Compiled Public Comments on Request for Information for Developing Consent Language for Research Using Digital Health Technologies

Guide Notice Number: NOT-OD-24-002

October 10, 2023 – December 12, 2023

Table of Contents

31. Computing Research Association
32. The Connected Health Initiative

Submit date: 2023-10-12

I am responding to this RFI: On behalf of myself

Name: Anita Esquerra-Zwiers

Name of Organization: Hope College

Type of Organization: Academic institution

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: Nursing

Utility and useability of this resource: I will use this in my studies.

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:

1. **Introduction:** None
2. **Procedures:** None
3. **Data sharing and ownership:** None
4. **Potential risks:** None
5. **Potential benefits:** None
6. **Cost:** Why no sample wording?
7. **Withdrawal:** Why no sample wording?

Hurdles or barriers to wider use of this resource by the community: Length this adds to the consent.

Other feedback relevant to this resource:

Submit date: 2023-10-13

I am responding to this RFI: On behalf of myself

Name: Robert SSEKUBUGU

Name of Organization: Rakai Health Sciences Program

Type of Organization: Non-profit research organization

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: Epide

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Submit date: 2023-10-17

I am responding to this RFI: On behalf of myself

Name: Carol Sorsoleil

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Other

Role - Other:

Domain of research:

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/DH-Carol-Sorsoleil-508.pdf

Description:

Submit date: 2023-10-18

I am responding to this RFI: On behalf of myself

Name: Lorraine Chavez-Davis

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Research participant patient advocate

Role - Other:

Domain of research:

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Email: lchavezdavis@gmail.com

Submit date: 2023-10-29

I am responding to this RFI: On behalf of myself

Name: Ayesha Nasir

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Other

Role - Other: Looking for clinical research position, have one year experience

Domain of research: Nutrition and healthy lifestyle, popultion observational research.

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Use of Artificial Intelligence in clinical research is needed, Japanese doctors are already using Large Language Model based AI program to summarise the symptoms and lifestyle habits of their patients.

AI can be used, and improved to gain informed consents from both adult patients and guardians of minor patients that is personslized and precise for each patient, and focuses on patient safety.

Furthermore to help patient make a truly informed decision, LLMs can be used to answer patient question, if patients have questions or need clarification during the informed consent process.

Email: azaymo2520@gmail.com

Submit date: 2023-11-06

I am responding to this RFI: On behalf of myself

Name: Maria V West

Name of Organization: Kings County Hospital

Type of Organization: Government agency

Type of Organization-Other:

Role: Institutional review oversight committee member

Role - Other:

Domain of research: Mental Health && Substance Use Disorders

Utility and useability of this resource: Many of our patients are used to inform mental health and drug use trends, policies and other impact for health equity and criminal justice systems. Providing framework that address the specific utility will provide a more comprehensive understanding of the expectations when a patient signs up for a service that their information may be used for these information and reported to specific agencies without identifying information; if required specific identifying information patient should give express consent for that ie communicable diseases, and other mandated reporting requirements.

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:

1. **Introduction:** Language should include that your "data, including age and other demographics "may" be used to inform trends about health, overdose, mental health and other health equity areas. Must be included on all consent forms for registering for treatment and services in the NYC area Please ensure that specific language exist about "data with non-identifying" data that are mandatory and are required to have an individual's identifying information. " - Health Equity Disparities

   - Underserved being over represented in data

   - Not a balanced data collection method

   - Bias" " - Information that can identify risks and potential ways to mitigate

   - new information to determine community needs and how specific populations are either served or respond to health and mental health risks" - may inform funding - n/a - availability of information via public forums, it should not only be when a person see a provider. Information about how your data is used for research must be transparent and have a public campaign to inform the public and communities n/a

   Maria.West@nychhc.org
2. **Procedures:**
3. **Data sharing and ownership:**

4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Use of Artificial Intelligence in clinical research is needed, Japanese doctors are already using Large Language Model based AI program to summarise the symptoms and lifestyle habits of their patients.

AI can be used, and improved to gain informed consents from both adult patients and guardians of minor patients that is personslized and precise for each patient, and focuses on patient safety.

Furthermore to help patient make a truly informed decision, LLMs can be used to answer patient question, if patients have questions or need clarification during the informed consent process.

Email: azaymo2520@gmail.com

Submit date: 2023-11-06

I am responding to this RFI: On behalf of myself

Name: Frances Ventress

Name of Organization: Not applicable

Type of Organization:

Type of Organization-Other:

Role: Member of the public

Role - Other:

Domain of research: All

Utility and useability of this resource: See #3

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:

1. **Introduction:** See #3
2. **Procedures:** See #3
3. **Data sharing and ownership:** See #3
4. **Potential risks:** See #3
5. **Potential benefits:** See #3
6. **Cost:** See #3
7. **Withdrawal:** See #3

Hurdles or barriers to wider use of this resource by the community: I suggest that the information you share with the general public, should not be verbose, but instead, make it plainly understood and easily digested. Engaging so that they feel comfortable in asking questions and In being receptive to your outreach.

Other feedback relevant to this resource:

Submit date: 2023-11-06

I am responding to this RFI: On behalf of myself

Name: Ms. Tab M Battle

Name of Organization: http://n/a

Type of Organization:

Type of Organization-Other:

Role: Other

Role - Other: n/a

Domain of research: n/a

Utility and useability of this resource: n/a

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:

1. **Introduction:** n/a
2. **Procedures:** n/a
3. **Data sharing and ownership:** n/a
4. **Potential risks:** n/a
5. **Potential benefits:** n/a
6. **Cost:** n/a
7. **Withdrawal:** n/a

Hurdles or barriers to wider use of this resource by the community: n/a

Other feedback relevant to this resource:

n/a

Uploaded File:

Description: n/a

Submit date: 2023-11-06

I am responding to this RFI: On behalf of myself

Name: Lynn E. Martin

Name of Organization: --

Type of Organization:

Type of Organization-Other:

Role: Member of the public

Role - Other:

Domain of research: Nutrition

Utility and useability of this resource: In your "Request for Information: Developing Consent Language. . . ." under "Background," in the next to last line, the word should be "aid,"

not "aide."

I notice this sort of thing, and if you'd like to run consent language past me I'd be happy to point out any errors.

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

See my spelling comment above.

Submit date: 2023-11-06

I am responding to this RFI: On behalf of myself

Name: Malcolm Anderson

Name of Organization: Disney Cruise Line

Type of Organization:

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: Disease and virology.

Utility and useability of this resource: Varies. Great resource.

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: Internet access.

Other feedback relevant to this resource:

Email: malcolmxanderson44@gmail.com

Submit date: 2023-11-08

I am responding to this RFI: On behalf of an organization

Name: Alvaro Enrique Solano Berrio

Name of Organization: Secretaría de Desarrollo de la Salud de Córdoba Colombia

Type of Organization: Government agency

Type of Organization-Other:

Role: Government official

Role - Other:

Domain of research: Mental Health Advisor

Utility and useability of this resource: Mental health policy, socia determinants, risks prevention, services and evaluation

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: Human resources, human resources competencies, medication-focused services

Other feedback relevant to this resource:

Very important for our intervention process in mental health

Uploaded File:

Description: PDF

Email: alensobe1948@hotmail.com

Submit date: 2023-11-13

I am responding to this RFI: On behalf of myself

Name: Frederick Shic

Name of Organization: Seattle Children's Research Institute

Type of Organization: Non-profit research organization

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: early child development, developmental conditions

Utility and useability of this resource: High utility, including many topics that some organizations or investigators may not have thought about. Usability is a question: if this remains in the current long form, I can see it being cumbersome to deliver. Efforts to streamline consenting processes should be considered. It is possible that many sources of privacy risk could be described and acknowledged more generally, and greater detail on the variety of possible threats presented as supplemental or upon request. These materials could also be built into an interface that facilitate inclusion of language after specific checkboxes are clicked by investigators creating consent/IRB materials.

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:

1. **Introduction:** - Second bullet beginning "Specify which digital health technology..." should draw a distinction between the device/technology deployed and the data collected (in terms of ownership/rights). In general, I believe the data is the more important part to discuss, and knowledge of the technology's proprietary nature not always paramount (e.g. if we consider a pedometer as a pedometer -- even though there will be variations in the implementations)

   - Some of the points in the preamble "if the technology has been approved by FDA..." -- "if efficacy of the technology is being studied" are important to include in some circumstances, but especially the explicit inverse "the technology has not been approved by FDA", "this study does not study efficacy" seem like they could be odd in for example very exploratory studies.

   I didn't see a clear relationship between the bullets and the sample language. Additional guidance could be developed to describe in what situations the inclusion of bullet point topics would be appropriate.

2. **Procedures:** Considerations may also include descriptions of support participants can expect, troubleshooting, and how the study team may remotely monitor and interact with the participant around the use, misuse, or unexpected performance of the device.

3. **Data sharing and ownership:** Today, these giant streams of data are being fed into machine learning models of various designs. Explicit language may need to be developed to describe the claim or lack of claim participants may have over derivative products of their data, with potentially deeper concern for models that may be implicitly embedding identifiable information regarding individuals within their parameters.

- I feel like the point "As capabilities evolve to enable linkages between digital health data and disparate data sources, consider the risk of re-identification and its implications on participant's privacy and confidentiality. Consider how the informed consent language informs participants of this potential risk" belongs in risk rather than ownership.

As an aside, I believe there should be more work towards developing practical strategies for anonymized data sharing, which de-risk sharing through differential privacy mechanisms and/or centralized/one-way data processing.

4. **Potential risks:** Regarding the above note on re-identification, deep description of multi-data-stream re-identification may be difficult to understand for participants. In general, the anonymous dense data of today is the identifiable dense data of tomorrow. Guidelines might be developed that explicitly divorce those characteristics which could lead to privacy concerns. What those features are might need to be considered and documented on a study-by-study basis. This goes beyond sensitive pieces of information such as a birthdate, sex, zipcodes, but could extend to, for instance, gait, typing patterns, kinematics of body movements, facial landmark locations, etc. While in the most likely scenario, deidentification would require a similarly obtained data stream for comparison -- current risk and future risk are difficult to evaluate. Minimizing identification risk may mean retaining some features, e.g. joint rotations, without retaining others (e.g. explicit body part lengths); or spatial positions over the course of a day without an indication of true north (that's not a great example, it's probably identifiable) in consideration of privacy-utility tradeoffs. At the same time, risk should not be overestimated. Given a set of a thousand individuals, for instance, within the narrow parameters of the study, what are the chances that the unique digital signature of an individual can be identified? Methods, infrastructure, and conventions for such statements are badly needed to provide realistic risk assessments to participants in a manner they can understand.

Figuring out who will be able to evaluate these risks will also be a challenge. The conservative approach of safeguarding against everything is needlessly restrictive, and a barrier to progress.

Similar, that models (derived from data) might expose information regarding source data and in that fashion also lead to privacy issues, should be considered. In general, regulations and guidelines will eventually be needed so that derived models are not used as an alternative strategy for near-perfect data retention.

5. **Potential benefits:**
6. **Cost:** If the data may be of value to the participant in the future, costs for storage/obtaining that data by participants should also be considered. It's already an issue for videos and some kinds of medical imaging.

7. **Withdrawal:** Research may extend to methods for immaculately recording data sharing, and being able to destroy data at a distance.

   NIH or some other regulatory agency might consider systems that search for and try to identify inappropriate public sharing of data resources.

