared to account for how factors such as complex relational dynamics and cultural and linguistic diversity may shape informational needs and the nature of decision-making about the long-term implications of participation. If investigators intend to gather information from families and carers for the purposes of the trial or post-trial device use, formal and separate consent must be obtained. If investigators believe that the nature of the intervention or target condition may have an effect on participants' capacity to consent to participate in or withdraw from the trial, this must be reflected in the trial design and approved by the HREC (e.g., Advanced Care Directives, nomination of Medical Treatment Decision

Makers)(see Recommendation 4 for more on the involvement of families and carers).

Unlike family and carer involvement, which must be carefully navigated according to each participant's individual circumstances, it is essential that participants' primary treating clinicians are actively engaged and consulted throughout the trial, rather than just at the beginning.⁸

Establishing connections with referring clinicians, including the sharing of participants' trial-related health information at the end of the trial, is critical to ensuring continuity of care. During the trial, the clinician may need to be informed by the research team of adverse events or changes to the participant's intervention. In some circumstances, participants' referring clinicians could be assisted to cultivate certain clinical and technical skills – commensurate with their training – to take on aspects of participants' ongoing care related to the trial intervention as part of a shared care arrangement. Negotiations may need to occur regarding which aspects of care sit with whom, depending on the participant's available clinical team. At a minimum, the primary clinician will be caring for the participant post-trial and will need to be aware of outcomes and future plans for the intervention (see also Recommendation 7).

4. Design of post-trial arrangements should be informed by those with lived experience of the condition or intervention, as well as their clinicians, family and carers, with Participants' hopes and expectations about their post-trial device-related healthcare and quality of life explored and ascertained during informed consent and throughout the trial.

It is routine to discuss participants' hopes and expectations about the nature and purpose of the research during informed consent. This is primarily to ensure participants appreciate the difference between a research trial and medical treatment; while participants may benefit from their participation, the purpose of a clinical trial is to investigate the

⁸NS, §2.2.6; PICF, §3

clinical impact of an intervention, including its safety and tolerability and/or efficacy. It is important to discuss hopes and expectations to ensure participants understand the scope and boundaries of investigator roles and expected outcomes of the trial (see also Recommendation 7).

However, participants will often hold certain hopes and expectations *about* their participation that do not strictly relate to the *purpose* of the trial. For example, participants may have specific ‘post-trial’ hopes and expectations about what trial participation will mean for their long-term healthcare and quality of life. Participants are likely to have had experiences with the standard of care, or with healthcare services more broadly, that have shaped their expectations or hopes with regard to continued use of the device after the trial has ended, access to the trial site, or ongoing relationships with the investigator team after the trial ends.

Realistic and appropriate post-trial care and support options should be discussed prior to protocol design. Families, carers and clinicians should be consulted prior to the design of the trial, and ideally co-design the trial with researchers and those with lived experience of the condition, including by identifying what post-trial care needs there may be, what flexibility may be required and what current resources there are for care. While study designs should not be configured to meet the post-trial hopes and expectations of individual participants, they should accommodate, or at least not needlessly obstruct, participants from pursuing post-trial goals – especially when these accommodations are relatively simple, not resource intensive, or can be incorporated in initial trial funding proposals (see Recommendation 6 for more on the configuration of post-trial arrangements).

It will often not be possible to canvass all of participants’ hopes and expectations during recruitment. As participants’ health, lifestyle, or preferences evolve during the trial – particularly in response to how well they benefit from the therapy – their goals for life after the trial may also

change. Participants' post-trial hopes, expectations, concerns, and fears should continuously be explored and ascertained, and should be used to inform future trial co-design. For example, if previous trials of similar devices have found that surgically removing devices caused participants psychological harm or distress, HRECs should consider requiring provisions for psychological and support services beyond the participant's involvement in the trial.

Importantly, careful consideration should be given to who is most appropriate and qualified to hold discussions about post-trial hopes and expectations. Discussions of participants hopes and expectations about their post-trial healthcare arrangements should only be with their primary treating clinicians as this is within their expertise and the scope of their role. Engaging in healthcare-related discussions with an investigator who is not clinically trained may introduce risks, particularly if they are not equipped to provide appropriate clinical advice or do not have all the information about the participant's health or health care. However, discussions of hopes and expectations limited in scope to the device and post-trial support (e.g., programming and calibration, software and hardware updates, repeat medical procedures) may be realistically explored by clinical trial personnel most knowledgeable about the likely outcomes and ongoing device-specific care to be offered. In some instances, there may be ambiguity as to whether certain post-trial hopes and expectations raised by participant are *clinical* in nature. Investigators must judge whether post-trial support issues fall within their remit, should be referred to the participant's primary healthcare provider, or require coordinated input to determine appropriate post-trial arrangements.

5. Study design and ethical review processes should identify and assess risks of harm, discomfort, and adversity from the discontinuation of clinical development of devices.

Most trials fail to deliver new therapeutics. There are numerous scenarios that could lead to the clinical development of an implantable

neural device being discontinued. A clinical trial may be terminated early due to safety concerns. Funding may not be obtained for investigator-initiated device development to progress to the next stage towards commercialisation. If clinical endpoints are not met, an industry trial sponsor may decide not to progress to the next stage of clinical development. A sponsor may change its commercial strategy and decide to shelve the product after the trial, or wind down operations entirely, if a device is not forecast to succeed on the market.

Discontinuing the development of an implantable device can expose participants to risks of harm, discomfort, and adversity. Risks to participants that arise as a consequence of trial termination or later discontinuation of device development should be addressed during HREC review. HRECs should, as part of the review process, work with trial investigators and sponsors to identify and assess risks of discontinuation. A pragmatic way to support this in Australia would be to amend the National Human Research Ethics Application to specifically ask about the potential risk of an implantable neural device being discontinued during the trial, along with corresponding mitigation and management strategies (54).

HRECs should require trial risk management plans to include strategies to minimise and manage risks if the trial is discontinued. As a matter of institutional governance, legal agreements signed between parties should, where possible, establish lines of accountability for risk mitigation. Clear lines of accountability should be identifiable to, and form part of, the HREC review process. Commitments from sponsors and device manufacturers will need to be secured beforehand.

In Australia, if a sponsor terminates a trial early the sponsor must notify all relevant parties without delay.⁹ After notifications of early trial termination have been made, Australian NHMRC guidance recommends that the HREC convenes to review processes for “informing participants”

⁹ ISO 14155, §1; 8.2.1. Sponsors must also promptly notify the TGA in accordance with the TGA’s scheme for the investigation of “unapproved” therapeutic goods (TGA, 2025).

and arrangements for “continued care and follow-up”.¹⁰ With respect to these Australian standards for trial termination, investigators should briefly engage and consult with participants, families, and caregivers to gather updated hopes and expectations at this point in time for the specific circumstances so that HRECs can take these perspectives into consideration when deciding on the most acceptable and appropriate arrangements for continued care.

6. Study design and ethical review processes should identify, assess for and mitigate risks of harm, discomfort, and adversity as a result of how participants are discharged from the trial or are transitioned into post-trial care.

Post-trial arrangements are often configured depending on the nature of the intervention and the stage of the trial. For certain implantable devices with prior regulatory approvals, participants may have the option of continuing to use the device *off-label* with occasional visits to the trial site for device maintenance. Other trials may write device removal into the trial protocol, for example if it is a first-in-human investigator-initiated trial where longer term safety and device support are less clear. In trials of permanently implantable devices, it may not be safe or feasible to remove the implant at the end of the study, even if it is a first-in-human trial.

This recommendation concerns risks to participants that may arise after the end of a trial because of the specific configuration of trial discharge procedures or follow-up arrangements. Our multidisciplinary panel accepted that planning for follow-up and continued care is established good clinical practice in Australia. Clinical trials are required to implement “appropriate” procedures for monitoring safety and tolerability, and for reporting and providing medical care for adverse events during the trial (56). Relevant GCP standards for medical device

¹⁰ NHMRC, ‘Safety monitoring and reporting in clinical trials involving therapeutic goods’, 2016, p.10.

trials lay out what is appropriate for safety and monitoring for adverse events.¹¹

However, what constitutes ‘appropriate’ follow-up – beyond the cadence of visits to the trial site for safety monitoring – is less clear for implantable neural devices. Loss of access to the device or device-related support, or changes in how a participant is able to use the device, may cause harms that are neither well understood nor simple to monitor. Evidence suggests that when participants exit these trials they face potential psychological and social harms, as well as discomforts and burdens, that are more subtle and difficult to detect than the physical risks of continued device implantation or removal (24,26). For example, during the trial, participants attend regular study visits over several years, building close, collaborative, and empowering relationships with the research team (53,57,58). By contrast, post-trial follow-up may involve few or no site visits, with only ad hoc communication about safety or data collection over a limited period. Such arrangements may be appropriate for the purposes of safety and tolerability monitoring, but they can overlook potential feelings of isolation, loss of connection, and diminished sense of meaning that participants may experience after the trial has ended. Similarly, participants in some early first-in-human studies may be required by the protocol to undergo surgical device removal at the end of the trial (17). This has the potential to lead to distress or unwelcome changes in personality, identity, or sense of agency, particularly if the device had been experienced as effective or empowering during the trial (26).

Investigators and sponsors should work with HRECs to identify and assess more subtle risks of psychological and social harm, distress, discomfort, burden and vulnerability that may arise as participants’ transition out of the trial or at the conclusion of the follow-up period. Ethics approval of arrangements for follow-up and continued use should consider whether there are appropriate risk minimisation, mitigation and

¹¹ ISO 14155, §6.7, 10.7

management procedures in place. Importantly, if the trial protocol involves optional surgical removal of the device at its conclusion, or if device removal is clinically recommended for other reasons by investigators, HRECs must ensure that participants are not subjected to undue pressure to undergo surgical removal procedures (59).

7. Study design and ethical review processes should take into account how post-trial device-related support will be managed after the trial ends, and by whom.

Device maintenance and care for participants with implanted devices often requires ongoing specialised clinical and technical expertise. After the trial, participants may need to return to trial investigators or the sponsor for kinds of care and support outside the clinical competencies of their primary treating physician (e.g., device repair and maintenance). If continued use is an option for participants, it is current best practice for investigators to contact and even seek approval from a participant's personal physician at the start of the trial, so that personal physicians would have the information and resources needed to manage ongoing care after the trial.¹²

If elements of post-trial care cannot be carried out by the participants' primary care provider after the trial, certain members of the research team with the requisite specialist or technical skills may need to take on ongoing support responsibilities for trial participants. For example, clinical psychiatrists or neurologists involved as investigators in a DBS trial may assume responsibility for device calibration, while bioengineers in a BCI trial may be the only ones with the expertise to perform programming and software updates.

For participants who continue to use a device after the trial has ended, reliance on a lone or small number of trial investigators poses a risk to their ongoing care if these individuals become unavailable due to retirement, relocation, or other reasons. For these trial investigators with

¹² ISO 14555 §5.8.4

exclusive clinical or technical expertise to manage the device - many of whom may be passionate about seeing these participants continue to benefit - there may be no reimbursement for ongoing device-related procedures if these devices are not yet covered by health insurance, and the time commitment involved may limit the researchers' capacity for other clinical research projects or provision of clinical care to other patients. Academic clinical researchers may not obtain sustainable funding for ongoing research programs and may therefore no longer be able to offer support to previous participants. There may also be issues with liability and insurance coverage for these experts if they provide support to participants when they are no longer covered by clinical trial insurance, which may then lead to reluctance to provide any post-trial support.

HREC review processes should require that investigators consider both the feasibility of research team members providing ongoing device maintenance for participants and the risk of technological obsolescence, which could compromise long-term usability and participant safety. Attention should be given to device software and hardware maintenance responsibilities that are likely to accumulate, and which members of the research team are likely to assume these responsibilities. These discussions between HRECs and investigators should occur during initial ethical review of the clinical investigation plan, rather than being deferred until ethical review of follow-up extension studies, or until participants have already completed the trial. HRECs should work with investigators, sponsors, and the trial institution to consider what supports (e.g., financial, technical, legal) can be made available to help research team members manage long-term device support responsibilities, and who will assume these responsibilities if the originally responsible persons become unavailable (see Recommendation 10).

