

Appendix A.: Application for the Use of Recombinant DNA in Research

Directions for Completing "Application for the Use of Recombinant DNA in Research"

Submission and approval of "Application for the Use of Recombinant DNA in Research" by the IBC is required for experiments described in the NIH Guidelines (May 1999), Sections III A through E. Additional approval by other agency(s) is also indicated for experiments described in the NIH Guidelines (May 1999), Sections III A through C.

1. Exemptions

The rDNA experiments listed below are exempt from NIH Guidelines (Section III F) and therefore do not require IBC approval (or completion of "Application for the Use of Recombinant DNA in Research"):

- A. Experiments using DNA that is not in an organism or virus. [Section III, F-1 of the NIH Guidelines]
- B. Experiments using DNA segments from a single nonchromosomal or viral DNA source. [Section III, F-2 of the NIH Guidelines]
- C. Experiments using DNA entirely from a prokaryotic host propagated only in that host. [Section III, F-3 of the NIH Guidelines]
- D. Experiments using DNA entirely from an eukaryotic host propagated only in that host. [Section III, F-4 of the NIH Guidelines]
- E. Experiments (exclusively) using DNA segments from different species that exchange DNA by known physiologic processes [Section III, F-5 of the NIH Guidelines].
- F. Experiments using DNA that are exempt under Appendix C-II of the NIH Guidelines.

If the experiments that are proposed are exempt according to the NIH Guidelines, do not complete "Application for the Use of Recombinant DNA in Research," instead complete the "Principal Investigator's Statement of Exemption" included in this packet and return it to the Environmental Health and Safety Office, attention BSO.

2. Information required for proposed experimental protocol (number 9 of the application):

In order for the IBC to thoroughly evaluate the proposed experiment(s), the Principal Investigator must provide the Committee with the following information:

- A. Sources of DNA (species, organ or tissue, etc.).
- B. Nature of the inserted DNA sequence.
- C. Describe hosts and vectors, and the host/vector combination(s) that will be used.
- D. Will a deliberate attempt be made to obtain expression of a foreign gene? If so, what protein will be produced?

- E. A risk assessment which addresses the following:
 - a. Virulence.
 - b. Pathogenicity.
 - c. Infectious dose.
 - d. Agent/environmental stability.
 - e. Route of spread.
 - f. Communicability.
 - g. Quantity, i.e., volume(s)/concentration(s) of the culture(s).
 - h. Availability of effective prophylaxis.
 - i. Gene product effects (e.g., toxicity, physiological activity, and allergenicity).
- F. Biosafety level specified in the NIH Recombinant DNA Guidelines.
- G. Procedures for storage, transport (both within and outside Old Dominion University), and disposal.
- H. Provisions for laboratory security including access control.
- I. Microbiological techniques that will be used. (e.g., mechanical pipettes, gloves, lab coats, etc.) Safety controls that are available for use when performing the experiment(s).
- J. Provisions for medical intervention (if necessary), either preventative or therapeutic available to laboratory personnel.
- K. A description of containment equipment (e.g., biosafety cabinets, centrifuge caps etc.) that will be used when manipulating the agent(s).
- L. Procedures for disinfecting surfaces and equipment, and sterilizing viable cultures of the agent(s) before disposal.
- M. Emergency procedures that will be taken in case of spills and personal contamination.
- N. Instruction and training for laboratory personnel.

Principal investigators should address each item such that there is enough detail for the IBC to decide whether the safety controls that will be employed comply with NIH Guidelines and are adequate to protect the safety of the employees and others and protect the environment. The IBC will review the information and consult with the Principal Investigator if there are any questions or concerns. The Principal Investigator will receive confirmation to proceed with the experiment(s) after all concerns are addressed.

IBC No.: _____

Date: _____

**Old Dominion University
Institutional Biosafety Committee**

Application for the Use of Recombinant DNA in Research

1. Principal Investigator: _____

Department: _____

Bldg.: _____ Room No.: _____

Phone No.: _____ Fax No.: _____

E-Mail: _____

2. Project Title* _____

3. Funding Source/ODURF No.: _____

4. Co-Investigator(s):

Investigator: _____ Phone: _____

Investigator: _____ Phone: _____

Investigator: _____ Phone: _____

5. Project Site(s):
(List each site where activities/procedures will be performed)

A. Investigator: _____ Site: _____

Activity/Procedure: _____

B. Investigator: _____ Site: _____

Activity/Procedure: _____

C. Investigator: _____ Site: _____

Activity/Procedure: _____

6. Laboratory Personnel: List laboratory personnel who will be working with the agents, and other persons who have a reasonable opportunity to frequent the laboratory. Specify the average amount of time per week the person(s) will be working with the agents:

7. Additional Committee Reviews Required (check appropriate box):

Radiation Safety Committee Human Subjects Committee Animal Care & Use Committee

8. Federally Mandated Category of Review: Check the boxes that describe all of the proposed uses of rDNA. Refer to the NIH Guidelines for a more detailed description of each category.

