NIH Guidelines – Covered Experiments

**Instructions:**

1. *Enter the Kuali protocol number for the application.*

**PROTOCOL NUMBER:**

1. *Identify the appropriate NIH Guidelines Section(s) for the covered experiments:*
   1. *Select the type of experiment being reported: Ctrl + Click on one of the Table titles in section C; you will be directed to the corresponding table;*
   2. *In the table, check the appropriate checkbox(es) corresponding to the experiment being conducted;*
   3. *Return to the top of this document and repeat Steps B1-3, or scroll through the tables, to identify all applicable NIH Guidelines Sections.*
2. *Experiment Type Tables:*
   * [**Table1: Experiments involving non-viral host-vector systems**](#Table1)
   * [**Table 2: Experiments involving the use of viruses in tissue culture systems**](#Table2)
   * [**Table 3: Experiments using whole animals**](#Table3)
   * [**Table 4: Other experiments involving recombinant or synthetic nucleic acids (r/sNA)**](#Table4)
   * [**Table 5: Experiments requiring federal review & approval**](#Table5)
3. **Experiments involving non-viral host-vector systems**

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| --- | --- | --- |
| **Experiment** | **Standard Biosafety Level** | **Guidelines Section** |
| Experiments involving the introduction of **recombinant or synthetic nucleic acid (r/sNA)** molecules into [Risk Group 2 agents](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457095) | BSL2 | III-D-1-a |
| Experiments involving the introduction of r/sNA molecules into [Risk Group 3 agents](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457100) | BSL3 | III-D-1-b |
| Experiments involving the introduction of r/sNA molecules into [Risk Group 4 agents](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457105) | BSL4 | III-D-1-c |
| Experiments involving the introduction of r/sNA molecules into **restricted agents** | BSL set by NIH | III-D-1-d |
| Experiments involving the introduction of r/sNA from RG2, RG3, or RG4\* agents into **nonpathogenic prokaryotes or lower eukaryotes**. \**CAN demonstrate that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant* | BSL2 | III-D-2-a |
| Experiments involving the introduction of r/sNA from RG4\* agents transferred into **nonpathogenic prokaryotes or lower eukaryotes**. \**CANNOT demonstrate that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant* | BSL4 | III-D-2-a |
| Experiments in which r/sNA from **restricted agents** is transferred into **nonpathogenic prokaryotes or lower eukaryotes** | BSL set by NIH | III-D-2-b |
| Experiments using ***Escherichia coli* K-12** host-vector systems | BSL1 | III-F-8  Appx C-II |
| Experiments involving ***Saccharomyces cerevisiae*** or ***Saccharomyces uvarum*** host-vector systems | BSL1 | III-F-8  Appx C-III |
| Experiments involving ***Kluyveromyces lactis*** host-vector systems | BSL1 | III-F-8  Appx C-IV |
| Experiments involving ***Bacillus subtilis*** or ***Bacillus licheniformis*** host-vector Systems | BSL1 | III-F-8  Appx C-V |
| Experiments that don’t fall into any other category, e.g., experiments involving the introduction of RG1 r/sNA into RG1 organisms such as *E. coli* BL21, or non-viral RG1 or RG2 r/sNA used in tissue culture systems. | BSL1 | III-E |

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1. **Experiments involving the use of viruses in tissue culture systems**

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| **Experiment** | **Standard Biosafety Level** | **Section** |
| Experiments involving the use of infectious or defective [Risk Group 2 viruses](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457099) **in the presence of helper virus**  **Common Examples: Adenovirus, AAV, Epstein-Barr,** | BSL2 | III-D-3-a |
| Experiments involving the use of infectious or defective [Risk Group 3 viruses](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457104) **in the presence of helper virus** | BSL3 | III-D-3-b |
| Experiments involving the use of infectious or defective [Risk Group 4 viruses](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457109) **in the presence of helper virus** | BSL4 | III-D-3-c |
| Experiments involving the use of infectious or defective **restricted poxviruses** **in the presence of helper virus** | BSL set by NIH | III-D-3-d |
| Experiments involving the use of infectious or defective viruses **in the presence of helper virus which are not covered in Sections III-D-3-a through III-D-3-d** | BSL1 | III-D-3-e |
| Formation of r/sNA containing **no more than 2/3 of the genome of non-lentivirus, eukaryotic virus**; propagated and maintained in tissue culture **cells demonstrated to LACK helper virus** for the specific family of defective viruses being used | BSL1 | III-E-1 |
| Formation of r/sNA containing **no more than 2/3 of the genome of any Lentivirus**; propagated and maintained in tissue culture cells demonstrated to lack helper virus | BSL2 | III-E-1 |
| Formation of r/sNA containing **no more than 2/3 of the genome of any eukaryotic virus**; propagated and maintained in tissue culture **cells demonstrated to CONTAIN helper virus** for the specific family of defective viruses being used | BSL2, 3, or 4 | III-D-3 |

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1. **Experiments using whole animals**
   1. **Purchase, transfer, creation or propagation of transgenic animals**