8. *Barriers to prospective participants accessing clinical trials and post-trial support should be identified and addressed.*

Socioeconomic and geographic barriers put many approved implantable neural devices (e.g., DBS) out of reach for many who need them (60). These barriers also prevent many eligible individuals with neurological and psychiatric disorders from participating in trials. For example, a potential participant may be excluded from a trial due to concerns that they will be unable to meet study demands, or that valid informed consent will be difficult to obtain (e.g., due to linguistic, cultural, or ethnic differences; fluctuating or reduced decisional capacity). Many individuals may not participate simply because they never have the opportunity to hear about the trial (e.g., due to geographic isolation or socioeconomic challenges).

Most of the time, these barriers are construed and addressed in terms of how they prevent otherwise eligible patients from participating. But barriers to accessing research should also be construed in terms of the disproportionate effects on participants' ability to continue accessing interventions *after* the trial. Some eligible individuals may be able to participate in a trial but will be disproportionately affected by barriers to continued use after the initial trial ends. Anticipating how their continued use will be impacted by barriers post-trial, some prospective participants may elect not to enrol in the trial on this basis. From the recruitment side, there is a risk that concerns about loss of participants to follow-up - and the implications for long-term monitoring and data collection - may tilt recruitment towards participants from more urban and economically privileged areas.

Investigators, HRECs and trial sponsors should work to identify and address barriers to follow-up and continued care. How identified barriers are addressed will depend on the context of the study and resources of the primary funding source. For example, in a late-stage clinical trial of a device, or where a device is approved for use in other conditions,

investigators and sponsors should strive to ensure that participants' socio-economic or geographic circumstances do not disproportionately impact post-trial use of the device. Doing so could involve enquiring as to whether disadvantaged participants are eligible for special access or financial support programs offered by the device manufacturer, relevant charitable organisations, or benefit schemes within the healthcare system.

Although most of the personal cost of continued use paid by past participants will be associated with specialist healthcare services and device maintenance, sponsors, investigators, and HRECs should also consider how the costs of travel (and in some cases, accommodation) for regular outpatient visits can act as a barrier. The level of reimbursement for travel and accommodation deemed acceptable during the trial may disproportionately affect participants who are geographically isolated or socio-economically challenged once the trial concludes. Decisions about reimbursement should recognise that while excessive payment may unduly influence participation, this issue is often overblown resulting in insufficient payment and can stand as a barrier to ongoing access (see Figure 2 for examples).

Recommendation 8: Barriers to prospective participants accessing clinical trials and post-trial support should be identified and addressed.

Some geographic and socioeconomic barriers to accessing trial participation and ongoing support are unique to the specific to the regulatory context and participants' personal circumstances.

Federal regulations



The Australian Prostheses List (PL) contains registered medical devices for which insurers must pay a benefit when a member has the relevant coverage (Private Health Insurance Act, 2007). The PL enables practitioners to choose the best available prostheses for privately insured patients without restrictions from health funds.

Some implantable neural devices are listed on the PL as they hold prior regulatory authorisations (e.g., DBS), even if they continue to be investigated in clinical trials for conditions that are not approved for.

Trial sponsors may have funding to cover devices and procedures only for duration of the trial. After the trial, if a privately insured individual continues using an investigational device outside the clinical trial, the participants' private insurance may be needed to cover the minimum benefit for hardware maintenance.

Barrier to accessing continued support

Many implantable devices require hardware maintenance and repair, and uses of approved devices in a research context may require more frequent maintenance procedures (e.g., DBS for certain psychiatric conditions).

Participants without private health insurance cannot access PL benefits for device replacements. They may instead need to obtain device hardware replacements (e.g., batteries) through the public health system. Accessing specialist services publicly can result in long wait times and uncertain availability.

The prospect of being unable to afford continued use of a device may discourage some individuals from participating in clinical trials in the first place.

Interstate regulatory differences



In some Australian states and territories, psychosurgery is prohibited.

The New South Wales Mental Health Act 2007 (NSW, s.83) and the Northern Territory Mental Health and Related Services Act 1998 (NT, s.58) prohibit psychosurgery, including the use of neurosurgical devices (e.g., DBS) for psychiatric conditions.

Trial participants living in these states who receive investigational DBS for a psychiatric condition cannot legally access care for the use of this device, such as device calibration, lead adjustment, or surgical battery replacement (RANZCP, 2022)

Barrier to accessing continued support

If participants are eligible to enrol in a psychosurgical DBS trial in a state where the procedure is legal (e.g., Victoria or Queensland) but live in or later move to a jurisdiction where it is prohibited (e.g., NSW or NT), they would need to travel interstate to undergo the procedure and receive ongoing outpatient care.

During the trial, this typically involves sponsor-funded flights and accommodation for surgery, device calibration, and follow-up visits at the study site. However, once the trial concludes, or if funding does not extend into follow-up phases, participants may lose this financial support.

Without sponsor coverage, the costs of regular interstate travel could create substantial financial, logistical, and psychosocial burdens, leading to inequities in access compared to participants living in jurisdictions where the procedure is permitted.

State regulations



The Victorian Patient Transport Assistance Scheme (VPTAS) subsidises travel and accommodation costs for Victorians who must travel long distances (>100km) to access specialist treatment.

The scheme excludes patients receiving specialist care for interventions received as part of clinical trials or experimental treatments.

Barrier to accessing continued support

In trials of implantable neural devices, participants are typically reimbursed for travel and accommodation costs during the primary trial period, but not for outpatient visits over follow-up extension studies, as the budget has typically been exhausted.

Because these follow-up visits are still considered part of a clinical trial (they are receiving care for an 'unapproved' therapy), participants may not be eligible for VPTAS support for travel related to device maintenance.

Those living long distances from the study site could face disproportionate financial burdens associated with travelling to the study site for care related to continued use without the support of this benefit scheme.

Figure 2: Examples of barriers to accessing clinical trials and post-trial support in implantable neural devices trials in Australia

9. Trial insurance and compensation agreements should stipulate whether and what post-trial participation-related harms are covered. This must be discussed with participants during informed consent, and investigators should be prepared to explain it or assist participants with finding answers to questions outside their competency.