A. Experiments that require IBC approval, RAC (Recombinant DNA Advisory Committee), and NIH approval prior to initiation (Major Actions).

Deliberate transfer of a drug resistant trait to microorganisms not known to acquire this trait naturally. [Section III, A of the NIH Guidelines]

B. Experiments that require IBC and NIH/ORDA (Office of Recombinant DNA Activities) approval before initiation.

Cloning of Toxic molecules with LD 50 of less than 100 nanogram per kg of body weight. [Section III, B of the NIH Guidelines]

C. Experiments that require IBC and Institutional Review Board approval and NIH/ORDA registration prior to initiation.

Deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA into one or more human subjects. [Section III, C of the NIH Guidelines]

D. Experiments that require IBC approval before initiation

Using risk group 2,3, or 4 restricted agents as Host-Vector Systems [Section III, D-1 of the NIH Guidelines]

Cloning DNA for risk group 2, 3, or 4 restricted agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems. [Section III, D-2 of the NIH Guidelines]

Using infectious or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems. [Section III, D-3 of the NIH Guidelines]

Using whole animals. [Section III, D-4 of the NIH Guidelines]

Using whole plants. [see Sections III, D-5 E-2 of the NIH Guidelines]

Using more than 10 liters of culture. [Section III, D-6 of the NIH Guidelines]

E. Experiments that require IBC notice simultaneous with initiation

Forming rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus. [Section III, E-1 of the NIH Guidelines]

Using whole plants. [see Sections III, D-5 and E-2 of the NIH Guidelines]

Experiments involving transgenic rodents. [Section III, E-3 of the NIH Guidelines]

9. Using the Directions for Completing "Application for the Use of Recombinant DNA in Research as a guide, attach a description of the proposed experiments. Include all information as outlined in the directions.

10. Principal Investigator's Certification

I attest that the information contained in this application is accurate and complete. I agree to comply with the requirements pertaining to shipment, handling, transfer, and disposal of biohazardous agents, and rDNA. I am familiar with and agree to abide by the provisions of the current NIH Guidelines and other specific granting agency instructions pertaining to the proposed project.

I further attest that all my research personnel are familiar with and understand the potential biohazards, proposed precautions, and appropriate emergency procedures, and that the practices and techniques required to ensure safety will be followed. I agree to accept responsibility for training of all laboratory workers involved in the project.

I will submit written reports, as required, to the IBC (through the Environmental Health and Safety Office) concerning:

- A. Any accident that results in inoculation, ingestion, and inhalation of biohazardous agents or any incident causing serious exposure of personnel or danger of environmental contamination.
- B. Any problems pertaining to operation and implementation of biological and physical containment safety procedures or equipment or facility failure.
- C. Any new information bearing on the Guidelines such as technical information relating to hazards and safety procedures or innovations.

I will not carry out the work described in this application until it has been filed and/or approved by the IBC or until the requirements of all sponsoring agency(s) have been met.

Signature: _____

Date: _____

<p><i>For IBC use only</i></p> <p>Approval:</p> <p>IBC Chair _____</p> <p>BSO _____</p> <p>Member _____</p> <p>Member _____</p> <p>Date of Approval: _____</p>
--

Principal Investigator's Statement of Exemption

The following is a list of exempt activities for the use of rDNA under the NIH Guidelines (May 1999), Section III F. For more details, reference the NIH Guidelines. Check the appropriate box corresponding to the type of experiment(s) that you propose to conduct:

- Experiments using DNA that is not in an organism or virus. [Section III, F-1 of the NIH Guidelines]
- Experiments using DNA segments from a single nonchromosomal or viral DNA source. [Section III, F-2 of the NIH Guidelines]
- Experiments using DNA entirely from a prokaryotic host propagated only in that host. [Section III, F-3 of the NIH Guidelines]
- Experiments using DNA entirely from an eukaryotic host propagated only in that host. [Section III, F-4 of the NIH Guidelines]
- Experiments (exclusively) using DNA segments from different species that exchange DNA by known physiologic processes. [Section III, F-5 of the NIH Guidelines].
- Experiments using DNA that are exempt under Appendix C-II of the NIH Guidelines.

Submit this statement to the IBC (in care of the Environmental Health and Safety Office, attn. BSO) prior to initiating the experiment(s).

By submitting this statement to the IBC, I confirm that the project for which I am proposing to undertake is exempt from NIH Guidelines and that I acknowledge if non-exempt agents will be used, I will submit "Application for the Use of Recombinant DNA in Research" prior to acquisition/use of those agents.

Signature: _____

Date: _____