NOVEL AND EXCEPTIONAL TECHNOLOGY AND RESEARCH ADVISORY COMMITTEE

Minutes of Meeting

June 25, 2021

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH (NIH)
NOVEL AND EXCEPTIONAL TECHNOLOGY AND RESEARCH ADVISORY COMMITTEE (NExTRAC)
Minutes of Meeting
June 25, 2021

MEMBERS IN ATTENDANCE
Richard Whitley, M.D. (Chair)
Zach N. Adelman, Ph.D.
Lorraine M. Albritton, Ph.D.
Cinnamon Bloss, Ph.D.
Kathleen Boris-Lawrie, Ph.D.
Mildred Cho, Ph.D.
Gigi Kwik Gronvall, Ph.D.
Benhur Lee, M.D.
Dean A. Lee, M.D., Ph.D.
Alan I. Leshner, Ph.D.
Freda C. Lewis-Hall, M.D., DFAPA
Douglas McCarty, Ph.D.
Pilar N. Ossorio, Ph.D., J.D.
Kenneth Oye, Ph.D.
Matthew Porteus, M.D., Ph.D.
Margaret F. Riley, J.D.
Leigh Turner, Ph.D.

NExTRAC is a federal advisory committee that provides recommendations to the NIH Director and serves as a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies. NExTRAC proceedings, reports, and links to meeting videocasts are posted on the website of the NIH Office of Science Policy to enhance their accessibility to the scientific and lay public.

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WELCOME
Lyric Jorgenson, Ph.D., and Richard Whitley, M.D., NExTRAC Chair

Dr. Whitley called the virtual meeting to order at 1:01 p.m. E.T.

Dr. Jorgenson welcomed the committee members, the Gene Drives in Biomedical Research Working Group members, NIH staff, and members of the public to the third meeting of the NExTRAC, which provides advice to the NIH Director about scientific, safety, ethical, and social issues associated with emerging biotechnologies and their potential application. She announced that at this third meeting of the NExTRAC, the committee would be discussing the draft report to be presented by the co-chairs of the Gene Drives in Biomedical Research Working Group, which was formed in response to a charge from the NIH Director in December 2019.

ACKNOWLEDGMENT OF DEPARTING NExTRAC MEMBERS
Dr. Jorgenson acknowledged four NExTRAC members who are completing their terms of service at the end of July: Richard Whitley, M.D., Mildred Cho, Ph.D., Dean Lee, M.D., Ph.D., and Douglas McCarty, Ph.D. These members began their service to NIH as part of the Recombinant DNA Advisory Committee and continued advising NIH as NExTRAC members. Dr. Jorgenson expressed her gratitude for the time and effort that these members gave to the NExTRAC and offered a special thanks to Dr. Whitley for serving as chair. Cinnamon Bloss, Ph.D., will serve as acting chair.

CONFLICT OF INTEREST DISCLOSURES
Jessica Tucker, Ph.D., the NExTRAC Executive Secretary, reminded the committee members about the rules of conduct that apply to them as Special Government Employees, read the conflict-of-interest (COI) statement into the record, and indicated that related questions could be addressed to the Committee Management Office.

Dr. Tucker also announced that the meeting was open to the public and was being videocast and recorded.

PRESENTATION OF THE DRAFT REPORT OF THE GENE DRIVES IN BIOMEDICAL RESEARCH WORKING GROUP
Zach Adelman, Ph.D., and Cinnamon Bloss, Ph.D., Gene Drives in Biomedical Research Working Group Co-chairs

Dr. Bloss and Dr. Adelman presented background information on the working group's charge, their process for drafting the report, and an overview of each report section.

In December 2019, NIH Director Francis Collins, M.D., Ph.D., announced that NIH would create a working group within the NExTRAC to assist in the development of a path forward for biomedical research involving gene drive modified organisms. The Gene Drives in Biomedical Research Working Group (WG) was charged with the following:

1. Consider whether existing biosafety guidance is adequate for contained laboratory research utilizing gene drive technology.

2. Outline conditions (if any) under which NIH could consider supporting field release of gene drive modified organisms.

This working group is composed of NExTRAC members and *ad hoc* subject matter experts (SMEs). The WG met bimonthly beginning in early February 2020. The first meetings involved presentations from subject matter experts who provided insight on relevant topics. As part of the November 2020 NExTRAC meeting, a public workshop, Gene Drives: Biosafety Guidance and Conditions for Field Release Research, was held, which included presentations from experts across disciplines relevant to gene drive research, both domestic and international, as well as feedback from key stakeholders and workshop attendees. The WG used the information from the SMEs and feedback from the workshop to inform the report. The areas of focus for the report were adequacy of biosafety guidance for research conducted in contained laboratory settings, biological and environmental risk mitigation strategies, risk/benefit assessments, and stakeholder engagement.

The report is divided into seven sections, and the recommendations are covered in four sections (Sections III through VI). For each section, Dr. Bloss and Dr. Adelman highlighted which part of the charge these recommendations can be applied to, some of the relevant considerations that the WG discussed for each topic throughout their deliberations prior to this meeting, and the recommendations.

Section III. Biosafety Guidance for Contained Research
Section III applies to the first part of the WG's charge.

Recommendation 3.1. NIH should develop guidance for uniform standards for the design and construction of containment facilities, biosafety considerations for work practices, and the diverse species that could be used in gene drive research.

> During previous WG deliberations, the WG considered that U.S. biosafety guidance does not specifically address gene drive research in contained laboratory settings. It also considered that specific containment conditions for many species likely to be used in gene drive research is limited or not available.

Recommendation 3.2. NIH should provide guidance on the considerations for risk assessments for laboratory gene drive research to assist investigators, biosafety officers (BSOs), and institutional biosafety committees (IBCs) in determining appropriate conditions for contained research (e.g., dealing with complexity, uncertainty, and context).

> WG considerations included that current guidance, including the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, does not consider recombinant or synthetic nucleic acid molecules that have the potential to spread and/or persist in the environment, unlike gene drive research that presents different or increased risks compared to more traditional genetic modifications to

organisms. Additionally, there is a need to identify the key scientific questions that need to be asked, as well as what data is needed to facilitate a robust risk assessment.

Recommendation 3.3. NIH should require appropriate expertise in the review of gene drive research by developing guidance on specific IBC expertise needed for review of gene drive research (e.g., entomology, ecology, evolutionary biology) and requiring a BSO to be appointed to the IBC when conducting experiments with gene drive modified organisms capable of spreading in the environment.

The WG noted that currently IBCs typically do not conduct assessments of potential risks to the environment posed by the escape of gene drive modified organisms. Inspections of facilities that house gene drive modified organisms are critical to ensure containment standards are rigorously followed.

Section IV. Biological and Environmental Risk Mitigation Approaches
Section IV can be applied to the first and second parts of the WG's charge.

Recommendation 4.1. NIH should support research on biological risk mitigation strategies, including the identification of critical areas of uncertainty and approaches to mitigate them.

In their previous deliberations, the WG considered that biological risk mitigation strategies are at the theoretical or early proof-of-concept stages and require additional research to provide evidence of effectiveness before use as potential safeguards in both laboratory and field release studies. It is challenging to evaluate approaches for risk mitigation strategies separately from studies focused on the development of the gene drive technology itself.

Recommendation 4.2. NIH should require that the Approach section of the NIH application or proposal include a localization plan for field trials, which articulates how the gene drive is proposed to be confined and/or reversed.

The WG considered that experimental designs that are confinable and/or reversible should exhibit a more clearly defined risk profile than approaches with the potential to spread more widely. The ability to constrain the spread of a gene drive depends on specific molecular architecture, target organisms, conditions of release, local environments, availability of mitigation approaches, and social contexts.

Recommendation 4.3. NIH should support research on environmental risk mitigation strategies based on evaluation of potential impact on eco-evolutionary dynamics and informed by stakeholder engagement.

The WG considered that risk mitigation strategies need to be informed by an understanding of likely ecological and evolutionary interactions. Perspectives of local communities and indigenous knowledge are critical to understanding the environmental risk profile for specific locations.

Section V. Strategies for Risk/Benefit Assessment for Field Release of Gene Drive Modified Organisms

Section V applies to the second part of the group's charge.

Recommendation 5.1. NIH should require that all requests for support of field trials involving gene drive modified organisms include in the Approach section of the NIH application or proposal a risk/benefit assessment plan addressing potential benefits and potential harms to populations and environments.

During previous WG meetings, the WG's considerations included that risk/benefit assessments should balance potential benefits and potential harms, compare the research approach with existing interventions, address ecological and evolutionary complexity, and consider potential social and ethical benefits/harms.

Recommendation 5.2. NIH should require that all requests for support of field trials involving gene drive modified organisms include in the Approach section of the NIH application or proposal phased research plans with activities designed to proceed from lower to higher risk.

The WG built on the 2016 report *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values* from the National Academies of Sciences, Engineering, and Medicine (NASEM) and considered that the risk/benefit assessment should be informed by data accrued from each phase of research, from laboratory to field release, and by the potential impact of the research if the field release ultimately does not occur.

Recommendation 5.3. NIH should require that all requests for support of field trials involving gene drive modified organisms include in the Approach section of the NIH application or proposal milestones for decisions regarding whether to proceed to the next phase of a research plan.

WG considerations included that iterative risk/benefit assessments are needed to inform the decision to move to the next phase of research and whether the research plan needs to be modified. The decision to move to the next phase of research will vary with the context of particular research projects, locations, and communities.

Recommendation 5.4. NIH should require all requests for support of field trials involving gene drive modified organisms to utilize an independent board to provide input on assessments of potential benefits and harms, milestones, and any associated recommendations.

The WG considered that U.S. regulatory processes for evaluating gene drive technology are limited in how and what information is shared with communities/publics and how input from these groups is used in decision making. Independent evaluation is key to building the trust essential to any potential field trial.

Recommendation 5.5. NIH should make risk/benefit assessments and any associated recommendations from the independent board publicly available.

> WG considerations included that NIH's role in supporting research of risk/benefit assessments to prevent disease and improve human health is based in stewardship and promoting safe and responsible conduct of research. Transparency in decision making is vital to promoting public trust and engagement.

Section VI. Strategies for Stakeholder Engagement Regarding Gene Drive Modified Organisms

Section VI is applicable to the first and second parts of the group's charge.

Recommendation 6.1. NIH should support planning projects to identify potential trial sites and associated stakeholders and conduct preliminary engagement activities that could inform future trials.

> The WG noted in their previous deliberations that effective stakeholder and community engagement should consider the interests, values, goals, and perspectives of stakeholders to promote public trust. This engagement should also involve establishing support or funding for project planning and early engagement.

Recommendation 6.2. NIH should require all requests for support of field release research involving gene drive modified organisms to include in the Approach section of the NIH application or proposal a plan for stakeholder engagement that articulates who will perform engagement activities, how input will be incorporated into decisions about experimental design, and whether to proceed through the phases of the research plan.

> WG considerations included that stakeholder engagement plans should address identification of affected groups, engagement strategies, a balance of maximal inclusivity with prioritization of those most directly affected, and consideration and incorporation of input.

Recommendation 6.3. NIH should support research on establishing best practices for stakeholder engagement for laboratory or field-based gene drive research.

> The WG considered the need for research to evaluate the effectiveness of engagement and establish best practices.

The draft report also includes a conceptual representation indicating recommended components of research that involves the field release of gene drive modified organisms. There will be bidirectional interactions between a research team and a potential field site, the community and stakeholders, and the broader ecosystem or society where the field research will occur. The research team will develop several different types of plans to account for the field site, community and stakeholders, and broader ecosystem. The localization plan serves as the framework for the molecular, environmental, and social

considerations to limit gene drive modified organisms or transgenes to the field site. The risk/benefit assessment plan assesses potential risks/benefits to the environment and populations and is refined/altered as evidence is gathered, and the engagement plan outlines how the research team will work with stakeholders and community and adapt the research plan based on their input. The research team will also interact with relevant regulatory agencies and the proposed independent board. The independent board will also directly interact with the stakeholders and community to address any concerns or values that were not shared with or addressed by the research team and to evaluate the research team's activities with the community.

The research team will also develop a phased plan that outlines the timing of various research activities and the milestones needed to justify moving to the next phase of the research, including field release of gene drive modified organisms. This phased plan would be submitted to the regulatory agencies and the independent board. When phase milestones appear to have been met, both the relevant regulatory agencies and the independent board decide or advise as to whether the research should proceed to the next phase. If approved by all relevant regulatory and local authorities and incorporating input from the independent board, the research team has the option of proceeding to field release. This entire process is iterative, with the cycle repeating as a research project moves from laboratory to small- to large-scale releases of gene drive modified organisms.

PUBLIC COMMENT

Dr. Whitley thanked the members of the public who submitted written comments, which are available on the NExTRAC website.