The insurance landscape surrounding clinical trials is notably complex. Fundamentally, trial insurance functions to provide financial and operational protection against liability claims brought on by adverse or unforeseen events during the trial. Sponsors running medical device trials in Australia use standard agreements that contain indemnity provisions requiring the sponsor to compensate participants for injuries or harms arising from their participation in the trial (61,62).

However, the basis for compensating participants becomes uncertain if harms are not clearly trial-related or if they only arise once the trial has been closed and these governance agreements have expired. For participants who continue using devices after the end of the trial, participants in trials of devices with prior regulatory approvals may be able to rely on public health coverage or private insurance to cover costs of device-related injuries or harms. On the other hand, participants continuing to use devices that are 'unapproved' may lack coverage and protection after the trial ends despite facing ongoing and potentially serious risks related to the intervention.

Sponsors and trial institutions responsible for these trials, along with research governance officers, should explicitly ensure that their policies meet agreed standards for compensation. There should also be clear and explicit communication to participants of the types of harms covered and duration of coverage. Participants must have a genuine opportunity during informed consent to discuss the insurance protections available for device-related harms that may arise after the trial concludes. The existence and nature of these protections may be a critical factor in participants' decisions to enrol, especially in trials where participants are

consenting to receive potentially lifelong or irreversible implantable devices.

Although investigators should not be expected (nor attempt to) fully explain legally dense indemnity and compensation agreements if outside their scope of competency, they should nonetheless be prepared to walk participants through the basic elements of these protections and entitlements and convey their significance in the context of the investigational device, or for the information to be provided in a way that is easily understandable. Crucial in this discussion is a disclosure of potential limitations of existing insurance protections once the trial ends. If participants have questions about compensation or insurance arrangements that investigators do not have the knowledge to answer accurately, investigators should promptly connect them with the trial designated person to address such queries.¹³ Designated trial persons must be prepared to provide clear explanations regarding whether, and to what extent, device-related injuries and other harms will be covered after the trial ends.

Organisations responsible for drafting and updating Australian standard compensation and insurance agreements used across industry and investigator-led trials should ensure that these guidelines reflect the latest ethical and professional standards regarding participant well-being in medical device trials. These organisations should ensure that any compensation guidelines reflect the range of clinical trial sponsors, trial designs, and insurers.¹⁴ Standard agreements should stipulate as clearly as possible whether, and to what extent, and for what duration, research-related harms, including psychological and social harms and distress due

¹³ PICF, §17

¹⁴ The MTAA Compensation Guidelines have not been updated since 2010 (1st version). Various federal and state-level research governance documents direct clinical trial organisers to use Medical Technology Association of Australia (MTAA) compensation guidelines and standard governance templates. For example, the Victorian Department of Health's Research Governance Checklist and Ethics Checklist for clinical trials both refer to standard MTAA agreement templates.

to the use of an investigational device, are covered after the trial has concluded.

10. Reform to medical device and clinical trial regulation should consider post-trial risks of participant harm, discomfort, and adversity. Regulators should be prepared to work with commercial and non-commercial device developers in addressing post-trial challenges.

National reforms to medical device regulation should consider post-trial harms specific to implantable medical device research (24). In 2019, the Australian TGA launched 'An Action Plan for Medical Devices' as part of a broader government reform effort to improve the quality and transparency of clinical investigations of medical devices (63). Some of these recent reforms have targeted oversight of higher-risk medical devices.

In implementing these reforms, consideration should be given to how trial organisers can be supported in managing the ongoing uncertainty around post-trial responsibilities, particularly in contexts where internal governance processes and current guidance are inadequate. Measures that increase scrutiny of medical device sponsors and improve long-term participant safety and wellbeing are welcome, but they should not impose an insurmountable burden on sponsors and investigators. For example, there was industry pushback against the TGA's commitment to review more devices under the more costly and extensive Clinical Trial Authorisation (CTA) pathway for clinical trial approval compared to the Clinical Trial Notification (CTN) pathway. An Australian industry consortium cautioned that higher costs and extended review times under the CTA scheme may reduce the number of first-in-human trials and subsequent studies conducted locally (64).

Regulatory bodies should explore mechanisms to support developers of implantable neural devices, especially investigator-initiated studies and start-up manufacturers, who may be disproportionately affected by the costs associated with providing post-trial support for users of irreversible

or lifelong devices. For example, the CTA scheme is currently under review as of 2025. If it requires sponsors to provide a plan detailing how they will manage long-term implants as part of trial authorisation (as recommended in other jurisdictions¹⁵), regulatory bodies should explore options to support sponsors in doing so. One option to support and encourage innovation while providing realistic and appropriate participant protection would be to establish a central fund to assist investigators and sponsors with the ongoing costs of device maintenance and repair where no reimbursement is available within the public health system (16,65).

11. Specific ethical guidelines and a framework of responsibility should be developed to inform the design, implementation and ethical review of post-trial arrangements.

There is a growing emphasis on life-cycle based approaches to the assessment, development, and use of medical devices (66,67). This has been reflected in recent reforms that have enshrined clear responsibilities for device sponsors and manufacturers across the entire life span of devices. In Australia, recent reforms reflecting this life-cycle approach include the requirement (introduced in 2025) for device manufacturers to submit and maintain unique device identifiers for approved medical devices (UDIs) (68) and expanded post-market surveillance and adverse event reporting obligations (69).

For trials of implantable neural devices, the incorporation of life-cycle based approaches into local decision-making about post-trial responsibilities can be challenging. If it is accepted that a key aspect of HREC review is how an investigational implantable device will be used after the trial ends, then review processes must necessarily look ahead to

¹⁵For example, see recommendation 12 of the UK Regulatory Horizons Council report in 2022 'The regulation of neurotechnology': "As part of its plans to amend the UK Medical Devices Regulations to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance and vigilance system, the MHRA should consider requiring manufacturers to present a plan describing how they intend to manage long-term implants installed in patients, as part of their submission to Approved Bodies.

later stages of the device lifecycle, particularly where the intervention is an implantable and potentially lifelong device. The question of which stakeholders should assume responsibility for post-trial support is complicated by the range of possible developmental trajectories the device may follow, and by the competitive commercial pressures of medical device research and development, which can render commitments to post-trial support unrealistic.

