RDRQ Instruction Guide

Please contact the IBC office at ibc@ohsu.edu or 503-494-7887 for further assistance in completing the RDRQ

OREGON HEALTH & SCIENCE UNIVERSITY

Recombinant DNA (rDNA) Research Questionnaire

All research involving rDNA must be reviewed by the IBC, regardless of funding. For more information on these requirements, please see

NIH Guidelines for Research Involving Recombinant DNA Molecules

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

Principal Investigator Last Name, First Name, Degree			Years of laboratory experience relevant to this agent(s)
Telephone Number	Email Address	Mail Code	Laboratory Contact Please supply a lab contact person that we can contact in case we cannot locate the PI for questions during the review process.
Protocol Title Please organize your protocols by a main protocol or project name. Use the Grant/Project Titles section below to list out the grants and other projects where the rDNA work would be covered under this main protocol, if applicable. You may choose to submit the RDRQ based on all the rDNA work conducted within a certain grant or aim of the laboratory, or by agent used (e.g., submit a separate RDRQ for adenovirus and one for lentivirus, or one RDRQ for adenovirus and lentivirus used to study disease A, and a separate RDRQ for adenovirus and lentivirus used to study disease B).			

Grant/Project Title(s) covered by this protocol (insert additional rows as needed)	Project Sponsor	Check if Funded	Check if Pending

Additional research personnel to work with agent(s) on this project	Position	Years of relevant experience Years of experience should be relevant to the particular agent to be used.

Are non-recombinant infectious agents or biologically-derived toxins also involved in this project? If yes, you must also complete the Infectious Agent/toxin Questionnaire (http://www.ohsu.edu/research/rda/forms.shtml#rdna)	**Yes**	**No**
Are select agents involved in this project? See definition and FAQs at: http://www.ohsu.edu/research/rda/ibc/sa_faqs.shtml	**Yes**	**No**

For questions, contact the OHSU IBC Integrity Manager at (503) 494-6727, the OHSU Central Campus Biosafety Officer, (503) 494-0655, or the OHSU West Campus Biosafety Officer, (503) 690-5312.

Mail Code: L106RI

Please return signed original to Mail Code: L106RI and email to: ibc@ohsu.edu

Summary of proposed work (specifically address the use of recombinant DNA, including the rationale for the selection of the particular vector system(s) to be used). Please use language appropriate for a scientific academician working in an unrelated field

Please do not copy and paste specific aims from your grant, but rather address the use of rDNA and infectious agents in your project. Specifically indicate why you have chosen the particular vector system(s).

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In this application, please describe all *non-exempt* recombinant DNA molecules to be used in this protocol. Non-exempt rDNA molecules include (but are not limited to): virally based vectors, any vector (or recombinantly modified cells) to be injected into animals, non-standard host-vector systems (see Appendix C of NIH Guidelines), vectors containing genes from Risk Group 3 or 4 organisms or genes for the biosynthesis of toxin molecules, experiments involving > than 10 liters of culture. For more information on exempt rDNA, see http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261577

rDNA overview

1. Please provide overview of rDNA molecules to be used, and whether *in vivo* uses are proposed (use additional rows as necessary) – Please list all rDNA molecules to be used in this protocol, specifying which inserts and hosts will be used with which vectors if multiple vectors are proposed.

Vector type	Insert(s)	Host (cell type and/or species)
Example: lentivirus	*GFP*	*Mice (in vivo); human fibroblasts (in vitro)*
Adenovirus	*GFP*	*Mice (in vivo); human fibroblasts (in vitro)*
Adenovirus	*Gene X*	*Human fibroblasts (in vitro only)*

Vector Detail

2. Vectors to be used (plasmids, cosmids, phages, viruses)--specify type and strain, and give description. ***Please provide commercial product literature, a web link to specific information, a vector map, or a hard copy of any journal articles describing construction of vector*:**

In order to provide a proper review, it is important that the committee receives as much information as possible for each vector system proposed. For commercial systems, a link to the product information on the web is acceptable. For other systems, please provide maps or a detailed written description. The description should include information about the promoter and other foreign sequences contained within the vector. If there is a reference that provides this information, please attach the full article to your submission.

3. 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 or attenuated yellow fever virus (X% of the genome deleted)*]

In order to provide a proper review, please give enough information about the vector to determine its risk. For example, specify what genes are deleted resulting in replication deficiency. Or, if the virus has been attenuated, what percentage of the genome has been deleted? NIH regulations may allow exemption from IBC review if the percentage of the original genome remaining is less than 50%, as long as no helper virus is used.

4. Are antibiotic resistance genes included in the vector? List all antibiotic resistance genes contained. Could any of these antibiotic resistance genes compromise the use of the drug to control disease caused by this agent in humans, animals, or agriculture?