Hurdles or barriers to wider use of this resource by the community: This will need to be succinct. Where consents can be combined across multiple devices used in a single study, there needs to be easy routes to parsimony. Some may find highlighted considerations burdensome, or restrictive towards their ultimate goals -- some centralized certification (even if not centrally reviewed) might make researchers want to "play ball" with these kind of guidelines.

Heterogeneity in the rigor of IRB (which can be both too lax and too aggressive) will need to be managed.

As these documents are developed, it would be fantastic if translations in multiple languages could be shared as well .

Other feedback relevant to this resource:

I think this is incredibly topical and I think this is a great time to centralize recommendations for the research community.

Uploaded File:

Description:

Email: fshic@uw.edu

Submit date: 2023-11-19

I am responding to this RFI: On behalf of myself

Name: Erica Pau l

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Other

Role - Other: Individual

Domain of research:

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: .

Other feedback relevant to this resource:

I am a citizen. Is this AI? I hate AI. 1984

Metal health should be solely personal.

Submit date: 2023-12-01

I am responding to this RFI: On behalf of myself

Name: Shanda Hunt, Alicia Hofelich Mohr, Shannon Farrell

Name of Organization: Research Data Services, University of Minnesota Libraries

Type of Organization: Academic institution

Type of Organization-Other:

Role: Other

Role - Other: Data Librarian

Domain of research:

Utility and useability of this resource: This is an impressive resource with a comprehensive list of considerations. We appreciate the caveats that other issues need to be considered and this language alone is not sufficient. Also appreciate the guidance to align the consent with their Data Management and Sharing Plans. Template language is useful, but does not cover all the really important points mentioned in the "key points" to consider. Consider better aligning the sample language with these points (e.g. having more samples or more specific examples). The sample language is likely to be used without necessarily consulting all the points above. Since data sharing is expected and repository information is prompted, we would encourage discussion and sample language around potential future uses of the research data. With the goal of providing a resource that is equivalent to an 8th grade reading level, adjustments might be made to the overall length, technical language, and mentions of "terms and conditions" throughout the sample language. We are concerned that the length and some of the technical language might cause participants to disengage from the consent process, particularly in the Risks section. We also have concerns that the "terms and conditions" may not be fully understood by the PI, and therefore, would not be understood by the participants. Potential recommendations could be the PI interprets the terms and conditions for participants with the guidance of general counsel, and/or recruit participants who are already using the devices, who have already clicked through the terms and conditions on their own.

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:

1. **Introduction:** Concerned about PIs not knowing the specifics around proprietary tools and the relevant data ownership/privacy aspects. Is this the responsibility of the PI to read, understand, and distill down into an 8th grade reading comprehension for participants? Would they even have licenses to re-share the data collected on a commercial/proprietary device?

   These points are noted in the "points to consider" but there is no sample language to address them. We would like to see sample language that covers these points.

2. **Procedures:** Recommend emphasizing the general way participants will access/collect data

from the device, but NOT including the technical details in the consent document. This would make the consent very long to read and distract from important information about how their data will be used. Additionally, the specific steps may change as technology updates and changes.

Recommend including specific sample language calling out the "passive information" that will be collected and identifiable. PIs should understand the data that will be collected on participants.

3. **Data sharing and ownership:** The sample language suggests including data sharing information, which we deeply appreciate. The sample language prompts "basic summary information about the repository," and we encourage NIH to specifically include characteristics to describe in the consent, such as the specific repository, restricted versus open access, data to be shared versus withheld, and de-identification processes. The sample language suggests notifying participants that the commercial device company will have access to the data, and may retain the data with no control from the research team regarding protection of the data or privacy. This is concerning language and will likely alarm participants. The recommendation may be that PIs clearly understand the company's policies and share with study participants.
4. **Potential risks:** We recommend that the sample language around data breach and re-identification risk be more specific (e.g., what is being done to protect their identities and why is there still a risk involved). Language further down in the sample consent is a sufficient replacement for this vague beginning: "By using... there is a risk you may be identified as a study participant. This may occur if the... is lost, misplaced, or stolen. It may also occur if your identity and information recorded in the... is otherwise accessed by another person."
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: Local institutions likely have their own IRB templates, and it may be difficult for PIs to align this content with the recommended (and required) language in their institutional templates. We encourage NIH to connect with institutional IRB offices to recommend integrating this language with local templates and recommendations.

We'd like to reiterate a point made in #1 regarding the terms and conditions that come with third party contractors. It is unlikely these are at an 8th grade reading level and it is burdensome to the PIs to completely understand and translate these terms. However, we do applaud the efforts at transparency by bringing up other contracts and terms the participant may be agreeing to while participating in this study.

Other feedback relevant to this resource:

Email: hunt0081@umn.edu

Submit date: 2023-12-02

I am responding to this RFI: On behalf of myself

Name: Felipe Mejia-Medina

Name of Organization:

Type of Organization: Academic institution

Type of Organization-Other:

Role: Bioethicist

Role - Other:

Domain of research: digital public health

Utility and useability of this resource: The resource offers a series of considerations when designing informed consent associated with individual-level interventions in digital health.

I think it is important to point out that informed consent is effectively towards the individual and not, for example, towards population health or public health. In these two groups, the informed consent considerations have other characteristics. For example, if I design a health communication campaign aimed at the user population of a social network, informed consent should be designed differently or it could be impossible to carry out, requiring other management. This should be made clear in the introduction. I think that, in addition, the resource presents a vision of the uniqueness of digital technology, without considering when there are several interacting: an app on a smartphone and on a smartwatch that has a pulse meter, for example. This should be noted because situations of multiple digital technologies used, especially with the increasingly present wave of the Internet of Things, will be a common situation. The lack of plurals when referring to technology will create the sensation that there is only one, when there can be several, which can confuse the user when evaluating its impact.

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:

1. **Introduction:** "Provide explanation around what it means to be proprietary technology and how it may determine who owns or has access to or rights to distribute the data as well as implications for privacy and security." What Open Source is should also be explained and doing so at the required level of clarity while maintaining simple language is an enormous challenge.
2. **Procedures:** "The study team should clearly state under what conditions and how frequently participants will be asked to use or interact with the digital health technology for study purposes" or if the technology will act on its own by taking certain data from time to time and sending it, in such format, to such institution, person or group. This should also clarify the type of connection, will it be collected offline and sent later? or will it be sent in real time? What happens if the person is in an area without an internet connection and the device cannot send the data in time?
3. **Data sharing and ownership:**
4. **Potential risks:** Many users have no idea what the problem is with inadequate data

collection and re-identification. Explaining to them about the ownership of the data is not enough but it is necessary to explain to them, hopefully with examples, what are the impacts that said mishandling or re-identification could have at various levels of cases, from a low impact to a serious case.

5. **Potential benefits:** These benefits must be presented by associating probabilities. There are some benefits that are immediate or can be expected, while others may be less likely. This needs to be clarified.
6. **Cost:**
7. **Withdrawal:** And it should also be informed if it is possible for the participant to request a copy of the data collected.

Hurdles or barriers to wider use of this resource by the community: What do you mean by community here? To the researchers who would use this resource to create informed consent? Community usually refers to the beneficiaries or those who are the object of the intervention.

Other feedback relevant to this resource:

Email: Alephoric@gmail.com

Submit date: 2023-12-04

I am responding to this RFI: On behalf of myself

Name: Elizabeth Umberfield

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: Clinical Research Informatics

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: Particularly for data sharing and ownership, the "language" and content of consent forms should be interpretable and actionable by both humans and machines. Data sharing for research should be enabled at scale, allowing for participants to permit or restrict future sharing and use in a more granular way than just agreeing to any and all uses that pertains to the entire dataset or collection. However, this requires a data model (semantics) and controlled value sets (terminology/vocabulary) to be mappable to consent form content.

Other feedback relevant to this resource:

Submit date: 2023-12-06

I am responding to this RFI: On behalf of an organization

Name: David M. Prokop

Name of Organization: TruMedicines

Type of Organization: Industry

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: Using Ai to improve medication adherence and behavioral modification in addiction treatment

Utility and useability of this resource: Strengths:

Enhanced transparency: Providing participants with clear and concise information about the potential benefits and risks associated with digital health technologies in research empowers them to make informed decisions about their participation.

Tailored approach: The voluntary nature of the resource allows investigators and IRBs to adapt the sample language and points to consider to their specific research studies.

Flexibility and inclusivity: The proposal welcomes input from various stakeholders, including researchers, IRBs, participants, and professional organizations, which helps ensure diverse perspectives and comprehensive considerations.

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:

1. **Introduction:** Specific Comments on the Sample Language and Points to Consider

   Areas for improvement:

   Clarity: Some of the language may be too technical for lay audiences. Consider using more plain language and avoiding jargon.

   Comprehensiveness: Certain points to consider may require additional elaboration or clarification to address specific types of digital health technologies.

   Privacy and security: The discussion of potential privacy and security risks associated with data collection and storage could be expanded upon.

   Additional concepts to include:

2. **Procedures:** Additional concepts to include:

Data ownership and sharing: Participants should be informed about their rights regarding their data, including who owns it, how it will be shared, and how long it will be stored.

Algorithmic bias: Potential biases in algorithms used by digital health technologies should be acknowledged and addressed.

Access to study data: Participants should have the right to access their own data collected during the research study.

Discontinuation of participation: Participants should be informed about how they can withdraw from the study at any time.

3. **Data sharing and ownership:** Data ownership and sharing: Participants should be informed about their rights regarding their data, including who owns it, how it will be shared, and how long it will be stored.

Algorithmic bias: Potential biases in algorithms used by digital health technologies should be acknowledged and addressed.

Access to study data: Participants should have the right to access their own data collected during the research study.

Discontinuation of participation: Participants should be informed about how they can withdraw from the study at any time.

4. **Potential risks:** Potential limitations:

Resource utilization: The voluntary nature of the resource may limit its adoption by researchers and IRBs.

Complexity: The proposed language may be challenging for some participants to understand, requiring additional considerations for ensuring comprehension.

Evolving technology: The rapid pace of change in digital health technologies necessitates continuous updates and revisions to the sample language and points to consider.

5. **Potential benefits:** Utility and Usability of the Resource

The resource has the potential to be highly useful for researchers and IRBs by providing a starting point for developing informed consent documents. However, its usability could be enhanced by:

Developing user-friendly online tools and resources.

Providing training and workshops for researchers and IRBs on using the resource.

Collecting feedback from stakeholders on the resource's utility and usability.

6. **Cost:** Evolving technology: The rapid pace of change in digital health technologies necessitates continuous updates and revisions to the sample language and points to consider.
7. **Withdrawal:** Access to study data: Participants should have the right to access their own data collected during the research study.

Discontinuation of participation: Participants should be informed about how they can withdraw from the study at any time.

Hurdles or barriers to wider use of this resource by the community: Potential hurdles and barriers to voluntary use include:

Lack of awareness of the resource.

Time and resource constraints for researchers and IRBs.

Concerns about the complexity of the resource.

Uncertainty about regulatory requirements.

Other feedback relevant to this resource:

Recommendations

Disseminate information about the resource widely.

Offer training and support to researchers and IRBs on using the resource.

Collect feedback from stakeholders and iterate on the resource based on that feedback.

Consider developing a mandatory component for informed consent documents that addresses specific aspects of digital health technologies.

Explore the feasibility of integrating the resource with existing electronic informed consent platforms.

