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NATIONAL INSTITUTES OF HEALTH
Novel and Exceptional Technology and
Research Advisory Committee (NExTRAC)



Virtual Meeting
November 9-10, 2020 (All times EST)

AGENDA – Day 1

10:00 AM – 10:15 AM Welcome
Carrie Wolinetz, PhD and Richard Whitley, MD

NEXTRAC WORKSHOP
GENE DRIVES: BIOSAFETY GUIDANCE AND CONDITIONS FOR FIELD RELEASE RESEARCH

SESSION I: GENE DRIVES IN BIOMEDICAL RESEARCH

The charge to the Gene Drives in Biomedical Research Working Group will be presented, along with an overview of gene drive technologies and their applications.

10:15 AM – 10:30 AM [Overview of Charge to the Gene Drives in Biomedical Research Working Group](#)

Gene Drives Working Group Co-Chairs:
Zach Adelman, PhD and Cinnamon Bloss, PhD

10:30 AM – 11:00 AM [Overview of Gene Drive Technologies and Applications](#)
Anthony James, PhD

SESSION II: BIOSAFETY GUIDANCE FOR CONTAINED RESEARCH

Discuss existing landscape of biosafety guidance and examine what, if any, barriers exist for applying such guidance to contained gene drive research, and whether additional guidance would be useful.

11:00 AM – 12:30 PM Panel Discussion
Moderator: Zach Adelman, PhD

Panelists:

1. [Kathryn Harris, PhD RBP](#)
2. [Lyric Bartholomay, PhD](#)
3. [David Gillum, MS RBP](#)
4. [Ruth Müller, PhD](#)

- *Is current physical containment guidance adequate to address contained research with organisms containing gene drives?*
- *Would additional physical containment guidance for certain species*

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be useful?

- *Are existing general principles for biosafety risk assessment and management adequate for contained gene drive research? What additional guidance might be useful?*

12:30 PM – 1:30 PM

Break

SESSION III: SCIENCE OF BIOLOGICAL AND ENVIRONMENTAL RISK MITIGATION APPROACHES

Discuss current scientific approaches, application to different species, and knowledge gaps for biological and environmental risk mitigation for gene drives, whether for contained research or to mitigate risks in field release.

1:30 PM – 3:00 PM

Panel Discussion

Moderator: Kathleen Boris-Lawrie, PhD

Panelists:

1. [Antoinette Piaggio, PhD](#)
2. [Omar Akbari, PhD](#)
3. [Fred Gould, PhD](#)
4. [Philipp Messer, PhD](#)

- *What are current “state of the art” strategies for biological risk mitigation?*
- *What are current environmental risk mitigation approaches for different species?*
- *Are adequate biological and environmental strategies available for risk mitigation? What additional knowledge would be useful?*

3:00 PM – 3:15 PM

Break

SESSION IV: STRATEGIES FOR ASSESSING RISK AND BENEFIT FOR GENE DRIVE FIELD RELEASE

Identify strategies that exist for risk and benefit assessments for gene drive field release, including strengths and weaknesses.

3:15 PM – 4:45 PM

Panel Discussion

Moderator: Jason Delborne, PhD

Panelists:

1. Sarah Hartley, PhD
2. [Keith Hayes, PhD](#)
3. [Raul Medina, PhD](#)
4. Bradley White, PhD

- *What strategies exist for risk and benefit assessments for gene drives or research with similar issues? What additional knowledge would be useful for conducting such assessments?*

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- *What challenges exist for conducting environmental risk assessments for gene drive field release?*
- *What broader domains beyond environmental considerations should be considered when conducting a risk and benefit assessment for field release of gene drives?*

4:45 PM – 5:15 PM

Wrap-Up Day 1

Richard Whitley, MD

5:15 PM

Adjournment

AGENDA – DAY 2

10:00 AM – 10:15 AM

Welcome Day 2

Richard Whitley, MD

SESSION V: US AND INTERNATIONAL POLICY DISCUSSIONS AND OVERSIGHT FRAMEWORKS FOR RESEARCH INVOLVING GENE DRIVE FIELD RELEASE

Provide overview of some recent gene drives efforts, including findings of NASEM and other groups, and oversight frameworks for field release research.

10:15 AM – 11:45 AM

Panel Discussion

Moderator: James Collins, PhD

Panelists:

1. [Elizabeth Heitman, PhD](#)
2. [Stephanie James, PhD](#)
3. [Wadzanayi Mandivenyi, MS](#)
4. [Todd Kuiken, PhD](#)
5. Lisa Knolhoff, PhD

- *How has the state of conversation and knowledge (in terms of science and the regulatory framework) advanced since the time of the 2016 NASEM report?*
- *What knowledge, regulatory, and infrastructure gaps in the area of field release research still exist, since the 2016 report? What advances have been made?*
- *What is the status of oversight for research involving field release of gene drives, domestically and internationally?*

11:45 AM – 12:45 PM

Break

SESSION VI: PUBLIC ENGAGEMENT- INPUT FROM LOCAL COMMUNITIES

Hear perspectives from public health professionals and communicators from communities impacted by relevant diseases and releases of genetically modified organisms.

12:45 PM – 2:00 PM

Panel Discussion

Moderator: Cinnamon Bloss, PhD

Panelists:

1. Beth Ranson
2. [Steve Mulligan](#)
3. Fredros Okumu, PhD

- *What are the considerations of a local public health authority or communicator in the testing/use of modified organisms for the purposes of protecting public health?*
- *In your experiences, how have decisions been made at the local level regarding whether or not to test/use modified organisms?*
- *In your experiences, what were the primary concerns of relevant communities? What aspects of release of modified organisms had support of local communities?*

SESSION VII: STRATEGIES FOR STAKEHOLDER AND PUBLIC ENGAGEMENT

Discuss frameworks, considerations, and strategies for public engagement for gene drive research or research with similar issues/concerns.

2:00 PM – 3:30 PM

Panel Discussion

Moderator: Cinnamon Bloss, PhD

Panelists:

1. James Lavery, PhD
2. [Abdoulaye Diabaté, PhD](#)
3. [Thomas Dietz, PhD](#)
4. [Jennifer Kuzma, PhD](#)

- *What frameworks exist for public engagement for research that may involve similar issues/concerns as gene drives?*
- *What strategies have been used to consider appropriate locations for phased field release studies, carefully considering local community engagement? How effective have they been?*
- *What evidence can/should be presented to illustrate that engagement has been done appropriately?*

3:30 PM – 3:45 PM

Break

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SESSION VIII: DRAFT REPORT OF THE WORKING GROUP TO ESTABLISH A NEXTRAC FRAMEWORK

Working Group will present draft report for consideration and discussion by the full committee.

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| 3:45 PM – 4:00 PM | <u>Presentation of the Draft Report of the Working Group to Establish a NExTRAC Framework</u> |
| | Framework Working Group Co-Chairs: Margaret Riley, JD and Gigi Gronvall, PhD |
| 4:00 PM – 4:20 PM | Public Comments |
| 4:20 PM – 5:00 PM | NExTRAC Deliberation of the Draft Report of the Working Group to Establish a NExTRAC Framework |
| 5:00 PM – 5:15 PM | Wrap-Up Day 2 Richard Whitley, MD |
| 5:15 PM | Adjournment |