

University Biosafety Committee  
Standard Operating Procedures

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University of Delaware Biosafety Committee  
Standard Operating Procedures

1. Mission Statement

The University of Delaware recognizes the importance of conducting a broad spectrum of original research that may employ the use of biological agents. Cognizant that these activities may be accompanied by some risks and regulatory requirements, the University requires that research activities using biological agents be reviewed and approved by the University Biosafety Committee (UBC) to ensure that it is conducted in accordance with the National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the methods outlines in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual, and the University of Delaware Biosafety Manual.

As a research intensive institution, the University of Delaware supports basic research in these fields, but recognizes limitations on the types of agents that may be currently employed in research at the University. We do not currently have the capacity at the University of Delaware to work with Biosafety Level 4 agents or perform research involving the use of non-human primates. Moreover, research involving Biosafety Level 3 agents is highly restricted and reviewed on a case-by-case basis.

2. Policy Statement

It is the policy of the University of Delaware to ensure all activities related to the use of biological materials are conducted in a safe manner and in compliance with all federal, state, local, and University regulations (University Policy 7-19).

This policy governs the receipt, storage, transport, use, and disposal of hazardous biological agents and materials. It applies to all research, teaching or other activities using hazardous biological materials conducted at the University campus or by University faculty, staff or students when acting as representatives of the University at off-campus locations. All projects must conform to the guidelines and requirements set forth in the National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual, and/or the University Biosafety Manual.

3. UBC Charter

Date approved by committee: 10/3/13

Meetings:

The Committee shall meet no less than twice per year.

A quorum of the smaller of four or the majority of members shall be required to conduct the business of the Committee, to include at least a representative from Environmental Health and Safety, a faculty member, and a plant and/or animal expert if research involving this work will be reviewed at the meeting. Teleconference or videoconference meetings may be used.

Membership:

The committee will consist of at least one representative from each college performing biological research at the University, with a minimum of five members. There will be at least one animal containment expert and one plant containment expert on the committee. In addition, two community members who are not affiliated with the University will be appointed to the committee. The Director

of Environmental Health and Safety and a representative from the Provost's office are ex-officio non-voting members of the Committee. The Biosafety Officer is an ex-officio voting member of the Committee. The Biosafety Officer will serve as the Executive Secretary for the committee.

Prospective members of the committee are identified by the Biosafety Officer and the departments/colleges to be represented. Community members are identified by the Biosafety Officer or other members of the UBC. Once a member is identified who is interested in serving, the recommendation is sent to the Vice Provost for Research for his/her consideration and appointment. Members of the committee will be appointed for three year terms, with the option of being re-appointed. Committee members are expected to attend the UBC meetings.

The candidate for chair of the committee will be selected by a vote of the committee membership. The recommendation is submitted to the Vice Provost for Research for his/her consideration and appointment. The chair must be a tenured faculty member. The chair will serve for two years, with the option of being re-appointed.

#### Responsibilities:

Review and approve grants involving recombinant DNA research in accordance with the NIH *Guidelines*. This will include the following responsibilities:

Establish review procedures. Conduct initial review and approve or disapprove all proposals involving recombinant DNA research. Investigators will be notified of committee decisions.

Conduct periodic review of recombinant DNA research at the University of Delaware to ensure compliance with NIH *Guidelines*. Reviews will be done on an annual basis.

Set containment levels as specified in NIH *Guidelines*.

Adopt emergency plans for accidental spills and personal contamination.

Report any problems, violations, accidents, or illnesses and their investigation/resolution related to recombinant DNA research to the Provost or his designee and to NIH/OBA.

Withhold authorization of any experiments involving recombinant DNA not explicitly covered by NIH *Guidelines* until NIH establishes the containment requirements.

Maintain records of meeting minutes, protocol reviews, and other documents related to the committee's work and the use of recombinant DNA at the University.

Arrange for dissemination of review requirements, containment levels, emergency plans, and other information related to recombinant DNA research to researchers and technical staff.

Assume the responsibility for the biological safety aspects of all University programs involving the use of biohazardous agents (reference Policy 7-19).

The Biosafety Officer will act on behalf of the UBC to review and grant (or deny) permission for the use of biohazardous agents within the University. Approval is necessary before a project involving these agents can be initiated.

Review and prescribe special conditions, requirements, and restrictions that may be necessary for safe handling of biohazardous agents. For example, the Committee may require: students, staff and researchers to pass an oral or written examination, worker physical examinations (e.g. blood titers, PPD, respiratory protection, required vaccinations, etc), upgrading of facilities (biosafety cabinets, hoods, autoclaves, etc), special designation of areas of use within the laboratory, posting of additional caution signs, use of special disposal methods, use of special handling procedures, and special procedures to be followed after contamination events or incidents.

The Biosafety Officer and/or the Research Office will serve as a liaison with the NIH for research involving materials covered under the NIH *Guidelines*.

Receive and review periodic and/or urgent reports from the Biosafety Officer regarding:

- A. Exposures of individuals to biohazards and subsequent investigations.
- B. Loss or theft of biohazardous agents and subsequent investigations.
- C. Records of Select Agent purchase/transfer.

Recommend and/or initiate remedial actions when safe procedures are not followed under an authorized project, jeopardizing personnel or environmental safety, or when procedures are not in compliance with government regulations or University policy. If necessary, this may involve the termination of permits or authorizations of personnel, or confiscation of biohazardous agents. Authorize the resumption of operations, stopped by the Director of Environmental Health and Safety, when the operations are again in compliance with the regulations. This will be done according to the procedures in the University Biosafety Manual.

Keep a written record of actions taken in approving or disapproving the use of biohazardous agents and reports involved in the work of the Committee.

