

# Charge to the NExTRAC

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NExTRAC Meeting  
December 6, 2019

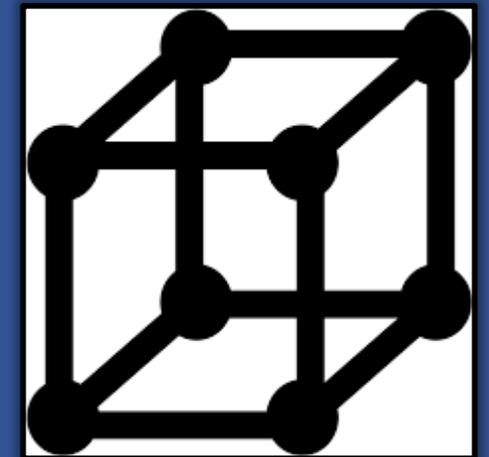


# NExTRAC – Moving Forward

- NIH will convene two Working Groups of the NExTRAC to:
  - Establish a framework for a thoughtful approach to assess the potential issues associated with new biotechnologies and their applications
  - Assist in the development of a path forward for biomedical research involving gene drive-modified organisms

# Working Group to Establish a NExTRAC Framework

- Charge
  - Describe effective approaches for prospectively identifying emerging biotechnologies or specific applications with reasonable potential to have important scientific, safety, or ethical considerations
  - Conceptualize a framework for NExTRAC deliberation of issues surrounding emerging biotechnologies and applications, including:
    - Guiding principles for when an emerging biotechnology or its applications would significantly benefit from further public deliberation
    - A potential process by which the NExTRAC will consider or evaluate any given emerging biotechnology or its applications



# Working Group to Establish a NExTRAC Framework

- Consider:
  - Applications of emerging biotechnologies, given that the way the biotechnology is used often generates the safety, social, or ethical issues
  - Effective horizon scanning approaches; focusing on biotechnologies and applications that are reasonably anticipated vs. hypothetical



# Working Group to Establish a NExTRAC Framework

- Consider:
  - Cross-cutting issues that may be relevant for a variety of emerging biotechnologies and applications
  - Strategies for committee engagement and soliciting feedback



# 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?



# Anticipated Next Steps

- **January 2020:** Two Working Groups Established
- **Summer/Fall 2020**
  - Working Group to establish NExTRAC Framework presents draft report to NExTRAC
  - Gene Drives Workshop
- **Fall/Winter 2020/21**
  - Working Group on Gene Drives in Biomedical Research presents draft report to NExTRAC

