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This form should be completed and returned to the Sponsored Research Office, MSC 71, or by email with electronic signature to sponsres@lclark.edu

LEWIS & CLARK COLLEGE

Recombinant DNA (recDNA) and/or Synthetic Nucleic Acid Molecules Research Questionnaire

All research involving recDNA and/or synthetic nucleic acid molecules must be reviewed by the IBC, regardless of funding source. For more information on these requirements, please see the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, available on the web at: http://oba.od.nih.gov/rdna/nih_guidelines_new.htm Please visit http://www.lclark.edu/dept/hrpolicy/researchdna.html for the College's policy on Research Involving Recombinant DNA.

Please answer questions completely and use additional space/pages as necessary.

Principal Investigator (last name, first name, degree)

Years of laboratory experience relevant to this agent(s) | Email address | Mail Code

Phone No. | Project Title

Project Sponsor | Lab Contact

Additional research personnel to work with agent(s) on this project | Position & Years of relevant experience

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.

Are select agents involved in this project?
A listing of HHS select agents and toxins in the new select agent regulation (42 CFR 73) is available at: http://www.cdc.gov/od/sap/docs/salist.pdf

Notes:
You may be asked to provide additional information concerning facilities and procedures for minimizing biosafety risk factors.
For questions, please contact the L&C IBC Chair.
Please returned signed original to the sponsored research office at MSC 71 or via email at: sponsres@lclark.edu

Brief Project Summary (specifically address the use of recombinant DNA and/or synthetic nucleic acid molecules). Please use language appropriate for a scientific academician working in an unrelated field. Include whether you believe the experiments to be exempt or non-exempt, referencing the relevant section(s) of the NIH Guidelines.

Please describe all recombinant DNA and/or synthetic nucleic acid molecules to be used in this specific project. This includes (but is 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 the NIH Guidelines at: **http://oba.od.nih.gov/rdna/nih_guidelines_new.htm#_Toc331174070**), vectors containing genes from Risk Group 3 or 4 organisms or genes for the biosynthesis of toxin molecules, experiments involving more than 10 liters of culture.

DNA Insert

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

2. Size of Sequence:

3. Genes contained in sequences:

4. If you are obtaining recDNA and/or synthetic nucleic acid molecules from outside sources, discuss source and transport arrangements.

Gene Expression, Function, and Source

5. Will you be expressing gene products from recombinant DNA and/or synthetic nucleic acid molecules? State products and their function.

6. Are any of the gene products potentially oncogenic or toxic for vertebrates? Discuss.

7. Would any of the gene products potentially increase the virulence of the recombinant virus or recombinant pathogenic organism? Discuss.

8. Will any gene be intentially mutated? Discuss.

9. Will recombinant DNA and/or synthetic nucleic acid molecules be used to significantly alter cellular function or metabolic pathways? Discuss.

Vector

10. 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.*

11. Describe component(s) contained in the vector that are derived from a virus or other pathogenic organism. Provide size(s) of these component(s) and relative percent size compared to originating wild-type source(s). *(For example, 1472 bases of 5'LTR and adjacent sequence comprises 25.2% of complete Moloney murine sarcoma virus genome.)*

12. Are antibiotic resistance genes included in the vector? List all antibiotic resistance genes contained. Discuss whether the use of any of these antibiotic resistance genes compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

13. Percentage size of DNA insert relative to substrate vector DNA:

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

15. For viral vectors, indicate packaging cell line used and include a description of the host range of the packaged viral vector.

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

Host

17. For *in vitro* use discuss host cells targeted (bacterial, eukaryotic, species).

18. For *in vivo* use discuss host species and target organs or systems. Provide IACUC number associated with this project.

19. Are helper viruses present in the host, which may lead to replication-competency for the recombinant construct? Discuss.

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

21. Are there biohazard implications including potential exposure to staff and animal colonies? Discuss. Specifically address the potential for shedding of the agent *in vivo* from the animal host.

22. Describe the containment facilities where these experiments (both *in vitro and in vivo)* will take place. Please include the location, manufacturer, type, and certification date of biosafety cabinets (tissue culture hoods) used for this project.

23. Are you using E. coli? If so, please indicate what strain you are using.

24. Are you using recombinant DNA and/or synthetic nucleic acid molecules in any of your courses or teaching labs? If so, please explain and note is this is part of research protocols already determined "exempt" or approved by the IBC.

Assurances

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 Lewis & Clark College policies and procedures for research involving recDNA and/or synthetic nucleic acid molecules. (For reference, these are : http://oba.od.nih.gov/rdna/nih_guidelines_new.htm ; http://www.cdc.gov/OD/ohs/biosfty/bmbl4/bmbl4toc.htm ; http://www.lclark.edu/dept/hrpolicy/researchdna.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 follow 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 a Project Modification Form 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 sponsres@lclark.edu. If you do not have an electronic signature , please print this document, sign the hard copy below, and return to MSC 71.

Principal Investigator Signature		Date	
Head of Lab (if different) Signature		Date	
Print name (head of lab)			