Current ethical guidance, good clinical practice standards, and even regulatory reforms that enshrine ongoing sponsor responsibilities do not provide clear guidance on what should be done in these situations. For example, it is unclear how HRECs should factor into their decision-making the foreseeability that a foreign trial sponsor might leave the country or disengage with participants after collecting local data, potentially leaving participants with implanted investigational devices but without local support. Similarly, it is unclear how HRECs should take into account that trials of certain implantable neural device systems (e.g., BCIs) foster unusually close, collaborative relationships between researchers and participants. These questions are particularly challenging when devices are intended to remain implanted for the lifetime of the device or the participant.

There is a need for an adaptable international ethical framework of post-trial responsibility to inform decision-making about the appropriateness of post-trial arrangements. Ethical guidance that can be specified in cross-jurisdictional contexts is needed because HRECs must be able to provide clear rationales for decisions to approve a trial, approve an extension, or suspend a trial. Current ethical guidelines do not support researchers to effectively design ethical post-trial arrangements, let alone equip HRECs to justify concerns regarding the ethical adequacy of post-trial arrangements.

This ethical framework should satisfy at least three desiderata. First, it must be capable of being adapted to the specific research context, including the legal, regulatory and healthcare systems in which the

research is taking place. Second, it should identify critical decision points where responsibilities may shift between stakeholders and outline a continuum of acceptable arrangements in light of various contingencies and possible scenarios. Finally, this guidance should be reasonably sensitive to a breadth of clinical, trial, and device-related factors, including but not limited to, the device's mode of administration, risk classification, intended duration of use, context of use (e.g., visits to the site vs. in-home care), as well as the trial phase, and whether the device has prior regulatory approvals.

This guidance should be developed through an interdisciplinary consultation and collaboration process, and relevant aspects should be incorporated into national research ethical guidance and clinical trial governance.

Discussion

Trials of implantable neural devices are increasing, with a number of neurotechnology companies preparing to launch large, multi-site, pivotal trials in the coming years. However, there is still considerable uncertainty over the post-trial responsibilities of trial stakeholders, and how these should be negotiated and communicated to participants throughout the trial. Existing guidance enshrined in international research ethics documents is inadequate in this area of medical device innovation. Meaningful progress will necessitate multi-disciplinary collaboration and attentiveness to how context shapes what is acceptable and feasible.

We outline 11 recommendations on post-trial responsibility. We designed these recommendations to be feasible and ethically desirable within current Australian governance and funding structures, and so some of the implementation groundwork has already been laid. As panellists reviewed provisional recommendations, they were prompted to consider the feasibility of each provisional recommendation in their evaluation of its desirability. Part of this consideration of feasibility required that panellists draw from an understanding of the general roles and

responsibilities of key actors working in clinical research, and the general limits of what can be reasonably expected of individuals or organisations (70). A key advantage of bringing together Australian multi-disciplinary experts, however, was that panellists were also able to assess the feasibility of recommendations in the Australian context, such as whether an ethically acceptable practice was already required under Australian governance frameworks, or whether a responsibility that might be appropriate elsewhere would be unnecessarily burdensome in the Australian setting.

We found that panellists most often voted against a recommendation when they disagreed about its feasibility in the Australian context. One form of disagreement came from panellists who felt that the post-trial responsibilities being proposed had already been represented in internal organisational policies or were routinely carried out in their area of professional practice. For example, one panel member's perspective was that large medical device companies had built many post-trial considerations into their standard operating procedures because they had the resources and translational experience to do so.

We were not surprised to discover differences in organisational or disciplinary preparedness for post-trial matters across our multidisciplinary panel. Implantable neural device research covers a variety of device types at different stages of development, regulatory approval, and integration into Australian clinical practice. It was, on the contrary, encouraging that some panellists reported their organisations or professions had already found ways to manage certain post-trial dilemmas to an acceptable standard, as this suggests implementation is feasible. Future empirical ethics work on this problem should also consider investigating local institutional policies and strategies that have been established to address post-trial issues. A recent attempt at this was published by Bassil & Jongsma (2025), who investigated the deliberations of Dutch HRECs on issues of post-trial responsibility using open-ended

questions to explore explantation decisions, post-trial care responsibilities, and consideration of risks of psychological harms.

We did not, however, regard reported successes in managing of post-trial tensions as sufficient reason to discard certain recommendations outright, nor as necessarily weakening their ethical appropriateness. It is promising that some Australian organisations and professional sub-disciplines perform better in particular areas of post-trial responsibility; however, this does not obviate the need for broader action and implementation in the Australian context. Grant-funded investigators new to clinical trials, and start-ups preparing their first studies, should not be left to navigate these issues without clear ethical guidance. A crucial step as the field continues to develop such guidance (see Recommendation 11) is recognising post-trial responsibility as a bona fide research ethics issue; hitherto, there has been a tendency to frame post-trial responsibility as a fragmented moral problem dispersed across the domains of law, corporate governance, and clinical care. These recommendations show how post-trial responsibilities can be embedded in research governance. They also suggest that, while few areas raise wholly unique ethical issues, some areas of innovation – such as implantable neural devices – require guidance tailored to their distinctive ethical, practical and regulatory challenges.

These recommendations and the process used to develop them are not without limitations.. Not all panellists who participated in the workshops completed the final survey (3 panellists and the core team members, who were not eligible to vote, did not complete the survey). While the response rate of 83% among eligible participants was high for a Delphi study (39), we acknowledge that this may limit the generalisability of the findings to Australian stakeholders and actors working in this innovation area and may increase the influence of individual perspectives.

Though our multidisciplinary group included several lived experience and disability advocates, to our knowledge none of the panellists were current or former users of implantable neural devices. Just as it is

essential to involve potential participants, co-researchers, and community representatives in study design and planning, it is crucial to engage them when developing ethical recommendations, so these reflect participants' priorities, values, and needs. Local lived experience community and consumers will be critical for informing the research governance in Australia. Consultation with local consumer groups in the development of ethical guidance should include those who have used or are using commercially available implants, rather than only those with general research participation experience as their lived experience will be essential in determining post-trial care needs. As the recommendations in this study bear out, post-trial issues are context-sensitive, and ethical risks and mitigation strategies in Australia may not translate directly to another.