Michael Santos, Ph.D., is the acting vice president for science at the Foundation for the National Institutes of Health and the director of GeneConvene Global Collaborative. Dr. Santos recognized NIH, NExTRAC and the WG for taking this important step to operationalize the guiding principles for responsible gene drive research and thanked them for the opportunity to provide feedback on the draft report. He said that the report should state which considerations (e.g., expertise in biosafety review, stakeholder engagement) are common to other areas and which are unique to gene drives.

Dr. Santos added that recommendation 3.1 should be clarified to emphasize the importance of a risk-based approach to physical containment to avoid implying a one-size-fits-all approach. He noted that the plans recommended for inclusion in funding proposals are likely to evolve after the proposal, and it is ultimately the implemented activities that support responsible research.

Dr Santos expressed that, given that the ongoing oversight of activities aligns more closely with regulatory and policy bodies than the NIH, the report should consider recommending that NIH defines its review in the context of a governance system that can include external advisory boards, IBCs, regulatory agencies, and local and national governments and could require applicants to describe the governance mechanisms that will provide accountability for the research program. He thought that this approach would enable NIH to evaluate whether the governance system as a whole provides sufficient

confidence that if the NIH funded the project, it would proceed responsibly, consistent with existing policies and practices.

NExTRAC DELIBERATION OF THE DRAFT REPORT OF GENE DRIVES IN BIOMEDICAL RESEARCH WORKING GROUP

Dr. Whitley opened the floor for NExTRAC's discussion on the draft report.

Alan I. Leshner, Ph.D., said that gene drives should be more clearly defined at the beginning of the report to help nonexperts understand the report. Also, the details of the independent board are unclear, including who would be part of the independent board, how the board would be formed, and to whom they would report. Dr. Adelman said that regarding the independent board, the WG discussed several different models at length but decided to purposefully keep the details vague. The WG did not want to restrict NIH to a specific model for the independent board that would be beyond its ability or purview. The report's recommendation is that the board should be independent, transparent, and viewed as legitimate by the community and research team. NIH can interpret the recommendation and how this independent board should operate and any specific attributes for the board. In response to a question from Dr. Bloss, Dr. Tucker said that the WG's charge was to consider under what conditions, if any, NIH could consider supporting field release of gene drive research. This recommendation does not provide specific implementation details, which is consistent with other recommendations in the report.

Pilar N. Ossorio, Ph.D., J.D., said that during the draft report presentation, it was mentioned that the go/no-go decision to move to the next phase of a research plan is a regulatory decision, but this may not be the best approach. Regulators might approve the research to move forward, but then NIH might decide, based on other criteria, that it cannot move forward. Regulators can be limited in their ability to consider public feedback or social and ethical impacts in the same way as NIH. An instance where the regulatory board approves but the independent board disapproves could be considered a hold or no-go by NIH until changes are made to the research plan. Dr. Adelman agreed and said that there are more details in the report about NIH's role in this process. The independent board is the transparent side of the process since the regulators are limited by federal regulations and other rules. Also, the independent board considers outside factors, such as community and stakeholder feedback, in their go/no-go decision. Since NIH controls funding, it can decide whether to continue funding or stop funding a project that does not meet its criteria.

Freda C. Lewis-Hall, M.D., DFAPA, asked whether NExTRAC needs to align its safety recommendations with any international, global, or local guidelines and, if so, how and when those guidelines will be incorporated in the WG's report. Kenneth Oye, Ph.D., said that the WG recognized the uncertainties regarding not only novel and exceptional technologies, including gene drives, and their effects but also that the international and national safety standards and policies around such technologies are also unclear. Based on this, the WG recommended that NIH engage with this uncertainty and gather and generate knowledge on any statutes, regulations, international treaties, and technical safeguards for localizing the effects of gene drive research.

Benhur Lee, M.D., said, in response to Dr. Leshner's comment about the readability of the report, Table 2 of the report highlights representative examples and definitions of gene drives. Dr. Leshner said that Table 2 is useful to include in the report, but there should be one or two paragraphs in either the introduction or the executive summary to provide a generic definition of gene drives, such as mechanisms that manipulate genes to promote a particular trait. There are other sections of the report where plain language descriptions could help the nonexpert reader understand the concepts presented in the report. If the WG assumes that their audience has a high level of knowledge around gene drives, that assumption will limit the report's readership and ability to be widely accepted. This suggestion does not disqualify the report from being approved, but it would be worth the effort to make these changes.

