

IBC Research Exemption Form

Under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, Middle Tennessee State University is directed to establish an Institutional Biosafety Committee (IBC) to monitor the construction and handling of:

- recombinant nucleic acid molecules
- synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules
- cells, organisms, and viruses containing recombinant or synthetic nucleic acid molecules

The guidelines clearly state that if an institution has NIH funding for research involving recombinant or synthetic nucleic acids, all other research in this area must comply with the *NIH Guidelines*. To ensure compliance, the IBC reviews protocols that describe the use and handling of recombinant/synthetic nucleic acids and works with investigators to ensure safety of the investigator and broader community. **However, some projects and experiments can be considered “Exempt” under the *NIH Guidelines* and do not require a detailed protocol.** This form aims to identify those who are doing exempt research under the *NIH Guidelines* so that those investigators are aware of what exempt means and their responsibilities as a researcher under the *NIH Guidelines*. Completion of this form provides important information to the IBC and Research Compliance Office so they may periodically survey and update the status of exempt investigators as the *NIH Guidelines* change.

Information on exempt experiments as defined by the *NIH Guidelines* as well as summaries of non-exempt research categories are included as attachments to this form.

If you know that your lab performs experiments that need to be monitored by the IBC, a protocol will need to be submitted through Cayuse.

If you have any questions, please contact Emily Anne Badger at compliance@mtsu.edu

PI Information

Name:

Department:

Email:

Project Title:

Laboratory Space(s):

Exemption Category:

Based on the *NIH Guidelines* for exempt experiments outlined in Section F, the research described below falls into the following category and is exempt:

Experiment Description:

Describe the experiments in this project that involve recombinant or synthetic nucleic acid molecules, including all associated organisms, including genus and species.

Biosafety:

Please describe the general biosafety plan for your project or experiment. If experiments are exempt under the *NIH Guidelines*, all investigators are still required to comply with the institution's biosafety guidelines. Please contact Environmental Health & Safety with questions regarding the appropriate safety measures for your project(s).

Your signature indicates you have reviewed the NIH Guidelines and are aware of the responsibilities as a PI under these guidelines. By signing below, you agree to comply with the required safety standards and ensure that all researchers will have documented training on the above standards.

Signature: _____ Date: _____

Submit this form to Research Compliance (compliance@mtsu.edu) & the IBC Chair (april.weissmiller@mtsu.edu)

For IBC Use:

Reviewed By:

Exemption Confirmed

Exemption Pending, questions attached

Exemption Denied, protocol needed per Section

Signature: _____ Date: _____

For IBC Office Use- IBC Exemption #

Experiments that are Exempt under NIH Guidelines:

- For synthetic nucleic acids, those that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section. (See Section III-F-1)
- Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. (See Section III-F-2)
- Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. (See Section III-F-3)
- Those that consist entirely of nucleic acids from a prokaryotic host or when transferred to another host by well-established physiological means. (See Section III-F-4)
- Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species). (See Section III-F-5) Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. (See Section III-F-6)
- Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. (See Section III-F-7)
- Those that do not present a significant risk to health or the environment as determined by the NIH Director, with advice from the RAC and public comment. (See Section III-F-8)
 - Appendix C of the *NIH Guidelines* details the specific classes of experiments that may be exempt under Section III-F-8

For more information, please review Section III-F, starting on page 24

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Non-Exempt Experiments Summarized from the NIH Guidelines

Section III-A: Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval Before Initiation

- The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally

Section III-B: Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation

- The deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 or less than 100 nanograms per kilogram body weight)

Section III-C: Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation

- The deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic molecules, into one (1) or more human research participants

Section III-D: Experiments that Require Institutional Biosafety Committee Approval Before Initiation

- Using risk group 2, 3, 4 or Restricted agents as host-vector systems
- DNA from risk group 2, 3, 4 or restricted agents being cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems
- The use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems
- Involve whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germline (transgenic animals) and require BSL2 or higher containment
- Viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals
- Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., responses to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules
- Involve research or production of more than 10 liters of cultures of viable organisms containing recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom into germline (transgenic animals) and require no higher than BSL1 containment
- Involve influenza viruses generated by recombinant or synthetic nucleic acid molecules (e.g., generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations)

Section III-E: Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation

- The formation of recombinant or synthetic nucleic acid molecules containing not more than 2/3 of the genome of any eukaryotic virus
- Experiments involving nucleic acid molecules-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecules-modified organisms associated with whole plants
- Experiments involving generations of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ line (transgenic rodents) and require no higher than BSL1 containment

If you believe your research may fall into one of the above categories, please read the applicable sections of the NIH Guidelines for more details:

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf