DANA-FARBER CANCER INSTITUTE

Biosafety Application

Unique ID: 150283

Project Number **15 - 7483** Date Submitted 10/20/2015

Principal Investigator Rasmussen, Robert A.,Ph.D.;

Additional Investigators

Project Title Blank application

Anticipated Starting Date 10/20/2015

IMPORTANT: Please fill out the fields above and save your form immediately using the Save button. You may then work on the form at your leisure using Save to keep changes until the form is ready to Submit. Use the "Submit" button at the bottom of the form to begin/continue the approval process.

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Brief overall summary of work in non-technical language. Per NIH-Office of Biotechnology Activities regulations, we have outside laypeople and community members on our Biohazard Control Committee. Therefore, this description should be written without any scientific jargon, abbreviations or terminology that might be unknown to the general public.

This is the box you complete describing your work in layman's terms..

Check all the Biosafety Registration Categories listed below that apply to your proposed work – if a given experiment involves more than one category, be sure all the applicable categories are checked. For example, proposing to use lentivirus-transduced primary human tumor cells would require checking and filling out Biosafety Registration Category I, Recombinant or synthetic nucleic acid molecules and Biosafety Registration Category II, Human or non-human primate (NHP) blood and tissue.

Biosafety Registration Categories

- [x] I. Recombinant or synthetic (genetically modified virus or vector derived solely by synthetic techniques) nucleic acid molecules
- [x] II. Human or non-human primate (NHP) blood or unfixed tissue
- [x] III. Infectious agents/non-recombinant pathogens (do not check if the infectious agents used in your work only include vectors for recombinant or synthetic nucleic acid molecules

I. Recombinant or Synthetic Nucleic Acid Molecules - Experiment 1

Types of experimental systems in this category can range from the simple generation of plasmid DNA to an experimental system consisting of plasmid generation + viral vector generation + cell transduction + inoculation of animals with the transduced cells.

For each type of planned experimental system complete both A) Component Description and B) Narrative Description

A) Component description of Recombinant or Synthetic Nucleic Acid Molecule work

1) Source of DNA - Specify the original source of the genetic sequence(s) or transgene(s), e.g. cDNA from a human breast tumor cell line:

2) Specific function of genetic sequence(s) or transgene(s), e.g. oncogene, tumor suppressor, siRNA (with gene target, if known):

3) Vector name(s) and type(s), e.g. plasmid, adenovirus, retrovirus, lentivirus. If a retroviral vector will be used, indicate if it is ecotropic or amphotropic. For lentiviral vectors, include the names of the transfer plasmid, the envelope plasmid (including the *env* gene origin, e.g. VSV-G protein), and all packaging plasmids used for construction:

4) Genetic host(s) – include the host for each of the experimental steps including the initial host, all intermediate host(s), and the final host, if appropriate. For example, if lentiviral vector-transduced cells are to be inoculated into mice, you should include: 1 - E. coli for plasmid preparations, 2 - 293T cells for multi-plasmid transfection to generate a lentiviral vector, 3 – human primary carcinoma cells for transduction and transgene expression, 4 – mouse fat pad for xenotransplantation of transduced cells.

5) Is volume of preparation large scale i.e. >10 liters? ○ Yes ○ No

6) Proposed containment level:

☐ BL1 ☐ BL2 ☐ BL2lenti ☐ BL2+

B) Narrative Description of Recombinant or Synthetic Nucleic Acid Molecule work

Check any Recombinant or Synthetic Nucleic Acid Molecule work procedures that might create aerosols that will be used:

☐ Cell Sorting ☐ Centrifugation ☐ Tissue Homogenization ☐ Sonication

☐ Check if Recombinant or Synthetic Nucleic Acid Molecule work will involve animals.

(link for ARF Policy on using viral vectors in rodents)

Please include in description:

1. Nature and purpose of research using recombinant or synthetic DNA.
2. For any viral vectors, indicate if it is replication-competent; if replication incompetent viral vectors are involved, describe how testing for RCV will be performed (link for BCC policy on RCV testing).
3. Outline of procedures and techniques to be employed.

Will you require the removal of lentivirus-transduced cells from a BL2lenti facility before the results of BCC-required replication competent virus tests are available?

○ Yes ○ No ○ Not Applicable

Location of Recombinant or Synthetic Nucleic Acid Molecule Work:

	Building	Room
Rooms where BL1 work will be done		
Rooms where BL2 work will be done		
Rooms where BL2+ work will be done		
Rooms where BL2lenti work will be done		

Non-D.F.C.I. Locations, e.g. Harvard Robotics Core

Personnel

Full Name	Position

Add Personnel

Risk Assessment Researchers

1) Are there any potential hazards associated with this work? ◉ Yes ○ No

Please elaborate, indicating what experimental components may be potentially hazardous, and what precautions will be taken when handling those components.