James Collins, Ph.D., a member of the Gene Drives WG, said that in early days of research with genetically modified organisms, there was a struggle with understanding the relationship between genetically engineered organisms and their impact on the environment. Between the WG's report and the NASEM report, the field has a better understanding of this relationship, and there is greater willingness on the part of the community to engage on environmental and molecular biology issues. The WG and NASEM reports also highlight that the social sciences can be used to think about the ethical and policy issues associated with the development and release of genetically engineered organisms. This report is the next important step in the shaping the gene drive research community and its engagement with these issues.

Dr. Cho said that the report's glossary with definitions was very useful. She asked whether the issue of responsibility for potential damages associated with gene drive studies funded by NIH was addressed in the report. This issue would be analogous to injuries to clinical trial participants. Dr. Adelman said that the WG did discuss how to address remediation or restoration of the site and considered that ensuring an understanding of the potential risks is part of the risk/benefit assessment plan and the community engagement plan. The research team needs to clearly define the potential consequences of the trial, and these risks must be accepted by the communities and the regulators. The WG did not come to a specific resolution of who would be responsible to address any such outcomes incurred during gene drive research, which is different than any other research trial. Dr. Oye said that the WG did not consider the liability frame, definition of damages, monetization of damages, and who is responsible for paying for these damages. Liability is an important issue that has not been well defined by the gene drive and technology research community, unlike clinical trial research. Dr. Cho said that this is an issue that should be considered, if not for this report, then by the NExTRAC in future discussions about other technologies.

In response to Dr. Cho's comment, Dr. D. Lee said that the WG did find that some of the regulatory processes in gene drive research were analogous to processes in clinical trial settings. Similar to informed consent for participation in a clinical trial, the community, regulators, and the research team should all be aware of and agree to the potential risks resulting from the gene drive trial before the research begins. Jason Delborne, Ph.D., a

member of the Gene Drives WG, said that the WG discussed how although the analogy to informed consent by individuals in a clinical trial is appealing, it does not translate well to community-level processes. The report does not lay out a process that would be applicable in all contexts, such as community consent. One of the strengths of the report is the emphasis on experimentation with stakeholder and community engagement to identify which approaches work best. Working with communities should not involve a license contract, such as informed consent, but something that is more community-level and collective.

Dr. Ossorio agreed that individual informed consents and community agreements are not the same and would not be treated the same way from a legal standpoint. A community's agreement to host a gene drive field trial would not ethically or legally equate to individual informed consent for being exposed to the experimental gene drive; nor would community agreement provide a liability waiver from any individual who experienced harm, such as property damage or adverse health outcomes, from the trial.

There are institutions that have broad liability insurance that covers any harm to humans caused during research. NIH could consider tracking the type of insurances that are carried by funded institutions and whether it covers harm during a research trial. Dr. Cho agreed that the informed consent model would not fit with gene drive field research. The stakeholder engagement process should look beyond liabilities and payment for damages. The engagement process should involve a public discussion, which would highlight NIH as a trustworthy organization that funds this research and will have open discussion about responsibility, even if taking full financial responsibility for these damages up front is not possible.

Lorraine M. Albritton, Ph.D., said that after this discussion about community and stakeholder engagement, adopting Dr. Leshner's suggestion to make the introduction of the report more generalized and lay friendly is essential. This section of the report could be referenced in the community engagement process. Although the report includes a glossary, the definitions are still somewhat technical. There are science writers at NIH who could paraphrase these definitions to make them more lay-friendly and include the revised definitions in the proposed, updated introduction. Dr. Adelman agreed that these suggestions for updating the earlier part of the report, including some lay-friendly definitions, would be very feasible.

Dr. Adelman moved to approve the Gene Drives in Biomedical Research Working Group report with modifications to the executive summary to include nontechnical definitions about gene drives technologies and additional information in the stakeholder engagement section about NIH's and the research team's responsibilities related to field research.

Dr. Oye seconded the motion. Dr. Tucker called the roll.

Vote: NExTRAC members voted to approve the draft document with the edits described.