By addressing these recommendations and concerns, NIH can encourage the wider adoption of this valuable resource and ensure that research involving digital health technologies is conducted ethically and with informed consent from participants.

Email: david@trumedicines.com

Submit date: 2023-12-06

I am responding to this RFI: On behalf of an organization

Name: Tara Federici

Name of Organization: AdvaMed

Type of Organization: Industry

Type of Organization-Other:

Role: Other

Role - Other: Vice President

Domain of research: medical device development

Utility and useability of this resource: Please find AdvaMed's comments on the RFI in the attached PDF file.

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:

1. **Introduction:** Please find AdvaMed's comments on the RFI in the attached PDF file.
2. **Procedures:** Please find AdvaMed's comments on the RFI in the attached PDF file.
3. **Data sharing and ownership:** Please find AdvaMed's comments on the RFI in the attached PDF file.
4. **Potential risks:** Please find AdvaMed's comments on the RFI in the attached PDF file.
5. **Potential benefits:** Please find AdvaMed's comments on the RFI in the attached PDF file.
6. **Cost:** Please find AdvaMed's comments on the RFI in the attached PDF file.
7. **Withdrawal:** Please find AdvaMed's comments on the RFI in the attached PDF file.

Hurdles or barriers to wider use of this resource by the community: Please find AdvaMed's comments on the RFI in the attached PDF file.

Other feedback relevant to this resource:

Please find AdvaMed's comments on the RFI in the attached PDF file.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/12-6-2023-AdvaMed-Response-to-NIH-RFI-on-IC-for-DHTs-Dkt-No-NOT-OD-24-002.pdf

Description:

Email: tfederici@advamed.org

Submit date: 2023-12-10

I am responding to this RFI: On behalf of myself

Name: John Torous

Name of Organization: BIDMC

Type of Organization: Academic institution

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: Digital Mental health

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:** The examples provided are very clear and logical. However, many people have challenges with these terms such as understanding the difference between "anonymization and de-identification" as one example. It may be easier for people to understand if there are visual examples of what that person will appear as in different stages/forms of the data sharing journey. For example, what the data looks like and what can be learned about a person will be different from what the PI has access to and perhaps what the NDA has access to (depending on the study).
4. **Potential risks:**
5. **Potential benefits:** Many apps can offer benefits. But these benefits are often overstated, especially when comparing the app against a digital placebo (eg mood tracking). Investigators should be encouraged to use balanced language that does not overstate what the benefits may be.
6. **Cost:** It would be useful to know if there is also a cost associated with wear-tear / use of the person's own smartphone or device. This would be related to say the cost of driving one's car and reimbursement for more than the cost of gas.
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: It would be useful, and feasible, to coordinate this with journals as they could add to checklists authors submit which would ask if this language was used. This may increase uptake and awareness.

Other feedback relevant to this resource:

With data being shared more broadly, it would be ideal to have a system where the person could check which datasets their data is now part of and which papers have resulted from use of their data. I

understand this is not simple to offer today, but it could be a system that would build more trust and excitement among the public in the future.

Submit date: 2023-12-11

I am responding to this RFI: On behalf of an organization

Name: Christine Suver

Name of Organization: Sage Bionetworks

Type of Organization: Non profit research organization

Type of Organization-Other:

Role: Other

Role - Other: VP Research Governance and Ethics

Domain of research: Responsible data sharing and research collaboration

Utility and useability of this resource: We commend the NIH for their foresight in developing a resource to guide informed consent in digital health technologies. We caution that this resource may not be used as intended-as a supplement to informed consent-but rather as a guide to informed consent for a digital health technology study. To this end, the NIH might consider further contextualizing this toolkit within informed consent guidance. This could be as light as a quick reminder of the elements of informed consent required by the Common Rule.

We strongly encourage the NIH to focus on the readability of the resource and alternatives to text-intensive presentation of information, which have been shown to increase the accessibility of digital health consent for diverse populations (insert references 1, 2, 3).

We further encourage NIH to highlight the role of informed consent not as a legal contract or mechanism to limit liability but as an informing dialogue between participants and device providers.

We strongly encourage the NIH to highlight the responsibilities of the research team to thoroughly vet the digital technology they propose to employ in their study. This intensive reading must include a complete review of the terms of use, privacy policy, and any other end-user license agreements (EULAs), as well as the commercial entity's data warehousing and data security procedures.

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:

1. **Introduction:**

   Include discussing cost in the introduction. This discussion should also briefly acknowledge whether participants may incur any expense.

   Include basic technology(ies) needed for participation in the introduction. These technologies may include WiFi access, Bluetooth, smartphone capabilities, text/data plans, or access to their devices.

Discuss the duration of the expected use of digital technology in the introduction.

Include a brief statement of purpose in the introduction, including template language.

We encourage NIH to offer sample language about what it means to be a proprietary technology to help set standards for the industry and all the other elements currently listed under "Considerations."

2. **Procedures:** We recommend including a prompt to specify whether the study team can access the participant's location data. This should include prompts about whether the location data are specific coordinates, generalized location, or another situation (e.g., triangulation with landmarks).
3. **Data sharing and ownership:** Specifically on this suggested language:

"[Insert company] will have access to, and may retain a copy of, any data collected by [insert digital health technology name/type]. When using [insert digital health technology name/type] you agree to the Terms and Conditions/Privacy Policy set out by the company. We do not have control over how [insert company] will protect your data and privacy."

We would like to highlight that the data collected by a commercial digital health technology goes FIRST to the commercial company. Then, a copy of those data is shared with researchers, rather than the other way around. We feel that the NIH's suggested language incorrectly implies that researchers have more control over the data than the company producing the technology.

Replace the language "may retain a copy" with specifics by making this an option, i.e., "[will retain a copy/will not retain a copy]

Add to the language, "Terms and Conditions," a link to the Terms and Conditions.

Add to the language "Terms and Conditions" additional document types, e.g., terms of use, privacy policy, EULA, and prompts to link to those documents.

Indicate that commercial entities' Terms and Privacy Policy may change over time and have multiple versions.

Remind researchers of the prohibition of exculpatory language provided by the Common Rule.

It is essential to note that there is a fundamental difference in public perception of commercial/public use of a digital device compared to using that same device within the research setting. For example, data breaches of commercial companies are a regular occurrence and now a near norm of public use of digital technologies. However, participants have understandably different expectations of data protection within research, even if that research includes a commercial device (and hence data warehoused by a commercial entity).

4. **Potential risks:** OAuth: Allows people to grant websites or apps access to their information on other websites/apps but without giving them the passwords and is a mechanism to allow

participants to BYOD; researchers must disclose the use of OAuth and specify the risks associated with OAuth usage (not just a "here be dragons" statement).

The suggested language contains sentences that are too long and too complex in their construction and uses terms that are not commonly understood, for example: "If you join this study, there is a potential risk that data you share might be accessed by unauthorized people or that someone may be able to identify you. These people may misuse the data you share with us in a way that leads to personal harm (e.g., discrimination)."?

It needs to be clarified from the language provided that the data used in the study is a subset of the data collected by the digital health technology vendor. We strongly recommend that this central truth is foregrounded to prospective participants.

We recommend splitting the risks of using the technology (discomfort from a watch, for example) from the risks associated with the data collected in the context of a research study. The risks associated with hardware should be separated from the risks associated with software and the risks of the data itself.

We do not see a specific disclosure of the circumstance of a participant using a family device (e.g., shared phone or tablet) to participate as a privacy risk.

If the device breaks or the participant needs technical support, will they call the support center of the device vendor? If so, what privacy protections, if any, are there associated with this support call, or will support be handled by the study team itself?

"Using [insert digital health technology name/type] requires that you agree to [insert company]'s "Terms of Service" and privacy policy. We do not control these terms and policies, which can change at any time. You should read the terms and the privacy policies before using [insert digital health technology name/type]. You should also review your privacy settings often. If any changes are made to [insert company] privacy policies, the research team [insert will or will not] notify you."

While this is very useful, the last sentence (If any changes are made to [insert company] privacy policies, the research team [insert will or will not] notify you.) is a false promise unless there is an enforcement mechanism.

5. **Potential benefits:** We need help understanding how this section is framed. While it is essential to disclose direct benefits (or the lack of direct benefit) to participants themselves, we would also recommend highlighting that the advantage of using digital technology is (presumably) to easily and quickly collect rich, diverse, and voluminous data that will advance (both speed and enrich) the study itself. If there is no benefit to using the technology, why would a participant be asked to use it?

6. **Cost:** This section seems lighter than it should be. For example, shipment costs of returning study devices have not been mentioned.

We recommend that the NIH provides example language here to assist with transparent disclosure of costs.

As already noted by the NIH, the data costs of BYOD (bring your own device) use must be disclosed. We suggest highlighting "wifi only" vs. "roaming" use of study devices.

7. **Withdrawal:** We recommend that the NIH provides example language here to assist with transparent disclosure. This language should clearly describe what steps are required to withdraw from the study and remove their data from the technology vendor's records if possible. If participants can't pull their data from the technology vendor, it must be disclosed. Further, the language should remind participants whether they can continue to participate in the study if they withdraw from using the digital technology or if they withdraw from the study entirely by withdrawing from the use of the digital technology.

Hurdles or barriers to wider use of this resource by the community: We are concerned that IRB's existing templates may stand in the way of broader use of this excellent resource.

We encourage the NIH to support extensive outreach to publicize this resource and promote its use in institutional templates. Further, connecting this effort with other large-scale consent language repository efforts like the global consent toolkit of the Global Alliance for Genomics and Health (see: https://www.ga4gh.org/product/consent-toolkit/) and/or research ethics trainings (e.g., CITI) might help it gain traction and become embedded in research norms more quickly.

Other feedback relevant to this resource:

Again, we commend the NIH for assembling this critical resource. This is a landmark step in increasing the transparency and trustworthiness of research practice in the digital age.

Resources: Sage's references:

Elements of informed consent: https://sagebionetworks.org/tools_resources/elements-of-informed-consent/

The original description of eConsent: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2769129

The AoURP consent paper: DOI: 10.1080/23294515.2020.1847214

The mPower consent: doi: 10.2196/mhealth.6521

Meg Doerr TED Talk: https://www.youtube.com/watch?v=m8zbLvxKJV8

Email: christine.suver@sagebase.org

Submit date: 2023-12-11

I am responding to this RFI: On behalf of an organization

Name: Steve Berman

Name of Organization: Biotechnology Innovation Organization (BIO)

Type of Organization: Professional organization association

Type of Organization-Other:

Role: Other

Role - Other:

Domain of research:

Utility and useability of this resource: Although BIO agrees with the topic areas being addressed in the NIH draft language, the level of detail of each is not appropriate and we recommend that NIH consider the minimum content necessary in order to provide patients with adequate informed consent. Although the NIH is presenting "points to consider", sponsors or IRBs may take the recommendations as a whole, which may increase patient burden and decrease understanding.

While the sample text is health literate, the sheer volume of the content places an additional burden on the reader and places too much emphasis on the technology as part of the decision-making to participate in the trial; the use of digital health technologies is only one component of the risks and benefits of participating in a trial.

Adding this amount of information to the informed consent content is not consistent with the desire to make the informed consent more optimized (both overall more health literate and streamlined per FDA and other IRB/RA feedback) to help a potential study participant to make an informed decision.