Conclusion

This study provides the first recommendations for post-trial responsibilities in implantable neural device research developed for a specific jurisdictional context: Australia. By embedding this consensus exercise in the Australian innovation context and linking prescriptive requirements to responsible parties, these 11 recommendations offer action-guiding direction to improve post-trial ethical practices. While their implementation will require further engagement with consumer groups, particularly with those with lived experience of the relevant conditions and prior or present use of related devices, our findings demonstrate both the feasibility and urgency of addressing post-trial responsibilities in a rapidly evolving innovation landscape. Building on existing organisational practices and expanding community involvement will be essential to ensure that participants are supported ethically and sustainably as neurotechnology advances.

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19. N/A

I am responding: On behalf of myself

Name: N/A

Name of Organization: N/A

Type of Organization: Academic Institution

Role: Bioethicist

Domain of research most important to you or your organization: neuroethics; neurotechnology ethics

Date Submitted: 5/25/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

This resource provides several clear and helpful recommendations for investigators to consider in planning for participants' post-trial needs. While these recommendations have the potential to become informal standards for investigators considering implantable device trials, they are explicitly voluntary and unenforceable. To encourage greater uptake throughout the field, the NIH could consider incorporating this resource into grant application instructions or into the review process for grant applications.

Additionally, the resource may provide a clearer roadmap for investigators with some slight rearranging. Specifically, element 2 provides some of the basis for element 1 (i.e. the decision and justification about whether or not a device will be explanted should be based at least in part on the identified risks and benefits of each outcome). This resource may therefore be easier to use if re-ordered.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 1- Plan/Options for Device Explanation or Remaining In Situ

- o As written, this element implies that each study should have an overarching decision about whether the device will be explanted or not. It may be beneficial to make explicit that in some situations, different options may be appropriate for different participants.
- o This element describes the options of the device being explanted or left in situ. However, the latter option itself includes two sub-options that should be acknowledged and described: whether the device is left in the body active or inactive. This choice has major ramifications, affecting whether or not participants continue to benefit from the device.

Element 2- Risks and Potential Benefits

- o This element correctly acknowledges loss of benefit as a negative outcome worth discussing, which is very important. However, the last two sentences alternate between referring to negative outcomes and risks, leaving some ambiguity as to why loss of technical support is classified as a risk and loss of benefit is classified as a negative outcome. The relationship between the concepts in these

sentences could be clarified in the text to improve usability.

Element 3- Anticipated Participants' Needs

- o This element helpfully calls attention to the need for outlining specific expertise participants will need post-trial; it would be made stronger by also recommending that investigators outline where and how participants can access this expertise and other resources they need. This recommendation could be made either here or in the following element ("Plan for Meeting...").
- o The impact on other care (e.g. MRI compatibility) is a major point, and it is good that this element calls specific attention to it.

Element 4- Plans for Meeting Former Participants' Anticipated Needs

- o In their plans to facilitate participants' transition off of the device for those who will be explanted, investigators should explicitly be prompted to consider psychosocial supports that may be needed to adjust to living without a device, especially if it had been providing benefit.
- o Similarly, in the section on participants whose devices will remain implanted, when investigators are asked to consider whether the device will remain functional or be deactivated, investigators should also be prompted to consider mental health support that may be needed to support the transition to an inactive device.

Element 6- Oversight of Long-Term Care Plan for Implantable Device Studies

- o This section could benefit from additional detail on establishing a Long-Term Care Plan for implantable device studies. For example, it could include guidance on creating resources for parties who are not the original research team to reference in order to appropriately support or maintain devices and users.

1.3 Hurdles or barriers to broad use of this resource by the research community

The major barrier to broad use of this resource will likely be financial—in the absence of clearly accessible funding opportunities to support the post-trial needs of participants, resource-limited investigators may struggle to implement the guidance offered in this resource.

1.4 Other feedback relevant to this resource

N/A

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

This resource offers clear and concrete guidelines and sample language for informed consent that can meaningfully inform investigators in preparing for implanted device trials. The structure and flow of the sample language provided is clear and easy to follow.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1- Introduction/Purpose

- o The last bullet point in General Points to Consider (“Within the informed consent process...”) recommends setting appropriate post-trial expectations for patients and notes that acknowledging potential outcomes like non-functionality after the trial may influence participants’ decisions to enroll. NIH should also take care to note that such disclosures may not be sufficient to enable participants who have not yet begun the trial to fully understand and anticipate post-trial realities. Therefore, the guidance should also recommend that investigators have ongoing conversations with participants about end-of-trial expectations.
- o The last section in Sample Language Components (“[Include if the device may be retained...]”) could be improved with more specificity regarding what efforts will be made to help participants with finding replacement parts/ appropriate medical care, how likely it is for these parts or care to be available, and what happens if they are unavailable. This can help set realistic expectations for participants.

Component 2- Procedures

- o In the parts of this section that deal with what happens at the end of the trial, it would be useful to prompt investigators to specify whether or not devices that are retained will remain functional.

Component 4- Potential Risks

- o The Sample Language Components lay out a good list of physical risks, but should also include some other risks such as psychological or mental health risks as alluded to in the “Risks related to having an implanted device...” subsection of this section.

Component 7- Cost

- o While it is important to fully inform participants about relevant costs at the outset, it is often challenging for potential participants to truly engage with the details of costs and future costs. Stronger recommendations could be made in this section for investigators to support participants in understanding costs in an ongoing fashion—e.g. establishing a point person for participants to talk to about costs.

Component 9- Withdrawal

- o This section should include some information on what happens to the participant and their device if they withdraw or are withdrawn from the study. For instance, will the device be explanted or retained? Will participants retain access to maintenance or other device-related resources if it is retained? Will they be offered any mental health support for the transition?

2.3 Hurdles or barriers to broad use of this resource by the research community

It is unclear what the incentives would be for investigators to use/adopt this resource. Since informed consent documents are relatively private and are not subject to review at the grant application process in the same way as some of the elements described in the first resource, uptake of these informed consent guidelines would have to be fully voluntary and intrinsically motivated.

