Applicable NIH Guidelines Sections

*For Classification of Experiments*

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| Use this form to identify the sections and subparts of the [*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules*](http://osp.od.nih.gov/biotechnology/nih-guidelines/) applicable to the experiments proposed in your IBC application. Enter the selected sections in the Kuali IBC application as instructed.  A more detailed description of the classifications under the NIH Guidelines for rDNA (including sections and subparts) is found here: *[https://osp.od.nih.gov/wp-content/uploads/NIH\_Guidelines.pdf]*  Additional web pages for information on classifying experiments involving whole animals:  NIH Classification Table for Animal experiments: [*https://osp.od.nih.gov/wp-content/uploads/Animal\_Activities\_Table.pdf*](https://osp.od.nih.gov/wp-content/uploads/Animal_Activities_Table.pdf)  NIH FAQs: [*http://osp.od.nih.gov/biotechnology/faqs-on-genetically-modified-transgenic-animals-and-the-use-of-recombinant-or-synthetic-nucleic-acid-molecules-in-animals/*](http://osp.od.nih.gov/biotechnology/faqs-on-genetically-modified-transgenic-animals-and-the-use-of-recombinant-or-synthetic-nucleic-acid-molecules-in-animals/)  *Projects under Section III A, B and C require additional approvals from NIH prior to starting.* |

**PROTOCOL NUMBER:**

| Check applicable section(s) | Check applicable subpart | NIH Guidelines Sections | |
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|  |  | Section III-A-1 | The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V-B, Footnotes and References of Sections I-IV), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will be reviewed by the RAC. |
|  |  | Section III-B-1  or B-2 | Experiments involving the cloning of toxin molecules with LD50 of less than 100 ng/kg of body weight |
|  |  | Section III-C-1 | Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants. |
| also check subpart | a b c d | Section III-D-1 | Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or restricted agents as host-vector systems. |
| also check subpart | a b | Section III-D-2 | Experiments in which DNA from Risk Group 2, Risk Group 3, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems. |
| also check subpart | a b c d e | Section III-D-3 | Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems. |
| also check subpart | a b c c1 c2 | Section III-D-4 | Experiments involving whole animals that cannot be done at BSL-1 |
| also check subpart | a b c d | Section III-D-5 | Experiments involving whole plants; Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g. response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules that cannot be done at BSL-1. |
|  |  | Section III-D-6 | Experiments involving more than 10 liters of culture. *(Also refer to Appendix K)* |
| also check subpart | a b c d | Section III-D-7 | Experiments involving Influenza viruses. |
|  |  | Section III-E-1 | Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any eukaryotic virus (BSL-1 experiments only). |
| also check subpart | a b b1 b2 b3 b4 b5 | Section III-E-2 | Experiments involving recombinant DNA-modified whole plants, and /or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-D, or III-F (BSL-1 experiments only). |
|  |  | Section III-E-3 | Experiments involving transgenic rodents modified by the stable introduction of recombinant or synthetic nucleic acid molecules into their genome, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). (BSL-1 experiments only). |
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| Section III-F categories requires IBC designated approval. IBC Full Committee Review is required if any part of this project falls under a specific exception or has other experiments falling under any of the above sections (III-A to E). | | | |
|  |  | Section III-F-1 | Experiments using synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell, (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of <100 ng/kg. |
|  |  | Section III-F-2 | Recombinant/synthetic molecules are not in organisms, cells, or viruses, and that have not been modified or manipulated to make cellular membrane penetration possible. |
|  |  | Section III-F-3 | Recombinant/synthetic molecules that consist entirely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists in nature. |
|  |  | Section III-F-4 | Recombinant/synthetic molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids, or viruses when propagated only in that host (or closely related strain of the same species), or when transferred to another host by well-established physiological means. |
|  |  | Section III-F-5 | Recombinant/synthetic molecules that consist entirely of DNA from 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). |
|  |  | Section III-F-6 | 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. A list of such exchangers is prepared and periodically revised by the NIH Director and can be found in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. |
|  |  | Section III-F-7 | Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. |
| also check applicable appendix | | Section III-F-8 | Those exemptions as determined by the NIH Director to not present a significant risk to health or the environment are listed in the appendices below. Also check all categories that apply. *Refer to the* [*NIHGuidelines*](https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf) *for exceptions (e.g., use of DNA with Risk Group 3 or 4 or restricted organisms, etc)* |
|  |  | Appendix C-I | Recombinant or synthetic nucleic acid molecules in tissue culture. |
|  |  | Appendix C-II | Escherichia coli K-12 host-vector systems. |
|  |  | Appendix C-III | Saccharomyces host-vector systems. |
|  |  | Appendix C-IV | Kluyveromyces host-vector systems. |
|  |  | Appendix C-V | Bacillus subtilis or Bacillus licheniformis host-vector systems. |
|  |  | Appendix C-VI | Extrachromosomal elements of gram positive organisms. |
|  |  | Appendix C-VII | The purchase or transfer of transgenic rodents *(Subsequent use of these animals is also exempt providing the experimental protocol is BSL1 and does not involve the use of recombinant or synthetic nucleic acid molecules.)* |
|  |  | Appendix C-VIII | Generation of BL1 transgenic rodents via breeding. |