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| **Experiment** | **Standard Biosafety Level** | **Section** |
| Purchase or transfer of **transgenic rodents** requiring BL1/BL1-N containment. Includes subsequent use of these animals provided no r/sNA/infectious material is used | BSL1/BSL1-N | III-F-8  Appx C-VII |
| Creation of **transgenic rodents** via breeding requiring BL1/BL1-N containment | BSL1/BSL1-N | III-F-8  Appx C-VIII |
| Creation of **transgenic rodents** in which the animal's genome has been altered by stable introduction of r/sNA molecules, or nucleic acids derived therefrom, into the germ-line | BSL1/BSL1-N | III-E-3-a |
| Creation of transgenic animals **other than rodents** by introduction of r/sNA from any source (except for greater than 2/3 of eukaryotic viral genome) into a non-human vertebrate or invertebrate organism requiring BL-1/BL1-N | BSL1/BSL1-N | III-D-4-a |
| Creation of transgenic animals **other than rodents** not covered by Section III-D-4-a | IBC sets BSL | III-D-4-b |
| Propagation of animals containing **viral vector sequences** not leading to transmissible infection | BSL1/BSL1-N | III-D-4-a |
| Purchase, transfer or creation of **transgenic animals** requiring BL2/BL2-N containment or higher | BSL2/BSL2-N or higher  IBC sets BSL | III-D-4-b |

* 1. **Introduction of rDNA-modified RG2, RG3, RG4 and restricted agents into animals**

|  |  |  |
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| **Experiment** | **Standard Biosafety Level** | **Section** |
| Experiments with r/sNA modified [RG2 microbes](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457095) in any animal (transgenic or otherwise) | BSL2/BSL2-N | III-D-1-a |
| Experiments with r/sNA modified [RG3 microbes](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457100) in any animal (transgenic or otherwise) | BSL3/BSL3-N | III-D-1-b |
| Experiments with r/sNA modified [RG4 microbes](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457105) in any animal (transgenic or otherwise) | BSL4/BSL4-N | III-D-1-c |
| Experiments with r/sNA modified **restricted agent** in any animal (transgenic or otherwise) | BSL4/BSL4-N | III-D-1-d  Reviewed by NIH |

* 1. **Other animal experiments**

|  |  |  |
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| **Experiment** | **Standard Biosafety Level** | **Section** |
| Any experiments with plant-associated arthropods or small animals modified by r/sNA or r/sNA -containing microorganisms and the r/sNA or microorganism has no recognized potential for serious detrimental impact on managed or natural ecosystems | BSL1-P | III-E-2-b-(5) |
| All other experiments with whole animals not listed in Tables 1A and 1B (i.e., NOT covered by Sections III-D-1 or III-D-4-a) | BSL set by IBC | III-D-4-b |

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1. **Other r/sNA experiments**

|  |  |  |
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| **Experiment** | **Standard Biosafety Level** | **Section** |
| Synthetic nucleic acids that **can’t replicate, can’t integrate into DNA or produce a toxin** that is lethal for vertebrates at an LD50 of less than 100 ng/kg body weight. | BSL1 | III-F-1 |
| r/sNA **not in organisms, cells, or viruses** and that has not been modified or manipulated to render it capable of penetrating cellular membranes.. | BSL1 | III-F-2 |
| r/sNA consisting of the **exact nucleic acid sequence from a single source** that exists contemporaneously in nature. | BSL1 | III-F-3 |
| r/sNA consisting of **nucleic acids from a prokaryotic host** when propagated only in that host or transferred to another host by well-established physiological means. | BSL1 | III-F-4 |
| r/sNA consisting of **nucleic acids from an eukaryotic host** when propagated only in that host (or closely related strain of same species). See natural exchangers list in Appendices A-I through A-VI. | BSL1 | III-F-5 |
| r/sNA consisting of **nucleic acids from different species** that exchange DNA by known physiological processes. | BSL1 | III-F-6 |
| Genomic DNA molecules that have acquired a **transposable element**, provided the transposable element does not contain any recombinant and/or synthetic DNA. | BSL1 | III-F-7 |
| r/sNA containing **less than one-half of any eukaryotic viral genome** propagated and maintained in cells in tissue culture | BSL1 | III-F-8  Appx C-I |
| r/sNA molecules derived entirely from **extrachromosomal elements of gram positive organisms** (listed in [Appendix C-VI](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457123)) and propagated and maintained in these organisms | BSL1 | III-F-8  Appx C-VI |
| Large scale experiments involving more than 10 liter of culture. Use [Appendix K](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457194) for large scale containment conditions. | BSL set by IBC | III-D-4-b |

1. **Experiments requiring federal review & approval (if not previously listed)**

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| --- | --- | --- |
| **Experiment** | **Oversight** | **Section** |
| Deliberate transfer of a drug resistant trait to microorganisms that compromises the control of disease agents in medicine | NIH OSP &  IBC | III-A-1-a |
| Cloning toxins that have an LD50 less than 100ng/kg body weight | NIH OSP &  IBC | III-B-1 |
| Deliberate transfer of r/sNA into human participants | FDA & IBC | III-C-1 |

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# Definitions:

1. **r/sNA:** refers to recombinant DNA molecules and DNA or RNA derived from recombinant DNA molecules and their synthetic equivalents.
2. **Transgenic animals:** foreign DNA is deliberately introduced into the animal using rDNA technology and is transmitted through the germ line resulting in every cell, including germ cells of the animal, containing the same modified genetic material.
3. **NIH OSP:** National Institutes of Health Office of Science Policy
4. **FDA:** U.S. Food & Drug Administration

**NIH Risk Group classifications**: Listed in [Appendix B of the Guidelines](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457093)

# NIH Containment requirements: Outlined in [Appendix G of the Guidelines](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457149)

Please contact the IBC Office at 504.568.4372 or [IBCOffice@lsuhsc.edu](mailto:IBCOffice@lsuhsc.edu) if you need assistance in determining which section(s) of the Guidelines apply to your experiments.

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