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:

1. Introduction: o Gaps or additional concepts that should be included or clarified within the points to consider:

1. If the data gathered from the DHT is used to support an exploratory endpoint, sponsors need to consider and state if choosing not to participate in the DHT portion would preclude patients from participating in the trial at all.

o Specific language proposed in the informed consent sample language:

1. "Specify which digital health technology will be used and whether it is open source or proprietary to the research team or an outside entity, such as a commercial company (e.g., manufacturers and/or software developers). Provide explanation around what it means to be

proprietary technology and how it may determine who owns or has access to or rights to distribute the data as well as implications for privacy and security."

a. The sample wording does not adequately address, and leaves unclear, what would be expected in addition to information on rights and access to data generated.

2. "IRBs should consider whether it is important to disclose to potential research participants any relationship (e.g., financial, board position, advisor) between investigators and the company that owns the digital health technology used in a study."

a. This language is quite onerous. Sponsors engage tech companies independently and tech companies have no say in, or even knowledge of, study investigator identities. Sponsors do not need to confirm such relationships for any other third parties involved in study activities (e.g., other data management technologies and third-party labs). BIO would encourage NIH to align the approach taken to DHT companies with the approach taken with other third party vendors.

2. Procedures:

3. Data sharing and ownership: o Gaps or additional concepts that should be included or clarified within the points to consider:

1. From an ethics perspective, it would be recommended that patients should not have to agree to any more use or sharing of data than what is necessary to meet the objectives of the study to participate in the study. However, sponsors are seeking to balance the data sharing restrictions within each specific study, with the need to use data for further development of digital measures specific to those DHTs described in the study. All other information that is requested to be gathered should be additional opt-ins with clear descriptions of the intended use, additional potential benefits and risks, sharing and retention needs and identifiability status.

2. Re-identification is a complicated and emerging topic, and it may be difficult for patients to understand the potential for this to occur.

o Specific language proposed in the informed consent sample language:

1. "Indicate... whether the data may be sold or shared to third parties without explicit participant consent."

a. We would recommend this is better phrased as a reminder that data will not be used outside the study, except where participants have agreed to further research.

4. Potential risks: o Gaps or additional concepts that should be included or clarified within the points to consider:

1. BIO recommends using less-concerning language for data, as most data will have encryption. Recommendations for alternative language can include, for example, not sharing passwords/usernames.

o Specific language proposed in the informed consent sample language:

1. "We cannot control if they collect more data than the study requires, or how [insert company] will protect your privacy... However, [insert company] may share or disclose information per their terms and conditions. We have no control over the data they collect or own. Please know that [insert company] may continue to have access to your data even after you stop being part of the study."

a. This does not appear to reflect the level of control and scrutiny required by Sponsors to ensure all third-party vendors ensure confidentiality and limited study use of sensitive participant data. It appears NIH are accepting a lower level of protection when using health technologies. BIO recommends NIH reinforce the need for Sponsors to properly scrutinize third party tech before deploying as part of clinical trials.

5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: BIO notes that eConsent may enable the presentation of information in alternative, less-burdensome ways, e.g., the ability to include short overview video about the trial and its use of DHTs. It may be helpful to elaborate that the information does not necessarily have to be included in the main section of a consent if provided to trial participants in another manner.

Other feedback relevant to this resource:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/BIO-Comment-Letter-Consent-Language-DHT-NOT-OD-24-002.docx

Description:

Email: nlaruan@bio.org

Submit date: 2023-12-11

I am responding to this RFI: On behalf of an organization

Name: Ruchika Dhussa

Name of Organization: University of California

Type of Organization: Academic institution

Type of Organization-Other:

Role: Other

Role - Other: Systemwide Research Policy Office

Domain of research:

Utility and useability of this resource: I write on behalf of the University of California (UC) system regarding the NIH's Request for Information on Developing Consent Language for Research Using Digital Health Technologies (DHT) issued on October 11, 2023.

The UC system - comprised of ten campuses, six academic health centers, and three affiliated U.S. Department of Energy national laboratories - stands at the forefront of cutting-edge research and technology development. As a system, UC receives approximately $7 billion annually of extramural awards to support research conducted throughout all UC locations. UC generally receives five to six percent of the NIH annual appropriations for research.

1. Utility and useability of this resource

UC appreciates NIH's recognition of the Institutional Review Board's (IRB) duty and aptitude for providing input on consent language. Consent language varies based on the nature of the study, the data collected, the research participant population, and any local considerations. The IRBs are best positioned in recommending language in consent forms for each particular study, so we appreciate NIH maintaining that the use of the NIH sample language is voluntary.

In response to NIH's RFI, UC's overall concerns with the proposed sample language is the following:

1) Length and readability of the sample language;

2) Inclusion of information beyond the scope of informed consent; and

3) Inclusion of content beyond the responsibility of researchers.

The sample language NIH provided is two pages in length. The two pages does not account for the information researchers would add to the sample language that would be specific to their study or health technology. We ask that NIH modify the sample language altogether for length.

Additionally, per the Revised Common Rule, informed consent should be concisely drafted at no higher than an 8th grade reading level. The Flesch-Kincaid grade level for the sample text (before researcher additions) is at the 11th grade reading level. If the intent is to be clear and accessible, then lower

reading level language should be used. Lengthy informed consent documents can be a deterrent during participant recruitment, so we suggest more concise and easily readable sample text.

We recognize though that NIH is requesting specific feedback on the components identified in the RFI. Below we provide the feedback to each component.

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:

1. **Introduction:** o Component 1 appears similar to the "Key Information" section required by the Revised

   Common Rule. The information is duplicative of what would typically be a part of the "Key Information" section in a consent form and increases the length of the informed consent. We ask that NIH clarify the intent of Component 1.

   o Component 1 states, "Provide explanation around what it means to be proprietary technology and how it may determine who owns or has access to or rights to distribute the data..." However, in Section III the RFI states "This resource does not address future use of data collected from digital health devices." These statements seem to be at odds with one another, so we request NIH clarify whether these are not mutually exclusive concepts or remove one of the statements. UC strongly advocates omitting from the guidance information regarding future use of data collected from DHTs as it is not a mandatory component of the informed consent, as prescribed by the Revised Common Rule, and institutions may have more suitable formats to present this information to participants.

2. **Procedures:** We suggest removing the recommendation to explain the legal terms of use and provide a technology tutorial for use of the DHT to research participants. We believe that these topics do not belong in an informed consent because they do not explain risks and benefits of the research to participants in the study. We propose removal of both the guidance and the sample language to avoid confusing researchers as to what the required and appropriate content is for informed consent forms.
3. **Data sharing and ownership:** UC recommends removing the information in the second bullet that directs researchers to educate participants on whether the data collected by the DHT is owned by the company, whether the data may be sold or shared to third parties without explicit participant consent, and to inform participants of end user agreements, terms and conditions, and terms of service. This information is not related to the risks and benefits of participating in the research. Adding this type of language to an informed consent is overly technical, doesn't further enhance protections over subjects, and may be beyond the scope of the researcher.
4. **Potential risks:** N/A
5. **Potential benefits:** The sample language in Component 5 appears to advocate for a separate benefits statement related to the use of DHT. Since the Revised Common Rule already requires a benefits statement, we recommend NIH delete the sample language here or provide sample language that combines the potential benefits of study participation overall. Duplication will

increase the length and complexity of text required to be read by participants, which can lead to complications with recruitment.

6. **Cost:** N/A
7. **Withdrawal:** N/A

Hurdles or barriers to wider use of this resource by the community: UC appreciates NIH's efforts to provide guidance and sample language that is not mandatory. However, we are concerned that the sample language can be interpreted as an authoritative reference for researchers. If all researchers begin using a lengthy and complex template without regard to what is appropriate to their study, participants may find the content too complex or time-consuming and there may be negative repercussions for study recruitment and retention. Additionally, because the sample consent expands the scope beyond what is traditionally included by researchers, there is a risk of inaccuracy of information. While the information recommended may be relevant to the study, such information may be best provided by another subject matter expert at the institution and outside the informed consent. Given the complexity and the variation in developing informed consent, we recommend that NIH remove the sample language and simply provide the guidance.

Other feedback relevant to this resource:

o We are happy to see the NIH note the requirement of data management and sharing plans and that researchers should ensure alignment of data management and sharing plans with informed consent language. We ask that NIH take this one step further and emphasize that PIs prepare protocols and IRB applications that are consistent with the data management and sharing plans. Because researchers must submit their data management plans far in advance of their development of informed consent language or their human subjects protocol, further reminders that researchers ensure alignment would be appreciated.

o We note in the Key Points, NIH states this consent resource does not address future use of data collected from DHTs, which may have additional considerations when developing or reviewing informed consent. UC interprets this to mean that NIH is not intending this language to meet the broad consent requirements.

o The sample language throughout the document includes places for insertion of the DHT's name. Numerous insertion points lead to a greater possibility of mistakes, particularly in templated language. UC proposes removal of multiple insertion points in the sample language and replacement with a sentence such as "In this study we will be using a piece of technology called [insert name]. In this consent form we will refer to this as the study's "digital technology."

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue. If you have any questions concerning these comments, please contact Ruchika Dhussa, Senior Research Policy Manager, at Ruchika.Dhussa@ucop.edu.

Sincerely,

Agnes Balla

Director

Research Policy Analysis & Coordination

University of California

1111 Franklin St., 11th Fl.

Oakland, CA 94607

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/UC-Comment-Letter-NIH-RFI_12.11.23.pdf

Description: University of California Comment Letter PDF

Email: ruchika.dhussa@ucop.edu

Submit date: 2023-12-11

I am responding to this RFI: On behalf of an organization

Name: Shahin A. Samiei, MPH

Name of Organization: mHealth Center for Discovery, Optimization & Translation of Temporally-Precise Interventions (mDOT Center)

Type of Organization: Academic institution

Type of Organization-Other:

Role: Organizational official

Role - Other:

Domain of research: Mobile health (mHealth)

Utility and useability of this resource: The utility of this resource is high. In our nearly ten years' service running and supporting mobile health (mHealth) studies, we have discerned the barrier to entry for studies of this type to be high at times. Part of the knowledge gap among investigators and research teams has involved the digital privacy and ethics components. While this learning curve is surmountable, we find that in the absence of sufficient staff collaborative expertise, and other supports, this realm can be very challenging, especially for new investigators. Being able to share best practices and lessons learned can lower the overhead of engineering and running such studies or components of studies. Having template language and the context around which that language can be wrapped can be extremely useful for new and seasoned investigators alike as digital health opportunities in research continue to grow. Already, we see the challenges of AI-generated template language that initially appears accurate but may indeed be filled with errors. Such an example has the propensity for harm among investigators (e.g., additional IRB delays in revision and review, damage to reputation for shoddy work), and possibly to participants and the wider research enterprise if such mistakes are not captured before deployment. We need NIH support for such a knowledge base -- even if only primers -- to support a culture of consent, compliance, and ethics to be promulgated and transcend the multiple domains of digital health research (e.g., computing sciences, behavioral sciences), for which human subjects' expertise widely ranges. The useability of this resource is also high, especially when wrapped in the appropriate context. Still, this can only serve as a primer; individual investigators and teams will have to fill in the details to adequately describe to participants and IRBs about the protocols they wish to perform. Our experience has been that both investigators and IRBs come with considerably varied levels of experience with digital health; in some cases these knowledge gaps at some institutions have created considerable delay, back-and-forth, miscommunication, and frustration across parties. In other cases, the familiarity with digital health technologies has empowered IRB members to ask cogent, direct, and concise questions of investigators that allow for the review process to be both more thorough and supportive of investigators needing to clarify their protocol and consent documents. I applaud the focus to widely include constituencies -- especially investigators *and* IRBs, as knowledge gaps on either side can be friction points for research to progress.

