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Recombinant DNA (rDNA) Research Questionnaire (RDRQ) for Non-Exempt Research

[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines)

(Please answer questions completely – Use additional space as necessary)

Submit form and all supporting documents to [ibc@reed.edu](mailto:ibc@reed.edu).

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| IBC # | Original Submit Date | | Modification | Five Year Renewal |
| **Annual Review Year 1 Date:** | **Annual Review Year 2 Date:** | **Annual Review Year 3 Date:** | **Annual Review Year 4 Date:** |

Project Title:

Department:

Telephone:

Email:

List all staff/faculty/students that will be working on project:

**Please answer all questions on this form. You may indicate “N/A” if a particular question is not applicable.**

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| 1. Please provide overview of rDNA molecules to be used, and whether *in vivo* uses are proposed   (use additional rows as necessary) |
| |  |  |  | | --- | --- | --- | | **Vector type/Agent** | **Insert(s) or deletions** | **Host (cell type and/or species)** | | *Example: lentivirus*  *Example: L. pneumophila* | *GFP*  *LP01* | *Mice (in vivo)*  *human fibroblasts (in vitro)* | |  |  |  | |  |  |  | |  |  |  | |
| Brief Project Summary (referencing the relevant section(s) of the NIH Guidelines). Include all work within your research laboratories as well as within your teaching laboratories. |
| Vector/Agent Detail  *Please attach commercial product literature, a vector map, a copy of any journal articles describing construction of vector or provide a web link to specific information within this document. Also state whether you will be producing the vectors, or obtaining them commercially*: |
| 1. A. Vectors to be used (plasmids, cosmids, phages, viruses)--specify type and strain, and give description. |
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| B**.** If plasmids are used in the packaging system for the viral vector, they must also be listed and described.    C. If a packaging cell line is used for the viral vector, it must also be listed. |
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| 1. A. For viral vectors, describe how the vector differs from the original virus (in terms of pathogenicity and genome size): [*e.g., E1 & E3 genes deleted from adenoviral vector*] |
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| B. For recombinant infectious agents, describe how it differs from the wild type infectious agent (in terms of pathogenicity, virulence, or immunogenicity): [*e.g., attenuated Listeria monocytogenes*] |
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| 1. List all drug resistance genes that are NOT for the purpose of plasmid propagation in *E.coli* or for plasmid transfection in *in vitro* cell culture. Could any of these drug resistance genes compromise the use of the drug to control disease caused by this agent in humans, animals, or agriculture? |
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| 1. Will infectious virus particles or other infectious agents, either replication-deficient or replication competent, be rescued, propagated or purified in your laboratory? |
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| 1. What is the host range of the viral vector or recombinant infectious agent? |
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| 1. Will there be surveillance for production of wild type or replication competent infectious agents? Discuss. |
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| DNA Insert(s) and Expression |
| 1. State DNA Source (species, tissue/cell, or microbiological agents). |
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| 1. What gene products will be expressed or knocked down (shRNA or gene deletion) and what is the functional impact of overexpression or knockdown? If the gene product being expressed is from a Commerce Control Agent please provide citations describing the function of the gene product. |
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| 1. Please describe potential human, animal, or plant health hazards of the gene product or its transcribed or translated products (e.g., could it be oncogenic or toxic?). Please provide the vertebrate LD50 for any genes encoding a biological toxin. |
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| 1. Would any of the gene inserts or deletions potentially increase the virulence of the recombinant virus or recombinant pathogenic organism or allow the infectious agent to evade the host immune response? If yes, discuss. |
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| 1. Will any gene be intentionally mutated? If yes, describe. |
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| Host (cell type and/or species) |
| 1. For *in vitro* experiments list host cells to be targeted (bacterial, eukaryotic, species). |
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| 1. If transduced or infected cells will be used for downstream applications (eg FACs sorting or in vivo transplant) when will these experiments occur relative to the time of transduction or infection?      1. Are viral sequences present in the host that could recombine with the vector and lead to replication-competency for the recombinant construct, or has the host been previously infected with another agent? |
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| 1. For *in vivo* experiments describe the method of delivery, including a range of doses and numbers of administrations for each animal/agent. Please list registered IACUC protocols. |
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| 1. For whole animals, could there be an adverse physiological impact? Discuss. |
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| 1. For *in vivo* experiments, specifically discuss the potential for shedding of the agentfrom the animal host. |
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| 1. For *in vivo* experiments, will fluids, tissues or cells be harvested from the animal? Briefly describe harvested material and discuss if the material is potentially infectious or may contain replication competent infectious material. |
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| Biosafety |
| 1. Discuss the biohazard implications including potential exposure to staff and animal colonies. Describe protective clothing/equipment that personnel are required to wear/use. Include other preventative measures (e.g., vaccinations) if applicable. |
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| 1. Describe consequences of and response to accidental exposure, e.g., spill, mucosal splash, inhalation, or inoculation, which might occur during experimental handling. 2. Describe additional locations where these experiments (both *in vitro* and *in vivo*) may take place. |
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| 1. Describe equipment to be used (e.g., flow cytometer, centrifuge, microscope, animal imaging), or transportation to other locations that may require additional biosafety precautions. |
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| 1. Describehow materials containing rDNA or infectious agents (viral or other gene expression vectors, transfected cell lines, infected tissues, etc.) will be disposed/discarded. |
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I will abide by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, the CDC Guidelines for Biosafety in Microbiological and Biomedical Laboratories, and Reed College policies and procedures for research involving rDNA and/or synthetic nucleic acid molecules. (For reference, these are : <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>; https://www.cdc.gov/labs/BMBL.html)

I will maintain a current record of any transfer of recombinant DNA and/or synthetic nucleic acid molecules, or vectors or host strains containing recombinant DNA and/or synthetic nucleic acid molecules, or infectious agents between investigators at this or other institutions. I will contact EHS or mail services before shipping any hazardous materials. I will follow DOT, IATA, and CITES requirements and will ensure any laboratory personnel have received the required training, when applicable, for shipment of biological materials.

I agree that as principal investigator it is my responsibility to make certain that prior to engaging in research involving known or potential pathogens, all laboratory and support personnel are properly trained in the practices and techniques required to ensure safety, and to supervise the safety performance of those involved ensuring that the required safety practices and techniques are employed. I agree to send all project modifications to the Institutional Biosafety Committee if changes are made to the recombinant DNA and/or synthetic nucleic acid molecule experiments described in this questionnaire.

If you have an electronic signature, please sign below, save, and return via email to ibc@reed.edu. If you do not have an electronic signature, please print this document, sign the hard copy below.

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Principal Investigator Signature Date

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Head of Lab (if different) Signature Date

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Biosafety Committee/BSO Approval Date