

# Form to determine the IBC exempt status of a Project

## Purpose

The National Institutes of Health mandate that James Madison University 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
- naturally hazardous biological agents

Projects that involve any of the above must notify the *Institutional Biosafety Committee or IBC*, which is charged with monitoring investigators to protect all stakeholders. 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 NIH guidelines and do not require a detailed protocol.** This form aims to identify those who are doing exempt research under NIH guidelines so that those investigators are aware of what exempt means and reduce the annual paperwork burden on the investigators and IBC. The IBC may periodically survey and update the status of exempt investigators as NIH guidelines change.

If you know that your lab performs experiments that need to be monitored by the IBC, please contact ORI to get the forms for IBC oversight. If you do not know, use this form and the IBC will help you determine your status. Experiments that are exempt are summarized on the back page of this form. Please type the information in the boxes below.

## PI information

Name:

Department:

Laboratory space(s):

Email:

## Experiment description

In 500 words or less, describe any experiments that involve recombinant or synthetic nucleic acid molecules. Please be specific about the associated organisms, including genus and species. Please also note the building and room(s) where the work is being performed. Finally, the IBC is composed of members of the JMU faculty, staff, and the broader community around JMU, so the language of the summary should be dear to all members of the IBC.

**Biosafety**

Please describe the general biosafety plan for your project or experiment. If experiments are exempt under NIH guidelines, all investigators are still required to comply with general BSL-1 guidelines from NIH. To ensure the PI understands these guidelines a BSL-1 self-check list must be submitted before final exemption approval.

*Signature:*

*Date:*

Your signature as a PI indicates you will comply with the required safety standards and ensure that all researchers will have documented training on the above standards.

Submit this form to [researchintegrity@jmu.edu](mailto:researchintegrity@jmu.edu)

*Received by IBC Chair:*

*Date:*

## Experiments that are Exempt under NIH guidelines

Detail directly from the NIH can be found [here](#).

Experiments that are exempt:

- 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, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), 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
- Certain recombinant or synthetic nucleic acid molecules that contain less than one-half of any eukaryotic viral genome when propagated and maintained in cells in tissue culture [Appendix C-I – see question 8 below for more information on the limits of this exemption]
- *Escherichia coli* K-12 host-vector systems [Appendix C-II]
- *Saccharomyces cerevisiae* or *Saccharomyces uvarum* host-vector systems [Appendix C-III]
- *Kluyveromyces lactis* host-vector Systems [Appendix C-IV]
- *Bacillus subtilis* or *Bacillus licheniformis* host-vector systems [Appendix C-V]
- Extrachromosomal elements of gram positive organisms [see specific list of organisms in Appendix C-VI]
- The purchase or transfer of transgenic rodents [Appendix C-VII]
- Generation of certain BL1 Transgenic Rodents via Breeding [Appendix C-VIII]