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:

1. **Introduction:** Both IRBs and investigators should thoughtfully consider disclosure of relationships between investigator(s) and digital technology platforms - these can be varied including device manufacturers, cloud platforms, and software development teams that are involved in the research. In other words, there may be more than one company or stakeholder behind the scenes.

2. **Procedures:** The sample language is good in supporting the study team's communication of what data collection expectations are, such as interactive components like responding to prompts or active interaction with the platform, or passive collections of data like certain thresholds for wearing/using the device (hours per day, number of events requested per unit time, etc.). This may have implications on the incentive (whether wholly or if a micro-incentive structure is used), and also the utility of the data/helping ensure the burden of participation yields meaningful contribution to the research.
3. **Data sharing and ownership:** Being clear about the re-identifiability or sensitivity of particular data elements is important here. For example, in previous experience, we have heard feedback from both junior investigators and participants that demonstrated a lack of appreciation about the sensitivity and identifiability of GPS (location) data. While we were able to successfully educate them on why we so belabored the procedures, risks, and confidentiality content about these data elements (sometimes receiving surprise once they realized and appreciated how sensitive those data elements really were), we know that health literacy runs across a highly variable spectrum, and digital health literacy even more so. Many people are used to freely giving location (and other) data to use certain apps; this can be an opportunity to support an appreciation of why data are being collected, for what purpose, the risks, and how they will be protected. This is somewhat highlighted in the subsequent risks section, but I think needs concise emphasis here as well.
4. **Potential risks:** Belaboring the point that sensitive biomarker data can be derived from seemingly innocuous raw data could be important here. Some people have an appreciation of how raw location data can be used to risk privacy and security, but it sometimes takes a stark example for people to fully appreciate those risks. The same can be true for derived biomarker data such as smoking, eating, or drug use. Someone may be in a study in which certain biomarkers are being considered for primary research questions, but in which other sensitive biomarkers can also be derived. Belaboring the point that future capabilities may derive the presence/absence of sensitive biomarkers (and perhaps offering some specific examples) can make this point very clear to researchers, IRBs, and participants.
5. **Potential benefits:** Perhaps also make clear that study incentives should be considered the same as indirect or ancillary benefits - that they are not true benefits of participation as defined in an informed consent document. Especially in the realm of behavioral research, we have been careful to belabor the point that possible benefits (e.g., awareness, mindfulness, etc.) are indeed possible and are not guaranteed.
6. **Cost:** The concise description here is well-done. In our geographical area, there are many

individuals living below the poverty line. Especially in the area of digital health technologies, there is a minority and low-income health disparity in the adoption and use of these technologies, part of which stems from access. Mindfully addressing these topics can help increase access to financially (and other) marginalized groups. It would also be good to include how equipment return procedures will be handled - who bears the cost of returning a sensor, device, or other hardware used in the study?

7. **Withdrawal:** Similar to the above point - what does return of study hardware (if applicable) look like? What other obligations or burden need to be considered upon withdrawal or study conclusion? What are some/the conditions in which an investigator may need to involuntarily withdraw a participant from the study? At what point is participant attrition/loss to follow-up defined? What are the mechanisms in which a participant may voluntarily withdraw from the study?

Hurdles or barriers to wider use of this resource by the community: Promulgation is a perennial challenge in the face of a rapidly growing and changing technological/research landscape. Simply connecting this resource with IRBs and various professional groups, clearinghouses, et al. will definitely help the community to use it. Using trusted stakeholders in the digital health space as ambassadors for this can help with penetration and further sharing among the community. Wrapping this kind of content within the context of a wider ethical/responsible research framework can help to give this content more emphasis, necessity, and importance. This is but one piece of trying to build a culture of competence and ethical consideration in using digital health tools in research.

Other feedback relevant to this resource:

We are providing an informed consent form from a fully virtual study that we undertook during the COVID-19 pandemic. Elements of this consent form required extensive description and stand to be updated from then-to-now (including with some of the content being proposed here), but have shared this with the research community to support investigators trying to articulate their own digital health procedures. We have attached a copy of this consent form for any possible inspiration among your team. In this document, we use graphics to detail the flow of data from raw to processed forms, and how esoteric raw data can be used to extract meaningful features with implications to both advancing research and to privacy concerns. We have received positive feedback from participants in explaining this flow of data, in that it helps make current and future uses of collected data less abstract (page 9).

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/MOODS_consent.pdf

Description: Consent form used in Mobile Open Observation of Daily Stressors (MOODS) fully virtual research study

Email: ssamiei@memphis.edu

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Melissa McMillian

Name of Organization: Society for Academic Emergency Medicine (SAEM) and American College of Emergency Physicians (ACEP)

Type of Organization: Professional organization association

Type of Organization-Other:

Role: Other

Role - Other: Director

Domain of research: Emergency Care Research

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Request for Information: Developing Consent Language for Research Using Digital Health Technologies

Notice Number:

NOT-OD-24-002

December 12, 2023

In this letter, the American College of Emergency Physicians (ACEP) and the Society for Academic Emergency Medicine (SAEM) are responding to the Request for Information: Developing Consent Language for Research Using Digital Health Technologies (NOT-OD-24-002). ACEP and SAEM recognize there is the tremendous potential for advancing science and the promotion of health by harnessing the expanding use of digital health technology, including wearable devices. However, both organizations believe that such potential must be critically balanced with promotion of ethical research principles to maintain the welfare of affected participants. The National Institutes of Health (NIH) proposal to

develop a structured model for informed consent language to be used in research studies involving digital health technologies is useful to promote subject safety and privacy. As proposed, the model for informed consent language adheres to the basic elements of informed consent including explanations of research purpose, procedures, subject risks, and potential benefits of research participation. Additional considerations for strengthening the model from our organizations are described within this response.

While disclosure regarding the current state of United States Food and Drug Administration (FDA) approval of devices for the purposes being studied is required, the current proposal does not differentiate safety protections between experimental devices compared to finalized commercial products. Research subjects may experience different levels of risk between these two device types, since commercial products benefit from wider user bases which can detect safety risks that might be unrecognized for devices still in the experimental phase. As the model applies to both research-grade and commercial products, this distinction should be specified clearly.

A section regarding costs appropriately addresses the potential financial risk to subjects as their electronic data submission in the study may be deducted from their own bandwidth allowance from their internet plans. However, the proposed language fails to address any compensation, financially or otherwise, that could be provided to subjects either for their participation or to offset any direct costs. The treatment protocols including financial responsibility for any injuries directly related to the study procedures are similarly not currently included within the consent language.

We agree that data privacy concerns are paramount when studies involve digital technologies, particularly at the scale which may be present in studies utilizing these products. The model as written includes language regarding data use and storage during the study, how the information could be used afterwards, and the procedures and duration of storage. We applaud this inclusion and encourage investigators to provide as many details regarding these processes as possible. The procedural considerations include prompts to explain security protections provided by researchers while noting that device companies may not protect data in the same way. Where the study is performed using data obtained through a commercial entity, these procedures should be described in more detail to study participants as risks may be greater than the standard which commercial end-user agreements assume.

Data sharing and ownership considerations described by this document include the use of subject data within the context of larger repositories. Given that health data ownership and sharing can have significant implications for subject privacy concerns, we believe this area of disclosure should be expanded and strengthened with a focus on limiting the use of patient data by groups not explicitly allowed by consenting subjects. We are pleased to see the concerns highlighted by the NIH in the withdrawal section of this proposed consent language, but we suggest addressing specifically whether deleting the study application or otherwise misusing or failing to use the technology may automatically lead to withdrawal, and whether subjects should expect any feedback or data to be provided following either the completion or withdrawal from the study involving their data.

The NIH proposal states that the respective Institutional Review Board (IRB) should consider whether it is important to disclose any relationship between study investigators and companies which produce the digital health technology used in the study, but we recommend that this be a required disclosure in the model consent language. Any possible commercial relationship which affects research interpretation must be transparent to all participants and regulators in research process.

Following the approval of these model guidelines, we encourage the NIH to distribute them to partners both in academia and industry for widespread use.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/NOT-OD-24-002-Consent-Language-for-Research-Using-Digital-Health-Response-PM120223.pdf

Description: Full response letter from SAEM and ACEP is attached.

Email: mmcmillian@saem.org

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Tayler Williams

Name of Organization: American Medical Informatics Association (AMIA)

Type of Organization: Professional organization association

Type of Organization-Other:

Role: Organizational official

Role - Other:

Domain of research: Medical Informatics

Utility and useability of this resource:

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:

1. **Introduction:** The skeleton wording leaves a significant amount for the individual team to adapt in describing their intervention/device. AMIA would want to ensure that samples of how to describe certain technologies be developed to reduce the risk of jargon being used (i.e., could see a team giving names of products that don't have meaning to the potential participant).
2. **Procedures:** 1) With the wording related to de-identification is there, AMIA is interested about devices that have location or other individual-specific data collected, and how to have the researcher be transparent about whether the data is 'truly' de-identified or just name/DOB type information is removed, or if re-identification is possible when triangulated with other data.

   2) AMIA notes a potential concern about the relatively sparing wording that essential says, 'refer to the companies' policies'. How likely is a participant to go and access that company to see what the data sharing they employ is? Or that they would be able to find it? I'm not sure the ideal wording, but seems important to consider greater transparency here, especially as this is one of the risks that does not start and end within the research team, and therefore could have greater risk of reducing participant trust in the process.

   3) The timeframe of data sharing may be important in some cases (i.e., is data shared in one bundle at the completion of participation or in real time?).

3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Email: twilliams@amia.org

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Jessica Cotto, MPH

Name of Organization: NIDA

Type of Organization: Government agency

Type of Organization-Other:

Role: Government official

Role - Other:

Domain of research:

Utility and useability of this resource:

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:

1. **Introduction:** One overarching suggestion/comment from our institute is to clarify the which technologies are included and excluded: The title indicates a very broad scope (all DHTs). Reading further, however, section "Key Points" clarifies that the notice is instead limited to a very specific sub-group of Digital Health Technologies, namely: "wearable devices, sensor technologies, and mobile software applications ("apps") most often used with tablets, watches, or phones"

   It also states: "The resource does not address considerations for implantable devices, artificial intelligence, or other types of digital health technologies."?

   After reading this, I am very unclear on which technologies are indeed included or excluded, and I am particularly confused by the broad exclusion of Artificial Intelligence. More specifically, for example:

   - Many wearables, mobile apps, and sensors may include AI-based algorithms. Would those be excluded?

   - Would extended-reality systems (not necessarily defined as "wearables, or sensors"?, but certainly included in "Digital Health Technologies"? also be excluded?

2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: See comment above.

Other feedback relevant to this resource:

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Lourah Kelly, Sarah Arias, Camille Nebeker, Catarina Kiefe, Barton W. Palmer, Katherine Dixon-Gordon, Edwin Boudreaux

Name of Organization: Center for Accelerating Practices to End Suicide (CAPES), University of Massachusetts Chan Medical School

Type of Organization: Academic institution

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: clinical digital health research and suicide prevention

Utility and useability of this resource: As faculty of the Center for Accelerating Practices to End Suicide (CAPES), we are submitting the below response to the request for consent language for digital health research. We provide specific input on digital health suicide prevention research when noted.

We very much appreciate the clear, accessible language recommendations and examples of informed consent language for digital health research. Below we outline additional considerations for suicide research with digital health interventions, digital assessment tools, and/or e-consenting and remote research procedures.

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:

1. **Introduction:** The example language does not include how much time the participant may be expected to spend using the digital health intervention or components, if the researchers are asking for participants to review content as part of the research, or if researchers are measuring usability and utilization of the intervention as an outcome.

   We suggest that the informed consent form/process include an explanation of what information is being requested of the participant as part of a digital health intervention versus what information is being requested as part of research assessments or data collection only (including wearables). They should also be made aware of what information is provided to a third party in either a digital intervention or data collection. When initially accessing a third party tool, we also recommend the privacy agreement and terms of service educate potential participants on how and what information is collected and what data management and privacy protections are in place. We recommend participants be given training and instruction on how to answer questions as part of a digital intervention and as part of research assessments. This could include screen shots or interactive media to show how to answer questions and access the digital health intervention/assessment.

2. Procedures: Study information tends to be understood more readily when information is provided in accessible ways. For example, consent procedures that include interactive media tend to result in better participant understanding than videos, which enhance understanding better than traditional consent documents (see Gesualdo et al., 2021; Yusof et al., 2022). One type of consent process has not emerged as the most acceptable to participants or the most likely to ensure understanding for all participants. Some people prefer and are more likely to understand study information from concise written consent forms, interactive media, video explainers, town halls, frequently-asked-questions and answers, or ongoing access to researchers (Kassam et al., 2023; Nebeker et al., 2016; Skelton et al., 2020). Other work suggests participants in digital health research prefer to be able to modify their consent depending on which data are being used and by whom (Muller et al., 2023). If multiple options for consent processes are given, researchers require funding and other resources to ensure the consent process fully informs all potential participants.

If persons are expected to essentially consent themselves in digital health research and e-consent forms, they should be given information in a readily accessible format that caters to various learning styles. Interactive media are more accessible than plain text and ensure the person spends adequate time receiving information and considering the benefits and risks of the study so they can make a fully informed decision about their participation (Gesualdo et al., 2021). Interactive media and consent processes should also take into consideration the population of interest, and the population's comfort and skills with digital media, as well as accessibility concerns. Such interactive media should include an introduction and teaching section, where potential participants are given instruction on how to navigate the consent document/media, to ensure they do not get frustrated or confused by the media platform. Such interactive approaches should also include as assessment of how well the participant understood and retained key pieces of information through short quizzes (e.g., Palmer et al., 2008). Researchers should also consider being available for questions before and during the interactive media consent process; essentially the interactive media consent process should not replace the researcher entirely.

If federally-funded researchers are to use best practice procedures that enhance understanding among potential research participants, such as interactive media described above, funds should be allocated and examples made freely available to researchers. The NIH has funded the development of tools, such as REDCap, to enhance digital data collection. Similarly, it would be helpful if a digital tool or list of industry partners that have the skills and expertise to translate a paper consent form to a digital, interactive consent process, could be recommended to researchers. Researchers without digital health expertise should not be expected to independently translate their paper consent forms to a digital platform and instead should be given guidance by those (e.g., industry partners, NIH Centers of Excellence) with such expertise.

Any researchers who have open text boxes in digital health studies could learn about safety concerns such as the unsolicited reporting of suicidal thoughts and behaviors. Digital health researchers may feel compelled to remove suicide or other safety-related items from measures in an effort to avoid safety protocols necessary when eliciting suicide-related items. Guidelines for when researchers should review open-ended responses and provision of resources are needed. Additional research to identify best practices for the timing of emergency outreach and

what outreach should be provided would be of benefit to researchers. Protocol papers or other NIH resources could also document the timing and type of resources for mental health and crisis support. Currently, researchers may cold email other researchers to request safety protocols; however, having a repository of safety protocols would be of benefit and establish standards for the field. In addition, rigorous studies that compare the timing and type of outreach when researchers do learn of safety concerns would be extremely beneficial and inform best practice recommendations.

3. **Data sharing and ownership:** Information on informed consent and ability to opt out of national data repositories is given by specific institutes - and the granularity and amount of data from wearables and from digital health interventions may need special consideration. Wearables can provide a considerable amount of granular, personal health information to third-party service providers. Prospective participants should be informed about the amount and granularity of data collected, and how it will be cleaned and shared with researchers and with national repositories. Moreover, prospective participants should understand how data may be used and reused as well as what protocols are in place for protecting participants from being identifiable. For instance, the NIAAA and NIMH have publicly shared example consent form language regarding data sharing with the NIAAA and NIMH Data Archives, respectively. The authors appreciate such sample language and recommend that the NIH also provide language around data sharing and ownership. The authors have also used the publicly available information on NIH's website to educate IRB members about what information is stored in national repositories and that participants can opt out of such national repositories.

Regarding the section [If the study is using commercial digital health technology]:

[Insert company] will have access to, and may retain a copy of, any data collected by [insert digital health technology name/type]. When using [insert digital health technology name/type] you agree to the Terms and Conditions set out by the company. We do not have control over how [insert company] will protect your data and privacy.

This section could have additional information regarding privacy protections - the recommended language of "We do not have control over how [insert company] will protect your data and privacy" could be followed by how the researcher then protects privacy in partnership with the third party company, if relevant. For example, we recommend that industry partners are given the fewest identifiers possible. For example, participants can receive an anonymous username or account number - that is not their research identification number - that is used with the digital intervention. This second layer of protection ensures that any information shared on a digital health platform is then not able to be associated with the participant's other research data and can also not be associated with their name or other identifiers. We also expect that any identifiers like gender, age, race/ethnicity, sexual orientation, or location, are only given to industry partners when it is an important part of the intervention - for example, if psychoeducation given within the digital health intervention differs based on gender identity, so it is necessary to ask about gender identity in the digital intervention. In addition, the researchers may choose not to share any additional data with third parties beyond what the participant directly enters into the third-party's portal. Third parties are therefore providing a

digital data collection and/or intervention service, and not gathering data on research participants for their own purposes. It would be ideal to have standards regarding data collection, monitoring, storage, and sharing that commercial entities would be required to agree to in order to partner on NIH-funded research projects.

4. **Potential risks:** For digital health research directed at suicide prevention, it is important to explain what data are collected and when it is reviewed by a researcher and a clinician. Ecological momentary assessment (EMA), daily diaries, and other remote research procedures and data collection used in suicide research are not always automatically communicated to a licensed clinician or reviewed immediately. This is important to note as most digital suicide intervention research is directed at adjunctive interventions that are not intended to replace clinical treatment. It is particularly important to ensure that proper wording is included in the informed consent and in the study explanation to the participant that contact through the digital health intervention (e.g., EMA, email, text message) should not be used as a crisis or emergency communication channel. However, there should be information included on resources available to the participant (e.g., the National Suicide Lifeline). When assessing suicidal thoughts and behaviors, it is reasonable to expect researchers to inform participants of how often and by whom responses are reviewed. To the extent that responses are not reviewed and responded to by clinical staff in real time, it may be helpful to remind participants of this response time and provide participants with resources. It may be useful to assess prospective participants understanding of this key point during the consenting process through a consent mini-quiz. Researchers may consider providing some automated reminders to offer real-time resources unless it would unacceptably compromise research validity. Researchers providing more frequent or intensive outreach is not always the most beneficial response for participants, and may unintentionally undermine accurate reporting of suicide-related items without the benefit of intervening when persons are at highest risk.
5. **Potential benefits:**
6. **Cost:** We agree that the informed consent process should inform participants that standard text rates may apply for digital health assessment and text message interventions. We also recommend adding language regarding high-speed internet, such as "If you do not have unlimited high speed internet services, your data plan may be depleted more quickly as a result of your participation in this study." In rural areas of the United States, high speed internet can cost roughly $150-$300 per month and participants should be informed of this potential cost.
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community: We expect that time, funds, and expertise may be barriers to use of this resource by the greater research community. Therefore, we recommend that the NIH provide direction regarding the industry partners or Centers of Excellence that can help support researchers in using interactive media in the consent process and supporting ethical digital health research. If such industry partners do not exist or the currently funded Centers of Excellence do not have expertise or support for this work, we recommend the NIH consider supporting the creation of Centers of Excellence to support ethical and responsible Artificial Intelligence and Digital Health research.

Other feedback relevant to this resource:

References

Gesualdo, F., Daverio, M., Palazzani, L., Dimitriou, D., Diez-Domingo, J., Fons-Martinez, J., Jackson, S., Vignally, P., Rizzo, C., & Tozzi, A. E. (2021). Digital tools in the informed consent process: a systematic review. BMC Medical Ethics, 22(1), 18. https://doi.org/10.1186/s12910-021-00585-8

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Skelton, E., Drey, N., Rutherford, M., Ayers, S., & Malamateniou, C. (2020). Electronic consenting for conducting research remotely: A review of current practice and key recommendations for using e-consenting. International Journal of Medical Informatics, 143, 104271. https://doi.org/10.1016/j.ijmedinf.2020.104271

Yusof, M.Y.P.M., Teo, C.H. & Ng, C.J. (2022). Electronic informed consent criteria for research ethics review: a scoping review. BMC Medical Ethics, 23, 117. https://doi.org/10.1186/s12910-022-00849-x

Email: lourah.kelly@umassmed.edu

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Corbin Evans

Name of Organization: American Psychological Association

Type of Organization: Non profit research organization

Type of Organization-Other:

Role: Organizational official

Role - Other:

Domain of research:

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/DRAFT-Response-to-NIH-RFI-Consent-Language-for-Research-.pdf

Description: See attached

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Stephanie Goldstein

Name of Organization: Brown-Lifespan Center for Digital Health

Type of Organization: Academic institution

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: The leadership team and affiliated faculty have strong content area expertise in the application of digital health technologies in the following areas: adolescent health, artificial intelligence, physiological sensors, behavioral health, depression, firearm use, health equity, HIV/AIDS/Hepatitis C, interpersonal violence, social media, suicide, substance use, and weight loss/management.

Utility and useability of this resource: The Brown-Lifespan Center for Digital Health (CDH) is an incubator for practical research, enabling the development of novel digital health science and tools focused on solving the needs of patients, providers, and populations. We therefore offer comment and perspective from this lens. Overall, our group believed this resource to be an important contribution to the field of digital health research. We think that this resource has potential to foster consistency across studies and research teams, which could ultimately lead to better aggregation of research protocols and more efficient IRB approvals.

We also noted that this resource could be of particular use among researchers who are newer to human subjects research and/or digital health research, thus encouraging more cross-disciplinary research efforts. Additionally, the resource offers clear and concise action for researchers whose institutions may not have the infrastructure or expertise to support digital health research. In this vein, we hope that this resource is the beginning of a series of NIH notices to support and guide investigators. We strongly recommend also including considerations for electronic consenting (i.e., e-consenting), given that this is a commonly employed practice in digital health research studies. In particular, this resource could introduce e-consenting and discuss common considerations (e.g., inclusion of hyperlinks and forward/backward navigation, offering assistance with e-consent technology and paper-based options, verification of identity, how to give potential participants the opportunity to ask questions/ensure understanding of the study, and provide copies of e-consents). The resource could also refer readers to guidance prepared by DHHS and FDA for more information.