2.4 Other feedback relevant to this resource

Given that participants’ experiences of, understanding of, and expectations about implanted device trials are known to change over time, it would be useful in general to recommend that investigators establish

plans to maintain ongoing discussion with participants about the points in this resource (e.g. by designating a team or point person).

20. Brandy Ellis

I am responding: On behalf of myself

Name: Brandy Ellis

Name of Organization: N/A

Type of Organization: Research Participant/Patient Advocacy Organization/Patient Advocate/Caregiver

Role: Research Participant/Patient/Advocate/Caregiver

Domain of research most important to you or your organization: Ongoing support for neural device implant clinical trial participants

Date Submitted: 5/26/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

As someone who received an investigational brain implant as part of a clinical trial, I am in support of the NIH creating these resources. I would like to request that the NIH actually incentivize the use of these resources when final, such as through grant scoring. I work with various organizations as an advocate since my DBS implantation, and every organization has indicated that resources such as these benefit everyone in the industry. They don't stifle innovation, they raise the caliber of clinical trials which benefits everyone. Best practices should be the standard, and any deviation from the use of the best practices should require justification.

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

My comments relate to the entire resource. I am appalled at the casual references to explantation as an equally ethical consideration for experimental implants. I am terrified at the prospect of explantation being used as a means to avoid providing ongoing care. First, nobody should ever be forced or coerced to have an additional surgery. When I joined the clinical trial where I received my deep brain stimulation implant for major depressive disorder that had not responded to every other approved treatment, I was desperate. I was convinced that my depression was terminal, and I was just hoping to help advance the science for those patients who came after me. I know with certainty that had my trial indicated they would explant the device at the end of the trial, I would have agreed. I would have had absolutely zero understanding of my patient rights to refuse such a surgery. I would not have understood what I would lose with explantation at the end of the trial, and at the time I would likely have considered that to be voluntary explantation. Fourteen years later, after over a decade of advocacy work in this space, talking with patients, I know now that post-trial explantation should be considered involuntary unless proven otherwise. Explantation as a means by which to prevent addressing the burdens associated with ongoing care for those patients who selflessly gave of their bodies, their time, and their resources to further research is so unethical that I am unable to find words to describe such a decision. The burden of planning, care, decision-making, and documentation that should be required to justify explantation should vastly exceed the burden of ongoing care for patients who are not explanted. There is no scenario

in which it should be possible for explantation to be considered an ethical alternative to providing continued care and access. Explantation should be reserved only for those situations at the patient's specific request, in their best medical, physical, and emotional health. The phrasing in Element 2 that says "losing a therapeutic benefit if the device is explanted COULD also be considered a negative outcome" is problematic for this exact reason. People who don't have other options COULD DIE from losing therapeutic benefit. That possibility should never be considered equivalent to providing ongoing care. The care of an individual patient should never be sacrificed. In my opinion this means explantation, deactivation, or rendering an implanted device non-functional should never be allowed when an individual is receiving therapeutic benefit, unless safety concerns for that patient exceed the benefit. I believe additional parameters regarding hardware/software/firmware that is open-source, non-proprietary, and requiring agreements to share intellectual property when a device manufacturer is unable or unwilling to provide ongoing support are the minimum standards for patient care.

1.3 Hurdles or barriers to broad use of this resource by the research community

Additional examples would be very helpful.

1.4 Other feedback relevant to this resource

I intended to give a thorough review of every aspect of these resources, and have consulted with several other entities and individuals who are providing similar feedback. However, I ultimately decided that my outrage at the causal acceptance of explantation needed to be the sole focus of my feedback. I consider experimental device explantation to be an existential threat to patient clinical trial participation. I hope that my voice as a patient who has an experimental implanted device will be loud enough to make sure this threat is given the priority it deserves.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

I support the development of this resources and hope that it is expanded with further examples.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

I reiterate my objections to explantation and the fact that it is referenced in the introduction as if it is an equally viable option. Investigators should go beyond CONSIDERING the development of a post-trial care plan, and be required to have one prior to enrolling patients. I would also like to point out that more emphasis should be placed on the likelihood of explantation being required due to the occurrence of any infection, even unrelated to the device or diagnosis.

2.3 Hurdles or barriers to broad use of this resource by the research community

Investigators should be able to obtain CPT codes for all aspects of device care and maintenance. Having these codes will enable patients to determine if care will be covered by their current insurance, when associated with their ICD code.

2.4 Other feedback relevant to this resource

Absent a catastrophic safety concern, the patient/participant is the only one who should be able to

decide on explantation. People who choose to maintain their device should never be penalized for such decision, regardless of if that decision is elective or based on necessity. Voluntary explantation at the patient's request should always be available. Consent should not be a single document at a single time in the clinical trial. Consent should be ongoing and reinforced at every stage of the trial, especially prior to the end of the consent term.

21. Arizona State University

I am responding: On behalf of an organization

Name: Kristy Macdonald

Name of Organization: Arizona State University

Type of Organization: Not Applicable

Role: Other

Role - Other: Associate Director - Research Compliance

Domain of research most important to you or your organization: N/A

Date Submitted: 5/26/2026

Comments related to Resource 1: Considerations in Planning for the Post-Trial Needs of Research Participants who Receive an Investigational Implantable Device

1.1 Utility and useability of this resource

a. This is a well-written and valuable resource that will be highly beneficial for researchers conducting implantable device studies. One recommendation is to expand the guidance to address participants who withdraw from a study prior to completion. Investigators should clearly define and communicate what constitutes “study end” within the informed consent process so participants understand the implications for ongoing device management and care.

b. For this document, and more broadly across implantable device research, consideration should be given to recommending a separate implantable device addendum for participants. Such an addendum could supplement the informed consent form by specifically addressing post-trial device considerations in greater detail. Resource 2 references this as a practical strategy that may improve participant understanding.

c. It may also be helpful to include direct references or links to the applicable federal regulations, including:

- 45 CFR 46 (2018 Revised Common Rule, Subpart A)
- FDA regulations governing protection of human participants (21 CFR Parts 50 and 56)
- FDA regulations governing investigational devices (21 CFR Part 812)

1.2 For each section of the resource, gaps or additional concepts that should be included or clarified

Element 1 – Plan/Options for Device Explanation or Remaining In Situ

a. The guidance should also address situations involving disruption or early termination of research funding. In such cases, participants should be notified of the proposed plan and available options. While the document discusses when device removal may occur, additional clarification is needed regarding who would perform the removal procedure, how associated costs would be covered, and who would assume responsibility for managing related risks, even if these considerations are addressed elsewhere in the resource.