CHARGE TO NExTRAC: DATA SCIENCE AND EMERGING TECHNOLOGIES
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH

On behalf of Dr. Francis Collins, Dr. Tabak presented a new charge for the NExTRAC to help NIH proactively address the ever-changing landscape of science and technology. NExTRAC's first charge was to orient the committee's efforts by developing a framework to guide deliberations and to assist NIH with identifying emerging biotechnologies and their applications that may have important scientific, safety, and/or ethical considerations. The result of this effort was NExTRAC's first report, the Report to Establish a NExTRAC Framework, a valuable resource that describes effective approaches for horizon scanning and highlighting the value and importance of public deliberation. The guiding principles of this report helped NIH develop this new charge.

NIH is fully invested in engaging its many and diverse stakeholders, and the NExTRAC's sense that engagement serves many purposes aligns with NIH's viewpoint. These engagement efforts can include broadening the frame of public debate related to emerging biotechnologies, increasing the transparency of public policy decisions, and promoting greater public awareness and engagement, particularly in circumstances where historically there have been issues of exclusion, distrust, or lack of transparency between government institutions and the public. These efforts are becoming increasingly valuable for considering implications of emerging technologies for individuals and broader society.

NIH's duty is to assess the scientific landscape to ensure research moves forward responsibly by engaging stakeholders. Rapid innovations in technology, such as digital health technologies, neural recordings, and high-throughput omics, are enabling researchers to pursue scientific studies that were previously unimaginable. The data generated through these technologies are increasingly becoming accessible through data sharing. Taken together, studies can now routinely combine, analyze, and visualize multidimensional datasets collected across research and non-research platforms, which is transforming how science is conducted and providing unprecedented insight into human health. Although they will provide immense benefit to understanding human health, these approaches raise questions about privacy, lack of control of certain data types, and issues around consent for use of data. One example of this complex issue is data collected from sensor-enabled smartphones, wearables, and smart speakers. If researchers partner with companies that collect these data, there are questions around who owns the data, who governs how the data are shared, how to accelerate research while maintaining participant privacy, obtaining participant consent for further data collection and analyses, and how data fidelity is ensured. Privacy and autonomy concerns associated with whole genome sequencing of individuals is another example.

To address these issues, NIH seeks to understand how technological advances can catalyze research and anticipate potential implications for the research participants, their families, the populations they represent, and the nation's investment in science. The NExTRAC should convene a working group to address its next charge:

1. Define and characterize the types of research questions that require increasing granularity and aggregation of data about individuals that are likely to be addressed through emerging technologies. The working group should consider (but not limit the scope to):
    - Goals of such research studies and how they advance the NIH mission;
    - Emerging technologies that may generate potentially sensitive datasets;
    - Data types generated and their sources (e.g., digital health devices, electronic health record platforms), with an emphasis on exploring new data types or unique sources; and
    - Data science platforms and tools that facilitate data access, combination, and analysis (e.g., artificial intelligence, cloud computing).

2. For those questions/technologies, consult with stakeholders to discuss and assess the value of and potential implications for individuals, groups (e.g., populations, regions), and society. The working group should consider (but not limit the scope to):
    - Attitudes and perspectives about sharing participant data to advance biomedical research, specifically through the lens of balancing research risk (e.g., privacy, autonomy) with research deliverables; and
    - How these perspectives may evolve depending on the context of who is to benefit or assume risk, whether it be at the individual level, through the community, or in terms of broader society's expectations for public health advancement.

NIH would like to establish a working group of NExTRAC members and *ad hoc* members who have subject matter expertise this summer. The working group should engage with a wide range of stakeholders, including research participants, patient groups, ethicists, privacy experts, data scientists, technology developers across sectors, and public health officials. The working group will meet to discuss these topics and engage with stakeholders to consider attitudes and perspectives about sharing participant data to advance biomedical research, specifically through the lens of balancing the risks (e.g., privacy, autonomy) with the benefits (e.g., returning value to participants), and how those perspectives may evolve depending on context (e.g., who will benefit, who will assume risk). The working group should also consider the deliberative process that was outlined in the Report to Establish a NExTRAC Framework and understand the broader societal expectations for public health advancement. The goal is for the working group to present a draft report to the full committee with its findings by late Spring 2023.

General Discussion

Dr. Whitley said that there are many potential benefits from addressing these questions, such as data warehouses and how that influences the design of clinical trials. Dr. Tabak agreed and said that data warehouses are also not constructed in a uniform way.