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:

1. **Introduction:** -Comment on the considerations: This section was well-written and clear; we have two comments for consideration: 1) This introduction should also include recommendations for the researcher to provide a brief overview of the frequency and duration that participants will be expected to use these digital health technologies (with the

acknowledgement that more detail will be provided in later sections); 2) For digital health technologies that offer a user the ability to see their own data, it should be introduced in this section what data will or will not be accessible to participants (with the acknowledgement that more detail will be provided in later sections).

-Comment on sample language: Digital health technology use and engagement, or lack thereof, is not always binary. For example, researchers may wish to impose minimal use criteria (e.g., participants must use technology X at least once per day) or may employ a digital health tool that has multiple components a user can enable and/or disable at any given time. We recommend that the provided sample language address 1-2 more use cases such as these.

2. **Procedures:** -Comment on the considerations: We have two additional recommendations for this section to address the following more explicitly: 1) the informed consent language should make it clear what materials or resources are needed by the participant in order to complete the study procedures (e.g., WiFi, plugs/chargers, outlets); 2) if applicable, informed consent should include instructions for what is expected of participants in the event of disruptions to data collection (e.g., what to do if devices need to be taken off the body or taken offline, run out of battery, break, etc, or how deviations from the protocol or non-compliance impact study earnings, eligibility, time in the study, etc).
3. **Data sharing and ownership:** -Comment on the considerations: We agreed that the notion of "identifiable" data needed additional clarification. Typically, researchers consider identifiability as a binary label when examined in isolation (i.e., data is either identifiable or it is not). However, any data can be identifiable when combined with other data source(s). As an alternative, we believe it may be helpful to encourage researchers to more openly state that all data (especially digital data) may be identifiable and that protecting privacy/confidentiality is often a matter of effort in de-identifying the participant (an analogy would be locks on a house as an approach to increase security but does not make the house completely inaccessible). If researchers do wish to state that their data is "identifiable" or "deidentified," then they should describe exactly what that means using terminology that potential participants can understand. Additionally, steps taken to ensure data remains deidentified should be clearly described.

We also think that there should be more specific recommendations for researchers using digital health technologies that offer users abilities to see their own data, namely: 1) it should be clearly described what data are/are not accessible, 2) why there are certain limitations on what data are made available to a user and the timeframe that they can access these data (e.g., immediately vs 24 hour wait, limits to how often requests to the system can be made), and 3) an explanation for the data (e.g., is it original data captured and stored by the device/online service, or if it is aggregate data, which is processed data of some form) and variables provided (e.g., for example if a value for "sleep quality" is 0.7, this is not useful without knowing how to interpret that, what is the range of values, how it is calculated, etc.

Lastly, we recommend that the resource also touch on the issue of how participants will be informed of study progress and results.

4. **Potential risks:** -Comment on the considerations: We noted multiple gaps in this section that, if addressed, would likely strengthen the resource: 1) The considerations should specifically mention the risk of re-identification for applicable technologies (e.g., social media, GPS/GIS). If relevant, researchers should explain in the informed consent the ways in which re-identification

is possible, steps taken to minimize risk of re-identifications, and what information would be disclosed should their study data be re-identified (e.g., highly sensitive health information vs. raw accelerometer data). 2) Considering the potential risks of technology can require advanced technical and/or legal expertise, and therefore this resource may wish to encourage researchers to consult relevant experts as necessary. Additionally, various institutions may have their own policies on using certain technologies (e.g., social media use, location tracking) that researchers will want to be aware of. 3) The existing recommendation to identify possible risks for non-participants (or bystanders) should also include guidance to describe what will be done by the research team to mitigate those risks wherever possible. 4) This resource, at present, does not adequately describe potential psychosocial risks and the limits of confidentiality when researchers become aware of reportable information. Because of the breadth of potential information we can obtain via digital health technologies, it is possible that disclosures of self-harm, suicidal ideation/intent, harm to others, abuse, etc could be unintentionally made to the research team. Therefore, we recommend that the resource instructs researchers to carefully consider these potential risks (even if the research is not specifically focused on psychosocial factors, disclosures such as these are always possible). If risk is present, researchers should develop/describe a thorough crisis mitigation plan, describe the frequency of monitoring, and discuss the conditions under which anonymity of participants will be maintained (vs. when confidentiality must be broken in accordance with state laws and other relevant mandates).

-Comment on sample language: Please include sample language of how to describe risks of discomfort or anxiety surrounding using technologies (e.g., answering questions in an app, wearing a study device that potentially identifies you as participating in research). This is a common and important consideration that researchers without behavioral/psychological training may have difficulty formulating text for.

5. **Potential benefits:** N/A
6. **Cost:** -Comment on the considerations: We believe the recommendations for this section were sufficient and have one minor suggestion to also explicitly consider commercial technologies that may offer in-app paid features. If using these tools, researchers should clearly describe who is responsible for those costs and explicitly state what participants are or are not expected to purchase.

-Comment on the sample language: We noticed that there was no sample language provided in this section and thought it may be helpful to include sample language for a common cost to engaging in digital health research, such as WiFi or phone data plans.

7. **Withdrawal:** -Comment on the considerations: Disengagement is a common issue in many digital health research studies. It may be helpful for this resource to also include recommendations to consider when "withdrawing" participants after periods of no contact/engagement (e.g., is no explicit contact with the research team requesting to drop out, but there is a complete lack of engagement in the research activities/outreach). If applicable, the researchers should define how long non-use/non-contact will be tolerated before a participant is considered "withdrawn" and how they will be informed (e.g., letters, emails, phone calls).

Hurdles or barriers to wider use of this resource by the community: While the CDH is of the opinion this resource will be very useful to many researchers, there were a few barriers noted to wider

adoption. First, we noted that there are several different guidelines to follow when drafting informed consent documents (i.e., NIH, local IRBs, FDA, DHHS) and so it may be confusing to add this resource to the list. To combat potential confusion, it might be helpful to clearly contextualize when and why researchers might decide to use this resource and to explicitly note the hierarchy of different recommendations (e.g., that this resource does not replace institutional guidance, federal guidance, etc). Second, the considerations within this resource may increase the barrier for clinical researchers who may not have technical and/or legal expertise to determine complex risk scenarios. To support and educate these individuals (vs. deterring them from doing the research), this resource may consider pointing individuals to additional reading or consultation. It may also be helpful to indicate areas, such as risk mitigation, where it might be especially relevant to consult an expert. Third, this resource fails to acknowledge the digital divide and address potential ways in which the use of digital tools can affect representation and inclusivity in research. For example, the resource should recommend that researchers describe all technologies and study procedures in ways that accommodate all levels of digital/health literacy and strive to do so at ~6th grade reading level. While the importance of 'clarity' is mentioned a few times, the resource would be more impactful if it explicitly described how to consider digital literacy in the development of consent forms and general advice for researchers aiming to describe digital tools at accessible reading levels. Relatedly, the resource itself might be more widely adopted if the language was more accessible to all stakeholders of digital health research. For example, individuals from the broader communities in which digital health research studies are taking place could also utilize this resource as a guide to conduct their own work or to be active partners in academic research.

Other feedback relevant to this resource:

Nothing else at this time

Email: stephanie_goldstein@brown.edu

Submit date: 2023-12-12

I am responding to this RFI: On behalf of myself

Name: Anaid Gonzalvez

Name of Organization:

Type of Organization:

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research:

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Haley Griffin

Name of Organization: Computing Research Association

Type of Organization: Professional organization association

Type of Organization-Other:

Role: Investigator researcher

Role - Other:

Domain of research: Computing Research

Utility and useability of this resource: It is important to repeat that all parts of this guidance document may not apply to all projects and can thus be applied piecemeal, and to solicit feedback from people who are trying to operationalize the guideline. Without being prescriptive about how to ask your end-user about their experience with the tool, we recommend looking for guidance from implementation science frameworks on your evaluation of the utility and usefulness. One example is the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework (https://re-aim.org/) and the companion website that offers a checklist that can help you think through the dimensions of providing a good tool.

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:

1. **Introduction:** Who is responsible for paying for cellular data/internet connection. This can be a significant unanticipated cost to the participant.

   As part of this study, [insert expectation of who is responsible for cellular data/internet connection].

   [If participant is expected to pay]: Participants must have their own [cellular data/internet connection], to be eligible to participate in this study. We anticipate participants will use no more than [data size (e.g., 1GB of data)] of their [cellular data/internet connection].

   [If researchers pay]: The research team will provide [describe how reimbursement will be provided (e.g., provide a check on the 1st Friday of each month to reimburse data costs; a separate phone with a paid data plan)].

   [Depending on expectations of study data needs (e.g., if participants live in an area with limited connectivity)]: If you do not have access to [cellular data/internet connection] [timing expectation (e.g., daily, all the time)], you should not agree to be in this study.

Inclusion/exclusion criteria. The below lists are to be provided verbally to potential participants before they sign the consent form:

Inclusion criteria for All Participants:

You have access to a usable Android or Apple smartphone.

You can download apps from your smartphone's app store.

You have an accessible email address or are willing to set up an email account.

You have a working phone with service with the ability to receive and send texts.

You live in the U.S.

You read, speak, and understand English.

You agree to voice/video recording during interviews.

You agree to consent to participate in the study.

[If participants have an Android Smartphones only]:

You must have a Gmail account or be willing to set up a Gmail account.

You will be excluded from the study if you meet the following criteria:

You do not fit into the inclusion criteria.

You have changed phone numbers more than twice in the past 365 days.

What constitutes a "medical device" versus what does not. Sometimes devices that don't serve a purpose related to medicine/treatment are inaccurately classified as medical devices.

Per Section 201(h)(1) of the Food, Drug, and Cosmetic Act, a medical device is:

"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

(A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)."

The FDA's Policy for Device Software Functions and Mobile Medical Applications should also be referenced as a guide

Technology should not be treated as a monolith, and so more specificity and/or customization should be provided for each item. For instance, there are significant differences with digital health data not collected through "devices", or digital health technologies like the following: Internet-connected/Not connected, Researcher owned/Third-party owned, Social Media/Internet of Things/Wearable/Virtual Reality, etc.

The health technology being used can be generally considered a form of [add tech type (e.g., mobile app, virtual reality, sensor, wearable device)], which is [give a general definition].

The health technology [is/is not] an internet-connected device that [will/will not] store data on the cloud.

The health technology was [developed by the research team/developed by a third-party] and the data will be stored and secured [locally on the device/at the research site/by the third-party].

Describe how AI is used in the system. Digital health technologies now include AI, but are not mentioned in this document. The draft document says "The resource does not address considerations for implantable devices, artificial intelligence, or other types of digital health technologies," but we believe that this document risks almost-immediate obsolescence if it fails to engage with "AI or other types of digital health technologies." For example, Epic's EHR currently has AI enabled communication from a physician. Thus, participants need to understand what communication is coming from a human vs. machine.

A recommendation would be to create a taxonomy of different digital health technologies, so that recommendations can be made specific to those contexts. The FDA has done significant work in this space and has released a list of topics and their benefits and risks.

The following are topics in the digital health field on which the FDA has been working to provide clarity using practical approaches that balance benefits and risks:

Software as a Medical Device (SaMD)

Artificial Intelligence and Machine Learning (AI/ML) in Software as a Medical Device

Cybersecurity

Device Software Functions, including Mobile Medical Applications

Health IT

Medical Device Data Systems

Medical Device Interoperability

Telemedicine

Wireless Medical Devices

2. Procedures: Baseline competencies. Researchers should create a brief training activity that participants complete to show they know how to use the device and who to contact if they have issues.