2) Are all researchers informed that any lentivirus exposure incidents should be promptly reported and that anti-retroviral drugs are available and may be offered? ○ Yes ○ No

3) Do you recommend any particular health practice, including vaccinations, appropriate for personnel engaged in this work?

Add Experiment

II. Human or Non-Human Primate Blood or Unfixed Tissues

Will animal work be done using primaryhuman blood or tissues? Yes No
link to Use of Human Materials in Rodents

Check anyHuman or non-human primate (NHP) blood or unfixed tissue work procedures that might create aerosols:

Cell Sorting Centrifugation Tissue Homogenization Sonication

Description of Human or Non-Human Primate Blood or Tissue work. Please include the nature and purpose of the research, the type of sample and source of human or non-human primate blood or tissue, what container the material will be provided in (e.g. apheresis collar link to Collecting Lymphocytes from Apheresis Collar SOP, Vacutainer tube(s) link to Vacutainer Cap Removal SOP, other container), how the material will be handled and manipulated.
(link to OSHA DFCI Bloodborne Pathogen Exposure Control Plan for Research Activities)

Location of Human or Non-Human Primate Blood or Unfixed Tissues:

	Building	Room
Rooms where BL2 work will be done		
Rooms where BL2+ work will be done		
Rooms where BL2lenti work will be done		
Non-D.F.C.I. Locations, e.g. Harvard Robotics Core		

Personnel

Full Name	Position

Insert item

Risk Assessment for Researchers

1) Are staff informed of appropriate prompt exposure reporting procedures? Yes No
Link to DFCI Exposure Card

2) Are staff using human blood or tissues informed that Hepatitis B vaccine and post-exposure prophylaxis treatment for Hepatitis B and C are available through Occupational Health? Yes No

3) Are staff using non-human primate blood or tissues aware that post-exposure prophylaxis for Macacine Herpesvirus1 (Herpes B) is available through Occupational Health? Yes No
http://www.cdc.gov/herpesbvirus/

4) Do you recommend any other particular health practice, including vaccinations, appropriate for personnel engaged in this work?

Add Experiment

III. Infectious Agent(s)/Non-Recombinant Pathogens - Experiment 1

Infectious agent

Infectious agent source

Will the infectious agent be grown or expanded in the laboratory Yes No

Shaker Flask Incubator

Laboratory procedures using non-recombinant microorganisms, including containment conditions and waste disposal:

Will infectious agents be used in animals? Yes No

1) Animal species

2) Special animal conditions (e.g. humanized mice)

3) Number of exposed animals housed at one time

Total number of animals to be used

4) Route of animal exposure

5) Dose to animals (concentration and volume)

6) Duration of animal experiment post-exposure

7) Can animal-to-animal transmission occur?

8) Can animal-to-human transmission occur?

9) Is environmental transmission to feral animals possible?

10) List any natural vectors involved in transmission in the wild?

Route of Transmission Urine Feces Saliva Respiratory Route

Location of Infectious Agent/Non-Recombinant Pathogen Work:

	Building	Room
Rooms where BL1 work will be done		
Rooms where BL2 work will be done		
Rooms where BL2+ work will be done		
Rooms where BL2lenti work will be done		

Non-D.F.C.I. Locations, e.g. Harvard School of Public Health

Personnel

Full Name	Position

Add Personnel

Risk Assessment for Researchers

1) Describe the biohazard potential of the infectious agent?

2) Is the infectious agent susceptible to commonly available therapeutic drugs?

3) Do you recommend any particular health practice, including vaccinations, appropriate for personnel engaged in this work?

Add Experiment

Principal Investigator Protocol Safety Assurance Statement

I attest that the information in this registration is accurate and complete. All research personnel are familiar with and understand the potential biohazards, as well as the required safety practices and emergency procedures.

I agree to:

1. accept responsibility for training and supervision of all laboratory workers involved in the project
2. require reporting of exposures to biological materials to Occupational Health Services (2-3016; 4-STIK beeper off-hours)
3. conduct research in compliance with applicable federal, state, and local regulations and Institute policies listed in the biosafety manual
4. consult the Biosafety office (617-632-3005 or DFCIBSaf@partners.org) on questions related to regulatory compliance
5. report spills, losses, or theft of biological materials to the Biosafety Office.

Attestation Rasmussen, Robert A.,Ph.D.; 10/20/2015

I attest that the information contained in this form is accurate to the best of my knowledge

Is this protocol now inactive? ○ Yes ◉ No

Approvals

BCC Reviewed and Accepted

BCC-Sanctioned Special Conditions

Submit Close