Dr. Oye asked whether the working group would have to determine how these issues are being addressed in other countries. Dr. Tabak said that there could be some important information gained from this type of comparison, and NIH could decide whether to accept or reject any of those perspectives. Dr. Jorgenson said that this is an interesting

issue, and the working group can discuss when determining the scope of their work and what will be most useful.

Dr. Albritton said that there is a prevailing issue of data from devices being automatically synced and stored by companies, often without people realizing it. Similarly, there is the issue of researchers using specific devices in their research study to collect data that is then synced and stored by the device company. In response to Dr. Albritton's comment, Dr. Tabak said that data ownership between researchers and device companies is a fair question that could be considered by the working group. It will be important to engage industry stakeholders who can discuss this issue with the working group.

Dr. Leshner asked about the emphasis on increased granularity in the charge. Dr. Tabak said that issues surrounding privacy increase as more data are collected. This is especially true in instances where data is collected from multiple sources and aggregated. Dr. Jorgenson added that aggregate data collection is an important facet of personalized medicine, since researchers want to understand a participant's health in the context of their location or lifestyle. There are privacy issues that have not been considered with this level of granularity, so the working group can think about what precautions need to be established as more data types are captured. Dr. Tabak said that although many members of the NExTRAC have expertise in artificial intelligence and machine learning, the working group should talk with leaders in these fields to inform their recommendations.

Dr. Ossorio asked about current NIH research initiatives or funded research that involves aggregated datasets for health-related research. Dr. Tabak said that aggregate datasets are used in cardiovascular, neurological, and health inequity research. Some fields are more sensitive to privacy issues related to aggregate data collection compared to others, so the working group can help NIH frame its thinking for all fields of research.

ADJOURNMENT

Dr. Whitley thanked the participants for their useful contributions. The meeting was adjourned at 2:57 p.m.

Date: September 23, 2021

Jessica M. Tucker -S
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Jessica Tucker, Ph.D.
NExTRAC Executive Secretary

I hereby acknowledge that, to the best of my knowledge, the foregoing Minutes and the following Attachments are accurate and complete.

This Minutes document will be considered formally by NExTRAC; any corrections or notations will be incorporated into the Minutes.

Date: September 23, 2021

Richard Whitley
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Richard Whitley, M.D.
Chair, Novel and Exceptional Technology and Research Advisory Committee

ACRONYMS AND ABBREVIATIONS

BSO	biosafety officer
IBC	institutional biosafety committee
NASEM	National Academies of Sciences, Engineering, and Medicine
NIH	National Institutes of Health
NExTRAC	Novel and Exceptional Technology and Research Advisory Committee
SME	subject matter expert

ATTACHMENT I: NOVEL AND EXCEPTIONAL TECHNOLOGY AND RESEARCH ADVISORY COMMITTEE ROSTER

Chair

WHITLEY, Richard, MD
Distinguished Professor
Director, Division of Pediatric Infectious Diseases
Loeb Eminent Scholar Chair in Pediatrics
Vice Chair for Research, UAB Pediatrics
Associate Director, Drug Discovery and Development, Comprehensive Cancer Center
Division of Pediatric Infectious Disease
School of Medicine
University of Alabama at Birmingham
Birmingham, AL 35233

Members

ADELMAN, Zach N., PhD
Professor and Presidential Impact Fellow
Department of Entomology
Texas A&M University
College Station, TX 77843

ALBRITTON, Lorraine M., PhD
Professor Emeritus
Department of Microbiology, Immunology, and Biochemistry
College of Medicine
The University of Tennessee Health Science Center
Memphis, TN 38163

BLOSS, Cinnamon, PhD
Professor
Herbert Wertheim School of Public Health and Human Longevity Science
University of California, San Diego
La Jolla, CA 92093

BORIS-LAWRIE, Kathleen, PhD
Professor
Department of Veterinary and Biomedical Sciences
University of Minnesota
Saint Paul, MN 55108

CHO, Mildred, PhD
Professor, Departments of Pediatrics and Medicine
Associate Director
Stanford Center for Biomedical Ethics
Stanford University School of Medicine
Stanford, CA 94305

DZIRASA, Kafui, MD, PhD
Associate Professor of Psychiatry and Behavioral Sciences
K. Ranga Rama Krishnan Endowed Associate Professor
Assistant Professor of Biomedical Engineering
Associate Professor in Neurobiology
Assistant Professor in Neurosurgery
Investigator in the Duke Institute for Brain Sciences
Duke University Medical Center
Durham, NC 27710