Before you start the study, the research team will ensure you can [baseline activities (e.g., log in; add what you ate)] with [insert digital health technology name/type]

Explainable AI. How is data going to be transformed, cleaned, and processed?

We will clean the data by [explain how data will be cleaned (e.g., removing information about you such as your location or IP addresses)].

Our AI system will [explain how data is processed (e.g., make suggestions based on your data, but we do not understand how the computer figures out those suggestions)]

If you requested to have your data deleted, [explain what data can be deleted, and the extent that the researchers have control of this process (e.g., your survey data can be deleted from university databases, however the 3rd party created application you use for diet management can only be deleted by the participant by contacting the [company and contact info])]

Differentiate between treatment/intervention versus data tracking/monitoring. Research could be either or both.

In this study, we will use the information you provide to [insert specific treatment/intervention] [insert and/or] [interest specific tracking/monitoring system]

Different consent and other procedures for children (e.g., Children Online Privacy Protection Act - COPPA)

Given that the data collected will be from a minor under the age of [insert relevant age], applicable regulatory laws [insert name of applicable regulatory law (i.e., Children's Online Privacy Protection Act (COPPA) or Family Educational Rights and Privacy Act (FERPA))] will apply to this research]. [Briefly describe the aspect of the law that is relevant to the participant].

Address "dark patterns" (e.g., Opt Out, nudges to consent) for obtaining consent for research as a prerequisite to receiving medical treatment. Most patients don't realize they can opt out of research, so they may unknowingly be enrolled because they need medical care. This is a form of duress/coercement if patients believe that medical care could be denied without consenting to research. We recommend research teams investigate how participants are recruited and change enrollment to opt in instead of opt out.

A research team is doing a study on [insert study name/purpose]. They would really appreciate you agreeing to share your [insert data the team is collecting]. Opt in by checking this box: [insert blank check box].

When parental consent is obtained for a minor, procedures and expectations need to be made clear to the minor at their literacy level throughout the study (especially since they are not reading the consent form).

A simplified statement of the informed consent agreed to by the parent should be read to the child to communicate key points, such as they are not required and will not be punished in any way if they do not want to answer any questions or decide they no longer want to take part in the study.

3. Data sharing and ownership: A tractable and understandable list out what data is tracked. We acknowledge that sometimes there is a vast list of data tracked, but an itemized full list, if feasible, or at least a summary accompanied by an easily understandable visual, would be ideal. For example, location while using app/location while not using app.

For example, instead of "You will be asked to share [insert types of data] via [insert digital health technology name/type] [insert frequency (e.g., at random intervals throughout the day, daily, weekly)]," we recommend:

You will be asked to share:

Data Type

Frequency

Who has access to the data

Your location when carrying [insert digital health technology name/type]

When using app

-Research Team

-Phone*

-Cellular provider*

Movements you make with [insert digital health technology name/type]

All the time

-Research Team

-Phone*

X Posts

All the time

-Research Team

-X*

* data is available to these groups independent of the study

Language regarding whether and how the data is protected by HIPAA (see Appendix I for an example). This is critical for any scientist whether or not they are in a health system.

Sample language from NIH can also be found here.

Researchers should consider obtaining a NIH Certificate of Confidentiality to protect participant data from legal discovery.

"Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except with the subject's consent or in a few specific situations. Researchers with a CoC may disclose identifiable, sensitive information ONLY in the following circumstances: 1. If required by other Federal, State, or local laws, such as evidence of child abuse or a subject's threatened violence to self or others; or 2. for the purposes of scientific research that is compliant with human subjects' regulations Researchers with a CoC must ensure that anyone who is conducting research as a sub-awardee or receives a copy of identifiable sensitive information protected by the policy understands they are also subject to the disclosure restrictions."

Participants should be informed of how inferences (e.g., machine learning classifications) from the data may be used/shared. In general, inferences about potential medical information (e.g., use of AI to predict potential cancers) are not automatically treated as private health information within US law. We propose instead that inferences to personal information should be treated as actual personal information, as is done in the California Privacy Rights Act (CPRA).

The data that you provide will be used to make inferences and predictions about [insert targets]. These inferences will be protected in the same ways that we protect your original data.

It is unreasonable to expect participants to read and digest the Terms and Conditions of an organization. Terms and Conditions are usually not at an 8th grade level or understandable. If they are relevant to the study, the onus should be on the researcher to summarize them at an 8th grade reading level.

Explicitly note what data participants can ask to be removed and what data they can not.

You may stop participating in the study at any time. If you want the data we previously collected to be removed from the study, [insert details about what researchers are able to remove and emphasize that they will remove as much as they can].

Make it explicit that participants do not own 3rd party data.

The research team does not own the data you supply on [insert social media platform or application name] and therefore can not guarantee how it will be [e.g., used, stored, retained after deletion].

Portability of the data - Can participants request raw data and/or synthesized reports based on their data for their own benefit? If so, researchers should provide details about how participants can obtain the data.

Participants [insert can/cannot] request raw data for their own benefit. Also they [insert can/cannot] request synthesized reports based on their data for their own benefit. [Insert details on how participants can obtain their raw data and/or synthesized report].

Appendix I: HIPAA Authorization Sample Language

Federal law provides additional protections of your medical records and related health information.

I agree to permit the Principal Investigator, [name], and research staff ("Researchers"), and [research organization] may use and disclose health information that identifies me for the purposes described below. I also agree to permit [health system name] and its affiliates, my doctors, and my other health care providers may disclose health information in my medical records to the Researchers and [research organization] for the purposes described below.

1. The health information that may be used and disclosed includes: all information collected during the research described in the Informed Consent Form; and health information in your medical records that is relevant to the research described in the Informed Consent Form.

2. The Researchers may:

use and share my health information to conduct the research;

disclose my health information to the sponsor of the research, [research organization] and its agents;

disclose my health information to [health system name] and its affiliates;

disclose my health information as required by law;

disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research; and

remove from my health information my name and other information that could be used to identify you.

3. Study Sponsor may:

use and share my health information to conduct the research;

use my health information as described in the Informed Consent;

disclose my health information as required by law;

disclose my health information to representatives of government organizations and other persons who are required to watch over the safety and effectiveness of medical products and therapies, and the conduct of research; and

remove from my health information my name and other information that could be used to identify me.

4. Once information that could be used to identify you has been removed, the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers and [research organization] as permitted by law.

5. Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure. However, the Researchers and [research organization] agree to protect your health information by using and disclosing it only as permitted by me in this Authorization and the Informed Consent. Also, no publication about the research will reveal my identity without my specific written permission. These limitations continue even if I revoke (take back) this Authorization.

6. Please note that:

You do not have to agree to this Authorization, but if you do not, you may not be allowed to participate in the research.

You may change your mind and revoke this authorization at any time. To revoke this Authorization, you must write to [principal investigator name and address]. However, if you revoke this Authorization, you may no longer be allowed to participate in the research. Also, even if you revoke this Authorization, the information already obtained by the Researchers and [research organization] may be used and disclosed as permitted by this Authorization and the Informed Consent.

While the research is in progress, you will not be allowed to see your health information that is created or collected in the course of the research. After the research is finished, however, you may see this information as described in [health system name] Notice of Privacy Practices.

7. This Authorization will expire 50 years from the date of signature.

4. **Potential risks:** Risks related to child mandated reporting status of the reseachers (e.g., child abuse, sexual abuse, imminent risk of harm).

If data collected from this study strongly indicates that you are at serious risk of physical injury, sexual abuse, mental injury, or physical neglect, we are required by law to report these types of imminent risks to the proper authorities.

The data collected during this study will not be monitored on a daily basis, so this study should not be considered as a form of real-time screening or reporting.

As mandated reporters, if we have reasonable suspicion that a child has been abused, neglected or threatened of harm in the state, we will contact the state hotline to report the incident. The Hotline counselor will determine if the information provided meets legal requirements to accept a report for investigation.

External and unbiased point of contact in case of harm. There should be a trustworthy individual documenting perceived harms that does not have a stake in the success of the research. Oftentimes, a participant's only option is a researcher or an "advocate" that is funded by the Research Institution. If there is not an option for an external individual, at minimum the priorities of the individual they are being asked to report to should be transparent from the beginning.

If you feel like you are being harmed in any way by this study, [insert title and contact information for an individual that they can reach out to, including information on who is funding this person's consulting and what their priorities are].

Proactive detection. Participants should know if they are going to be notified if there is bias/harm during or after the study.

The research team is monitoring the data collected for bias/harm throughout the study, and will continue to do so after it is complete. If you are ever negatively impacted by [insert type/s of harm that they could experience], and the research team finds out, you will be notified within [insert amount of time].

How to handle emotional distress.

If you become emotionally distressed and feel you need help, you can speak to your physician to ask for local resources or a local counselor. You can also call 211 or go to http://www.211.org/ to find the resources you need. If you need immediate help, you should call 211. The following are also available to you 24/7 to contact: National Parent Helpline 1-855-427-PARENT (2736); SAMHSA's National Helpline 1-800-662-HELP (4357); and National Suicide Prevention Lifeline 1-800-273-8255.

5. **Potential benefits:**
6. **Cost:** Clarity on responsibility for costs associated with potential risks of the intervention

Clarity on the cost for internet/cellular data access. Expectation of the amount of data the participant is expected to supply. Impact on overall bandwidth.

7. **Withdrawal:** Should be more clear that unless they physically are not able to figure out which data is yours, you can discontinue your involvement (including your data) at any time.

Whether data will be destroyed completely or retained without analysis based on data retention laws in the state.

When parental consent is obtained for a minor, it needs to be made clear to the minor during the study that they are allowed to withdraw/not answer at any time (since they are not reading the consent form).

Clarify that withdrawing from the study may not be the same as withdrawing the data already collected from the study.

Explicit the participant vs. researcher responsibility for deleting data (in consent form at beginning and/or handout later).

Clarify that the research team may withdraw them from the study if the participant no longer qualifies (e.g., no longer has a phone, data plan, etc.). This could also be the case if the research team identifies someone as fraudulent (e.g., a mobile study where people in the United States are participating, but the participant location continues to indicate they are in another country and have not disclosed international travel) ;

Explain that withdrawal will not adversely impact their standard medical care as provided prior to entry into the study.

Hurdles or barriers to wider use of this resource by the community: Table of Contents are very rarely at an 8th grade reading level, so it is problematic if consent language is outsourcing at all to Table of Contents. There should be a positive obligation on researchers to give 8th grade level summary, visuals, etc.

Other feedback relevant to this resource: Sometimes template language like this can manifest into required protocol without care being put into making sure it works for the study, and it is important to not require it as a blanket statement if it does not apply directly to the research.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/Digital-Health-RFI_NIH-Dec-2023-FINAL.pdf

Description:

Email: hgriffin@cra.org

Submit date: 2023-12-12

I am responding to this RFI: On behalf of an organization

Name: Leanna Wade

Name of Organization: The Connected Health Initiative

Type of Organization: Professional organization association

Type of Organization-Other:

Role: Other

Role - Other:

Domain of research:

Utility and useability of this resource:

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:

1. **Introduction:**
2. **Procedures:**
3. **Data sharing and ownership:**
4. **Potential risks:**
5. **Potential benefits:**
6. **Cost:**
7. **Withdrawal:**

Hurdles or barriers to wider use of this resource by the community:

Other feedback relevant to this resource:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/13/CHI-Comments-re-NIH-Developing-Consent-Language-for-Research-Using-Digital-Health-Technologies-121223-final.pdf

Description:

Email: lwade@actonline.org