Element 2 – Risks and Potential Benefits

- a. Additional risks that should be considered include the potential for electromagnetic interference (EMF) between the implanted device and other internal or external devices. Examples may include interactions with pacemakers or other implanted technologies, as well as common external devices such as mobile phones, wireless routers, or other electronic equipment.

Element 3 – Anticipated Participants’ Needs

- a. Clarification would be helpful regarding whether researchers are expected to provide follow-up communication to participants if the investigational device later receives FDA approval.

Element 4 – Plans for Meeting Former Participants’ Anticipated Needs

- a. The statement, “If continued access will not be available, address continuity of care plans,” is somewhat unclear and would benefit from additional explanation or examples to clarify expectations for investigators.
- b. The document should also address considerations for participants who were enrolled as minors but reach adulthood during long-term follow-up or post-trial care.

Element 5 – Financial Plan

- a. The informed consent document should explicitly state that NIH funding generally cannot be used to support participant care after the conclusion of the study. The implications of this limitation, including potential impacts on participants’ access to ongoing care or device management, should also be clearly explained during the consent process.

Element 6 – Oversight of Long-Term Care Plans for Implantable Device Studies

- a. The statement, “If the investigational device has a favorable risk-benefit profile, trial participants should be offered the option of keeping the device,” raises important questions regarding financial responsibility. Additional clarification is needed regarding how long-term costs associated with maintaining the device would be covered and whether any costs could ultimately become the responsibility of the participant.
- b. It would also be beneficial to provide examples of the ethical, medical, regulatory, or legal justifications that may support retaining or removing an investigational device after study completion.

Best Practice Consideration

- a. The document states that, ideally, post-trial financial planning should facilitate access to medically indicated care while minimizing out-of-pocket costs for participants. Additional discussion would be valuable regarding how investigators or institutions might realistically accomplish this when no study funds remain available.

1.3 Hurdles or barriers to broad use of this resource by the research community

- a. To maximize accessibility and adoption across the broader research community, the document should be written using as clear and plain language as possible.
- b. Although the document is relatively concise, inclusion of a table of contents may improve navigation and usability for readers.

1.4 Other feedback relevant to this resource

- a. Overall, this resource provides a useful and thoughtful overview of key issues related to post-trial management of investigational implantable devices.
- b. NIH could potentially increase adoption and implementation of this guidance by incorporating a

required section within grant applications addressing long-term post-trial device management considerations. Similar to current data management and sharing plans, investigators could be asked to include a post-trial management and monitoring plan for investigational devices.

Comments related to Resource 2: Informed Consent for Research Using Investigational Implantable Devices: Points to Consider & Sample Language Resource

2.1 Utility and useability of this resource

- a. As this resource is implemented and updated over time, it will be important to include clear version control practices. Each version should include the publication date, revision date, and version number, along with a brief summary of substantive updates or changes. This recommendation is based on the statement that “this document may be updated, and/or new resources may be developed to address unique considerations related to the scientific community’s evolving knowledge and understanding of how these technologies are used in research.”
- b. Including a table of contents specific to this document would improve navigation and overall usability for readers.

2.2 For each component section, gaps or additional concepts that should be included or clarified within the points to consider, as well as specific language proposed in the informed consent sample language

Component 1 – Introduction/Purpose

- a. The sample consent language for this section would benefit from additional detail regarding the investigational device itself. For example:
 - Has the device already received FDA approval for any medical indications?
 - Which company manufactures the device?
 - If the device is not commercially available, who developed or sponsors the technology?Providing this context may improve participant understanding of the device and its investigational status.
- b. It would also be helpful to provide direct hyperlinks or citations to the applicable federal regulations, including:
 - 45 CFR 46.116
 - FDA regulations governing the protection of human participants (21 CFR Parts 50 and 56)
- c. Under the “General Points to Consider,” the statement, “For more information on what a post-trial care plan might include, please see [insert reference to best practices document],” should include a direct reference or hyperlink to the corresponding best practices resource.

Component 2 – Procedures

- a. Within the “Key Facts” section, consideration should be given to including procedures for addressing situations in which the investigational device is damaged during transport, including how participants would be informed and what steps would follow.

Component 3 – Long-Term Practical Considerations

- a. The document states that investigators should, when practicable, provide information regarding potential care options depending on study outcomes (e.g., device efficacy, FDA approval status, or commercial availability). Additional clarification would be helpful regarding how this information would be communicated to participants and whether there would be an established process for ongoing

notification or follow-up after study completion.

Component 4 – Potential Risks

a. The statement, “If the study team has arranged for any mental health support for participants, they should also share these,” appears incomplete and would benefit from clarification. It is unclear whether this refers to mental health resources, counseling services, referrals, or other forms of participant support. Additional specificity would improve clarity for investigators and participants.

Component 5 – Potential Benefits

No additional comments at this time.

Component 6 – Alternatives

No additional comments at this time.

Component 7 – Cost

a. Where the document references “Compensation for Research-Related Injuries,” a direct hyperlink or cross-reference to the relevant section should be included to improve readability and ease of navigation.

Component 8 – Compensation for Research-Related Injury

No additional comments at this time.

Component 9 – Withdrawal

No additional comments at this time.

Component 10 – Questions

No additional comments at this time.

2.3 Hurdles or barriers to broad use of this resource by the research community

a. Including, at minimum, a table of contents would improve accessibility and usability for the broader research community.

b. Separating the sample informed consent language from the explanatory guidance sections may improve readability and make the document easier to follow and implement in practice.

2.4 Other feedback relevant to this resource

Overall, this resource provides a practical and thoughtful framework for informed consent considerations involving investigational implantable devices. The inclusion of sample language is especially helpful for investigators and research teams developing participant-facing materials. Additional structural refinements and clarifications, particularly around long-term communication, participant support, and document navigation, would further strengthen the resource and enhance usability across research settings.