Registration Number:

Registration Document for Recombinant/Synthetic DNA Experiments

Section I- Basic information: to be completed for *all* projects. For each proposed activity you must complete a separate registration document. The PI is responsible for completing this registration and obtaining approval from the IBC before commencing work. The PI must first contact EHS to have location and activities evaluated then will submit this completed form to IBC for approval.

Project Title:
Principal Investigator:
Department:
Phone Number: Fax:
Email:
Building and room numbers to be used:
Proposed start date for research:
Your signature below indicates that you acknowledge all requirements and restrictions of the most current NIH *Guidelines* for the biosafety level you have indicated, unless modified by the IBC, that you accept responsibility for the safe conduct of the experiments conducted at this biosafety level and that you have informed all associated personnel of the conditions required for this work. It is the Principal Investigator's responsibility to follow the NIH *Guidelines* and notify EHS and the IBC of any adverse events, including research-related accidents and illnesses. The Principal Investigator certifies that the work description is accurate. Any work performed that is not approved under this permit may be subject to the loss of grant funds. This registration must be updated every three years. PI (sign)/Date: Dept. chair(sign)/Date:

Experiments which are exempt and do not require a full registration:

Examples include rDNA that is: not in organisms and viruses; DNA segments entirely from a single nonchromosomal or viral DNA source; entire DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well established physiological means; entirel DNA from a eukaryotic host when propagated only in that host or a closely related strain of the same species; entirel DNA segments from different species that exchange DNA by known physiological processes; or DNA that is not a significant risk to health or the environment. NOTE: any large scale work greater than 10 liters is NOT considered exempt, even if it fits any of the above criteria.

Section II- Details of work: to be completed for covered (non-exempt) projects only

1. Source(s) of DNA/RNA sequences (include genus, species, gene name, and abbreviation):

2. Is a vector (virus, plasmid, phagemid, or any other) Yes ☐ No ☐
   a. If yes, identify specific phage, plasmid, or virus: _____
   b. If virus vector: Adenovirus ☐ Retrovirus ☐ Other ☐ None ☐
   c. If a virus vector, is it defective: Yes ☐ No ☐ N/A ☐
   d. If a virus vector, is it replication competent: Yes ☐ No ☐ N/A ☐
   e. If viral vector, what percent of the viral genome remains? _____
   f. If a viral vector is used, provide evidence or documentation to substantiate replication incompetence and method to ensure that replication-competent virus is not generated (attach).
   g. If a viral vector is used, and if packaging cells are used with murine retroviral vectors, does this broaden the host range of the virus (e.g. from ecotropic to amphotropic)? Explain (include packaging cell line, tropism, and added risk of a broadened host range, if applicable) (attach).

3. If the recombinant DNA contains viral DNA, does the insert represent more than 2/3 of the viral genome?
   Yes ☐ No ☐ N/A ☐

4. What is the biological activity of the gene product or inserted sequence?

5. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA? Yes ☐ No ☐
   a. If expression is obtained, protein or RNA name:

6. Host strain for propagation of the recombinant DNA (give genus, species, and parent strain):
   a. Is host strain pathogenic? Yes ☐ No ☐ N/A ☐

7. Is there transfer of a drug resistance gene? Yes ☐ No ☐
   a. If yes, what is the gene?
   b. If yes, is this drug resistance trait acquired naturally by the microorganism? Yes ☐ No ☐
   c. If yes, will the acquisition of the trait compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture? Yes ☐ No ☐

8. Does work involve cloning toxin molecules with an LD_{50} of < 100 ng/kg of body weight?
   a. If yes, what specific precautions are used to prevent accidental release of toxin (attach)?

9. Is there a target recipient of this recombinant DNA? Yes ☐ No ☐

a. If there is a recipient organism, indicate species or cell lines:

Animals: Tissue culture (see question 11):

Plant cells: Plants:

Yeast: Bacteria:

Other:

Specify target host(s):

b. If target is a plant or animal, is there the possibility of any form of horizontal transmission outside the laboratory setting? Yes ☐ No ☐

c. If target is a plant or animal, what precautions are taken to prevent release of recombinant organisms to the wild (attach)?

10 Is there production of transgenic organisms? Yes ☐ No ☐

a. If yes, what precautions are taken to prevent release of animals to the wild (attach)?

11. Is the work in cell or tissue culture? Yes ☐ No ☐ N/A ☐

a. If yes, do the recombinant DNA molecules contain > 1/2 of any eukaryotic viral genome?: Yes ☐ No ☐

b. If yes, identify cells or cell lines being used:

12. Relevant section of NIH guidelines:

13. Proposed biosafety level for project (check one): 1 ☐ 2 ☐

14. Physical containment:

15. List below all personnel (including students) who will be working on this project.

16. Have all personnel involved in this project been trained to the appropriate biosafety level? (attach screen shot for each training and each person)
Yes ☐ No ☐

Section III- Risks and safety: to be completed for covered (non-exempt) projects only

List the potential risks associated with the research and the safety precautions utilized to address those risks:
Potential Risks: Safety Precautions:

Section IV: An abstract of the research and objectives in layman's terms must also be submitted on a separate page. Some plans may require an additional form, "Registration of Potentially Infectious Material," to also be filed.

Below to be completed by EHS	
The laboratory was certified at BSL_____ on_____ by_____	Inspection was completed on_____ by_____
Below to be completed by the IBC Chair	
Registration approved on_____ by_____	This protocol approved for _____ and will be up for review _____