If applicable, consider what antibiotics are used to treat the disease caused by the agent in humans or animals. Sources to consult include: http://www.bt.cdc.gov/Agent/agentlist.asp and http://www.phac-aspc.gc.ca/msds-ftss/index.html

5. Will infectious virus particles or other infectious agents, either replication-deficient or wild type, be rescued, propagated or purified in your laboratory?

If you are producing the vector yourself, even if it is replication deficient, the answer to this question should be yes. If you are getting the vector with insert already produced and ready to inject, then you may answer no.

6. For viral vectors, indicate packaging cell line used and include a description of the host range of the resulting recombinant virus.

For example, is it amphotropic, ecotropic, or is it pseudotyped with VSV-G protein?

7. Will there be surveillance for production of wild type or replication competent infectious agents? Discuss.

For safety reasons, RCV testing is always preferred. For *in vivo* projects, replication competent virus (RCV) testing may be required for housing in regular animal housing areas. Refer to the IBC requirements posted at: http://www.ohsu.edu/research/rda/ibc/faqs.shtml#Vector

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DNA Insert(s) and Expression

8. State DNA Source (species, tissue/cell, or microbiological agents).

List source of DNA that will be cloned into the vector (e.g., human cDNA)

9. Genes contained in the inserted DNA sequences:

List all genes and other non-native sequences that have been inserted into the vector resulting in the rDNA molecule

10. What gene products will be expressed and what is their function?

11. Are any of the gene products potentially oncogenic or toxic for vertebrates? If yes, discuss.

If you are unsure, please also state this in the response.

12. Would any of the gene products potentially increase the virulence of the recombinant virus or recombinant pathogenic organism? If yes, discuss.

If you are unsure, please also state this in the response.

13. Will any gene be intentionally mutated? If yes, describe.

For random mutagenesis or other experiments where multiple mutants will be generated, describe the general scheme and technique used.

Host

14. For *in vitro* use list host cells to be targeted (bacterial, eukaryotic, species).

15. Are viral sequences present in the host that could recombine with the vector and lead to replication-competency for the recombinant construct?

Consider known sequences as well as endogenous viruses that may be present in the whole animal host or cell lines used.

16. For *in vivo* use list host species and target organs or systems and describe the method of delivery. Provide IACUC number associated with this project.

17. For whole animals, could there be an adverse physiological impact? Discuss.

18. For *in vivo* use, specifically discuss the potential for shedding of the agent from the animal host.

Could the virus be found in urine or feces? Consider the potential for generation of a replication competent virus in the response.

Biosafety

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19. Discuss the biohazard implications including potential exposure to staff and animal colonies. Consider the consequences of an accidental exposure, e.g., mucosal splash, inhalation, or inoculation, which might occur during experimental handling.

Specifically discuss the hazardous nature of the agent to be used. In the case of an accidental exposure, what are the possible harms to personnel? The IBC suggests consulting the Biosafety in Microbiological and Biomedical Laboratories (BMBL) publication: http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

20. Describe the containment facilities where these experiments (both *in vitro* and *in vivo*) will take place. Please include all of the following: location, manufacturer, type, and certification date of biosafety cabinets (tissue culture hoods) where these agents will be used.

21. Describe equipment to be used (e.g., flow cytometer, centrifuge, microscope), or transportation to other locations that may require additional biosafety precautions.

Will you need to transfer infected cells or animals from one part of OHSU to another part? What about shared equipment to be used? If applicable, please address how these activities will be accomplished safely.

22. Describe how materials containing rDNA or infectious agents (viral or other gene expression vectors, transfected cell lines, infected tissues, etc.) will be disposed/discarded.

Describe how animal carcasses, infected cultures & media will be disposed.

Assurance

I will abide by the NIH Guidelines for Research Involving Recombinant DNA Molecules the CDC Guidelines for Biosafety in Microbiological and Biomedical Laboratories, and OHSU policies and procedures for research involving rDNA molecules (http://www.ohsu.edu/research/rda/ibc/ibcpolicies.shtml).

I will maintain a current record of any transfer of recombinant DNA, or vectors or host strains containing recombinant DNA, or infectious agents between investigators at this or other institutions. I will follow IATA and CITES requirements and will ensure any laboratory personnel have received the required training, when applicable, for shipment of biological materials, (see http://ozone.ohsu.edu/ehrs/mh/pages/bio/infsub.shtml).

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 a Project Modification Form to the Institutional Biosafety Committee if changes are made to the recombinant DNA experiments described in this questionnaire.

Principal Investigator Signature _____ Date _____

Head of lab (if different) Signature _____ Date _____

Print name (head of lab) _____