

Overview of Charge to the Gene Drives in Biomedical Research Working Group

Zach Adelman, PhD
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NExTRAC Meeting
November 9, 2020



The Gene Drives in Biomedical Research Working Group

Charge:

- Consider whether existing biosafety guidance is adequate for contained laboratory research utilizing gene drive technology
- Outline conditions (if any) under which NIH could consider supporting field release of gene drive-modified organisms



The Gene Drives in Biomedical Research Working Group

Provide advice on the following issues:

- **Given the diverse applications and species that may be used in gene drive research with different risks, is the current landscape of biosafety guidance adequate for contained research?**
- **What knowledge and conditions should be in place to help ensure that field release research of gene drive-modified organisms could be conducted safely and ethically?**



Working Group Roster

Co-Chairs

- ADELMAN, Zach N., PhD (Texas A&M University)
- BLOSS, Cinnamon, PhD (University of California, San Diego)

Members

- BORIS-LAWRIE, Kathleen, PhD (University of Minnesota)
- LEE, Benhur, MD (Icahn School of Medicine at Mount Sinai)
- LEE, Dean A., MD, PhD (The Ohio State University)
- PORTEUS, Matthew, MD, PhD (Stanford University)
- OYE, Kenneth, PhD (Massachusetts Institute of Technology)

Ad Hoc Members

- COLLINS, James, PhD (Arizona State University)
- DELBORNE, Jason, PhD (North Carolina State University)
- HALL, Lee, MD, PhD (National Institutes of Health)
- HEITMAN, Elizabeth, PhD (University of Texas Southwestern Medical Center)

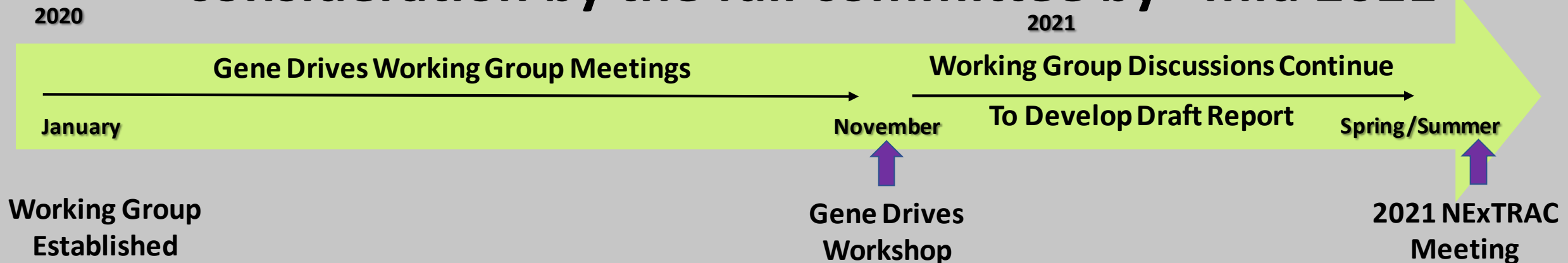


Working Group (WG) Activities

- **Met ~monthly, often with subject matter experts (SMEs)**
- **Topics discussed with WG member and SMEs include:**
 - Existing biosafety guidance for physical containment
 - Status of biological and environmental risk mitigation approaches
 - NASEM report and other relevant efforts and identification of knowledge gaps
 - Regulatory oversight of field release of gene drive research (Dr. Kuiken)
 - Strategies for field release risk assessment and risk mitigation (Dr. Hayes)
 - Strategies for public engagement regarding gene drives (Dr. Lavery)
- **Developed topics and discussion questions for this workshop to help inform deliberations**
 - These questions are critical to help the WG ultimately develop their draft report for NExTRAC consideration

Next Steps

- **WG will continue to meet and develop draft recommendations to address the charge**
 - **Workshop discussions will inform WG deliberations/draft report**
- **Anticipate a draft report will be ready for consideration by the full committee by ~mid 2021**



Meeting Agenda

Day 1 (November 9, 2020)

- **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.*

- **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.*

- **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.*

- **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.*

Meeting Agenda

Day 2 (November 10, 2020)

- **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.*
- **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.*
- **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.*
- **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.*

Questions and Comments

- To ask a question or contribute to the discussion, please click on the “Raise Hand” icon at the bottom of the screen (click Participants icon)
- Please remember to unmute/mute your microphone (far left of your screen) when you want to speak/are finished

