



UMBC

2024 Changes to the NIH Guidelines

The NIH changed the guidelines in an effort to harmonize with the CDC BMBL (*Biosafety in Microbiological and Biomedical Laboratories*) as well as implement recommendations from NExTRAC (Novel and Exceptional Technology Research Advisory Committee report, *Gene Drives in Biomedical Research*). The new guidelines will also begin to reference guides found in the BMBL such as the arthropod containment guide, etc.). An overview of the changes to the NIH Guidelines is listed below:

- Gene Drive Modified Organisms (GDMOs)
 - Added Definition of “gene drive” to Section I-E-7
 - Section I-E-7. “Gene drive” is defined as a technology whereby a particular heritable element biases inheritance in its favor, resulting in the heritable element becoming more prevalent than predicted by Mendelian laws of inheritance in a population over successive generations.
 - GDMO research will be for contained settings only.
 - Added gene drive clauses to sections and appendices throughout the document, specifically stating that this research will require a minimum of BL-2 containment.
 - Not currently included in the guidelines but the NIH published a quick reference sheet for research involving GDMOs that can be found here (<https://osp.od.nih.gov/wp-content/uploads/2024/03/gdmo-reference.pdf>)
- Additional considerations for risk assessments
 - Added risk assessment information for the Gene Drive research
- Reclassification of materials/agents
 - Removing the term “Helper viruses” and are now using “Helper Systems”. This is seen throughout Section III-D
 - Reclassified WNV(West Nile Virus) and SLEV (Saint Louis Encephalitis Virus) as risk group 2 agents for consistency with containment guidance provided in the BMBL. (Appendix B-II-D)
- Added additional responsibilities for IBCs, BSOs, and PIs (all pertain to GDMOs)
 - BSO
 - A BSO must be appointed if the institution engages in recombinant or synthetic nucleic acid molecule research that involves GDMOs. (Section IV-B-1-c)
 - IBC
 - Ad hoc consultant with expertise in ecological impacts should be used for review of research with GDMOs. An ad hoc consultant may be used and does not need to be local to the institution. The PI and IBC are responsible for assessing the impact on ecosystems as a result of GDMO research.