GRONVALL, Gigi Kwik, PhD
Associate Professor
Department of Environmental Health and Engineering
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD 21202

LEE, Benhur, MD
Professor
Department of Microbiology
Ward-Coleman Chair in Microbiology
Icahn School of Medicine at Mount Sinai
New York, NY 10029

LEE, Dean A., MD, PhD
Professor of Hematology, Oncology and Bone Marrow Transplantation
DiMarco Family Endowed Chair in Cell Based Therapy
Director, Cellular Therapy and Cancer Immunology Program
Nationwide Children's Hospital

The Ohio State University
Columbus, OH 43205

LESHNER, Alan I., PhD
Chief Executive Officer, Emeritus
American Association for the Advancement of Science
Potomac, MD 20854

LEWIS-HALL, Freda C., MD, DFAPA
Former Executive Vice President
Pfizer Inc.
New York, NY 10017

MCCARTY, Douglas, PhD
Senior Director, Vector Development
Pfizer Rare Disease Research Unit
Morrisville, NC 27560

OSSORIO, Pilar N., PhD, JD
Professor of Law and Bioethics
University of Wisconsin
Madison, WI 53706

OYE, Kenneth, PhD
Professor, Political Science and Data, Systems and Society
Director, Program on Emerging Technologies
Center for International Studies
Massachusetts Institute of Technology
Cambridge, Massachusetts 02139

PORTEUS, Matthew, MD, PhD
Professor of Pediatrics (Pediatric Stem Cell Transplantation)
Department of Pediatrics
Stanford Medical School
Stanford University
Stanford, CA 94305

RILEY, Margaret F., JD
Professor, School of Law
Professor of Public Health Science
School of Medicine
Professor of Public Policy
Batten School of Leadership and Public Policy
University of Virginia
Charlottesville VA 22903

THIBOLDEAUX, Kim D.
Chief Executive Officer
Cancer Support Community
Washington, DC 20005

TURNER, Leigh, PhD
Associate Professor
Center for Bioethics
School of Public Health
College of Pharmacy
University of Minnesota
Minneapolis, MN 55455

ATTACHMENT II: GENE DRIVES IN BIOMEDICAL RESEARCH WORKING GROUP ROSTER

Co-Chairs

ADELMAN, Zach N., PhD
Professor and Presidential Impact Fellow
Department of Entomology
Texas A&M University
College Station, TX 77843

BLOSS, Cinnamon, PhD
Professor
Herbert Wertheim School of Public Health and Human Longevity Science
University of California, San Diego
La Jolla, CA 92093

Members

BORIS-LAWRIE, Kathleen, PhD
Professor
Department of Veterinary & Biomedical Sciences
University of Minnesota
Saint Paul, MN 55108

LEE, Benhur, MD
Professor, Department of Microbiology
Ward-Coleman Chair in Microbiology
Icahn School of Medicine at Mount Sinai
New York, NY 10029

LEE, Dean A., MD, PhD
Professor of Hematology, Oncology and Bone Marrow Transplantation
DiMarco Family Endowed Chair in Cell Based Therapy
Director, Cellular Therapy and Cancer Immunology Program
Nationwide Children's Hospital
The Ohio State University
Columbus, OH 43205

OYE, Kenneth, PhD
Professor, Political Science and Data, Systems and Society
Director, Program on Emerging Technologies
Center for International Studies
Massachusetts Institute of Technology
Cambridge, Massachusetts 02139

PORTEUS, Matthew, MD, PhD
Professor of Pediatrics (Pediatric Stem Cell
Transplantation)
Department of Pediatrics
Stanford Medical School
Stanford University
Stanford, CA 94305

Ad Hoc Members

Collins, James, P., PhD
Virginia M. Ullman Professor of Natural History and the Environment
School of Life Sciences
Arizona State University
Tempe, AZ 85287

Delborne, Jason, PhD
Professor of Science, Policy, and Society
Department of Forestry and Environmental Resources
Genetic Engineering and Society Center
North Carolina State University
Raleigh, NC 27695

Hall, B. Fenton, MD, PhD
Chief
Parasitology and International Programs Branch
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Rockville, MD 20852

Heitman, Elizabeth, PhD
Professor
Program in Ethics in Science and Medicine
University of Texas Southwestern Center
Dallas, Medical TX 75390