Biosafety Modernization Initiative

Listening Session

2025

BLUF: Science and technology has evolved; Biosafety policy and oversight need to keep pace

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules have served as the foundation for USG wide practices for 40+ years
- Emerging biosafety risks are increasingly technology agnostic
- USG needs a risk-based, coordinated policy and oversight system

NIH is poised to usher in the next 40+ years of safe research!

TODAY'S GOAL: WE NEED YOUR FEEDBACK!

- To achieve the goal of **calibrating oversight to risk:**

- **SCOPE** of policy must address potential risks beyond recombinant or synthetic nucleic acid technologies
- **RED TAPE** can be reduced for certain low-risk recombinant technologies that may no longer warrant the oversight once deemed necessary

- NOTE: All draft options presented are a starting point; we welcome input on additional options that you think should be considered

NIH Guidelines for 21st Century Biosafety

CURRENT SCOPE

- **Technique-based**, focus on recombinant and synthetic nucleic acid molecules
- Includes plants, microbes for environmental remediation, vaccine/gene therapy
- Some covered research under purview of other agency authorities (e.g., USDA, FDA)

POTENTIAL FUTURE SCOPE

- **Risk-based**, expand to include wild type agents and other possible biohazards
- Focus on NIH-relevant contained **biomedical** laboratory research
- Resources allocated for oversight are titrated to risk posed

FOR INPUT: Scope Options

The option, or other option not considered here, that best achieves the goal of modernizing and strengthening biosafety policy to appropriately calibrate oversight to risk.

NIH Guidelines Plus

Current NIH biosafety policy scope of recombinant or synthetic nucleic acids PLUS research with other biohazards to possibly include wild-type agents, proteins (e.g., toxins, prions), others.

Harmonized with BMBL

Research involving infectious microorganisms (based on risk groups) and hazardous biological materials.

Life Sciences Research

Broad category accompanied by criteria, and additional guidance about what requires institutional or NIH oversight.

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FOR INPUT: Research requiring less oversight

Types of research that may require less local or NIH oversight based on accrued safety data or oversight by other federal authorities. Examples COULD include:

- Non-biomedical research with plants, agricultural animals, or certain microbes under the purview of other federal agencies such as USDA or EPA
- Clinical research under the purview of the FDA
- Low risk research (e.g., RG1 agents, some transgenic organisms, some expression plasmids)

Thoughts on proposed options?

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Individual opinions welcome on any aspect of this proposal. It would be most helpful in informing the policy to hear individuals' thoughts about:

- The appropriate scope for NIH's new biosafety policy;
- The types of research that should require less local or NIH oversight based on accrued safety data or oversight by other federal authorities;
- The options, or other options not considered here, that best achieve the goal of modernizing and strengthening biosafety policy to appropriately calibrate oversight to risk.