Registration of Research with RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES

http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm

Rev 03/13

RETURN ORIGINAL FORM TO: **Biosafety Officer**
2024 E. Monument Street, Room B-200
Baltimore, MD 21205-2223, SOM
410-955-5918
(Fax) 410-955-5929

JHU IBC#_____
DATE_____
BIOSAFETY LEVEL_____
ACTION_____
HSE Use Only. Do not write in this space.

Principal Investigator (must be faculty, see * below):	***JHED ID or Badge Number**:***
Academic Title:	***Email Address:***
Department:	***Division:***
Office Address:	***Lab Address:***
Office Phone:	***Office Fax:***
Project Title:	
Project Start Date:	***Project Duration:***
Name and Source of Material:	***Repository:*** ☐ ***Yes*** ☐ ***No***
Strain, Genotype, Catalog Number, or CAS Number:	***Freezer Serial No:*** _____
Type(s): ☐ ***Toxin*** ☐ ***Pathogen*** ☐ ***Oncogenic Material*** ☐ ***Human Material***	***Location:***

****Work involving the use or possession of INFECTIOUS AGENTS, PATHOGENS, VIRAL VECTORS, BIOLOGICAL TOXINS, or HUMAN TISSUES requires a current Registration Number or a new Registration of Research with Human Tissue, Infectious Agents, Pathogens or Toxins Form for this material.*

1. Will this project at any time involve shipping infectious materials over public thoroughfares? ☐ Yes ☐ No
2. Specify gene sequence of the recombinant or synthetic nucleic acid(s) _____
3. Identify vector(s), specific phage, plasmid or virus. For novel and viral constructs attach vector map, do not attach gene sequence.
4. Host or Environment: _____ (see #11 below)
5. Is Volume Large Scale, > 10 Liters Culture? ☐ Yes ☐ No
6. If virus source, is it more than 2/3 of the viral genome? ☐ Yes ☐ No
7. Is a helper virus, packaging system, complementary cell used? ☐ Yes ☐ No
8. Are intact animals exposed to the nucleic acid molecules? ☐ Yes ☐ No
9. Are mammalian cells exposed to the nucleic acid molecules? ☐ Yes ☐ No
10. Are Human Subjects exposed to the nucleic acid molecules? ☐ Yes ☐ No

For submissions involving Human Gene Therapy, please contact ibc@jhu.edu *for additional information.*

11. Please check the relevant situation(s) that apply to your project. For "Yes", indicate the Biosafety Level.

Host / Environment			**Biosafety Level**	
a. E. coli, K12	☐ Yes	☐ No	☐ BSL-1	☐ BSL-2
b. Other Bacteria	☐ Yes	☐ No	☐ BSL-1	☐ BSL-2
c. Non-pathogen	☐ Yes	☐ No	☐ BSL-1	
d. Pathogen	☐ Yes	☐ No	☐ BSL-2	☐ BSL-3
e. Toxin gene	☐ Yes	☐ No	☐ BSL-2	☐ BSL-3
f. Drug resistance Gene	☐ Yes	☐ No	☐ BSL-2	☐ BSL-3
g. Yeast / YAC	☐ Yes	☐ No	☐ BSL-1	☐ BSL-2

Tissue Culture Cells ☐ Yes ☐ No

a. R-DNA /plasmids /synth nucleic acids	☐ Yes	☐ No	☐ BSL-2	
b. Segment of virus	☐ Yes	☐ No	☐ BSL-2	☐ BSL-3
c. Virus vector	☐ Yes	☐ No	☐ BSL-2	☐ BSL-3
d. If virus vector:	☐ Adeno	☐ Retro	☐ Vaccinia	☐ Sindbis ☐ Other Virus _____
e. Defective viral vector	☐ Yes	☐ No		
f. Replication competent viral vector	☐ Yes	☐ No		

***Post-doctoral fellows, research associates, & instructors require co-signature of Department Chair and Laboratory Sponsor.**
****JHED ID is now preferred. JHU Badge/ID number is the number on your ID card. Contact the Biosafety Office if you are unsure of your ID number.**

Intact Lab Animal Recipient ☐ Yes ☐ No If yes, species: _____

a.	University Animal Use & Care Committee Protocol Number: _____			Approval Date: _____	
b.	Animal Housing (building & room no.) _____				
c.	R-DNA /Plasmid /Synth Nucleic Acid	☐ Yes	☐ No	☐ ABSL-1	☐ ABSL-2
d.	Transgenic	☐ Yes	☐ No	☐ ABSL-1	☐ ABSL-2
e.	Virus Vector	☐ Yes	☐ No	☐ ABSL-1	☐ ABSL-2 ☐ ABSL-3
f.	SCID / Nude	☐ Yes	☐ No	☐ ABSL-1	☐ ABSL-2 ☐ ABSL-3

Human Subject Recipient ☐ Yes ☐ No

a.	I.R.B. or RPN Protocol Number: _____			Approval Date: _____	
b.	R-DNA /Plasmid /Synth Nucleic Acid	☐ Yes	☐ No	☐ BSL-2	
c.	Pathogen	☐ Yes	☐ No	☐ BSL-2	
d.	Virus Vector	☐ Yes	☐ No	☐ BSL-2	

Plants ☐ Yes ☐ No **Insects** ☐ Yes ☐ No **Field Release** ☐ Yes ☐ No ☐ BSL-2-P ☐ BSL-3-P

12. Reference your experiment from the NIH Recombinant DNA Guidelines (see attachment). _____ (Required)

** Recombinant DNA inserts in plasmid and phage in E. coli K12, DH5 alpha or in transgenic knockout mice, not involving a viral gene, toxin, or pathogen source, or in large-scale culture (>10L), are EXEMPT from full IBC review and can be approved administratively by the Biosafety Officer. rDNA in tissue culture is not exempt. The use of knockouts (by creating or purchase) must be registered prior to use in research.

13. Please list all professional personnel (employees, student, post doctoral, visiting investigator) involved in the project who will come into contact with recombinant or synthetic nucleic acid materials:

Name	***Mailing Address***	***JHU-Badge/ID Number***

14. Prepare and attach a summary (not more than one page). Include the following information:

a) Nature and purpose of the research.
b) Viral vectors; name, source and key features including replication deficient or replication competent, identify marker genes and foreign insert genes.
c) Outline of the procedure and techniques to be employed.
d) Assessment of risks to personnel working with the agent or material.
e) Specific practices, equipment, and facilities that will be used to protect personnel from exposure to the agent or material.
f) Specific methods of inactivation or disposal of the agent or contaminated materials.

The registration form (summary and any attachments) must provide sufficient detail for the Institutional Biosafety Committee to understand and evaluate rDNA or other nucleic acid components in order to review the registration. For any attached references, please highlight pertinent paragraphs or sentences. Submissions that lack detail or are illegible will be deferred from action and returned for revision and resubmission. The project registration must be updated annually, and must include a summary of results and changes to the project. Major changes to the project require submission of a new registration form. **Incomplete registration forms will be returned.**

As Principal Investigator, I accept responsibility for the safe conduct of work with this material. I will ensure that all personnel receive training in regard to proper safety practices and personal protective equipment needed for this work.

Signature (Principal Investigator): _____ Date: _____

*Co-Signature (Dept. Chair): _____ Date: _____

***Post-doctoral fellows, research associates, & instructors require co-signature of Department Chair and Laboratory Sponsor.**