Delegate to the Biosafety Officer or their designee the authority to review, grant, or deny temporary authorizations for the use of biohazardous agents during the interim between meetings. Such authorizations shall be subject to final approval or denial after a review at the next scheduled Committee meeting.

Arrange for and/or conduct a periodic management audit of the Biosafety Program. The audit shall include a review of the overall effectiveness of the University Biosafety program. An audit report shall be presented to the Vice Provost for Research.

#### 4. Scheduling of Meetings

Meetings will be scheduled in advance and the dates will be posted on the UBC web page. If additional meetings are necessary they will be scheduled. Meetings are open to the public.

#### 5. Committee Votes

At meetings where 2/3 or more of the committee members are present, majority approval is needed for any committee business including rDNA project approvals. If a meeting consists of less than 2/3 membership, but above quorum, a unanimous approval is needed for committee business including rDNA project approvals.

#### 6. Conflict of Interest

UBC members will not be involved in the review or approval of a project in which they are taking part. Members will be expected to recuse themselves during review of projects in which they are involved. If needed, an alternate expert will be identified by the Biosafety Officer to advise on the project if the only area expert on the committee is involved in the project.

#### 7. UBC Minutes

Minutes will be maintained for all UBC meetings that take place. The meeting minutes will include at least the date, time, and place of the meeting, a list of persons in attendance of the meeting, approval of meeting minutes, major points of order and major motions, lists of rDNA approvals reviewed and/or approved, and time of adjournment. Minutes will be available upon request to the public.

#### 8. Reporting to NIH- annual registration, changes to committee, incident reporting

The committee membership registration will be updated with NIH OBA at least annually or when membership changes as per current NIH *Guidelines*. The UBC will notify NIH OBA of any significant problems or violations and any significant research related accidents and illnesses within 30 days as per the NIH *Guidelines*. This will be done by the Biosafety Officer and will be copied to the Compliance Officer. Information on incident reporting to NIH is available at <http://oba.od.nih.gov/oba/ibc/FAQs/FAQS%20about%20Incident%20Reporting.pdf> .

#### 9. Procedures for rDNA protocol reviews

Any research involving work with recombinant DNA must be registered with the UBC according to the NIH and University Policy. The *Recombinant DNA Registration Form* is completed by the researcher to initiate the process. A copy of the current NIH *Guidelines* is available on the website (<http://www.udel.edu/ehs>) as reference.

Upon completion of the registration form, a UBC member must review the project. Any UBC member may request additional members assist with this initial review of the proposal. When the committee member completes the review, the form is sent to the Biosafety Officer. If the UBC member and Biosafety Officer approve of the project, a copy of the signed registration form will be sent to the researcher as provisional approval of the project for grant application purposes. Exempt level projects may be initiated once the approval of the UBC member and Biosafety Officer are obtained. For non-exempt projects, the protocol must be reviewed at a UBC meeting in order to obtain final approval, thus permitting work to begin. The project must be reviewed and updated on an annual basis. The Biosafety Officer initiates this process.

A researcher may apply for a single approval of all related work that meets the **exempt** definition under the NIH *Guidelines*, rather than be approved on a project-by-project basis. To receive approval, the Principal Investigator (PI) must complete the *Recombinant DNA Registration Form*. Section I must be completed, using the "General Work Description" option to describe the type of procedures to be done by the lab group. "Project Title" is left blank. In Section II, Category A is marked. A description of the types of recombinant DNA procedures to be performed by the lab group is attached. The *Registration Form* is then submitted to a UBC member for approval, followed by the Biosafety Officer. This approved form is valid for one year from the date of the Biosafety Officer's signature. After one year, the *Recombinant DNA Registration Form* must be resubmitted and approved. It is the PI's responsibility to assure that the work being submitted with the grant complies with the submitted and approved procedures. If it is found that the grant was not under the exempt status, or the work procedures differed from what had been approved, the approval and funding for the project may be jeopardized. If a PI wishes to perform work that varies from what has been approved, he or she must complete a new registration form. These procedures apply to exempt work ONLY. All non-exempt work must be approved on a project-by-project basis.

Related rDNA projects may be registered using one "blanket" form, to cover more than one related rDNA project. This decreases the number of forms completed, as well as expediting the start of new, yet related, projects immediately, without having to wait for a new approval. This can be done if the rDNA work **does not** result in different gene functions of the recombinant DNA, relative to what is native in the genome.

An example of related projects includes analysis of gene function through targeted deletions of genes in one organism; if a handful of genes will be studied, they could be described in the registration form as "Targeted deletion of genes in the genome of organism X, in order to study gene function". This will eliminate the need to fill out a new form and get a new approval for each gene being deleted. A second example is if the rDNA work involves fusion proteins with reporter genes, a blanket rDNA form might be described as "Analysis of multiple gene functions in organism X, using reporter constructs".

Blanket registration forms may not be written for anything where the gene function is going to be altered or increased. Examples include, but are not limited to, over-expression of genes, and placing a gene from one organism into another.

If a "blanket" registration form is submitted, it will be up to the discretion of the UBC to determine whether this is acceptable and fits into the preceding guidelines.

#### 10. Lab Inspections

Lab inspections for biological use labs will be performed by an EHS member at least once every two years and in accordance with the risk assessment for the lab. Lab inspection records will be maintained for three years.

#### 11. Training for UBC members

The UBC committee will take part in training regarding their responsibilities. This will be provided at the committee meetings and may be provided as separate training sessions as well. The training will include,

at a minimum, the committee's responsibilities, implementation of the NIH *Guidelines*, and lab safety especially in regards to recombinant DNA. Records of this training will be maintained for three years.

#### 12. Training for Researchers using rDNA

All users of biological materials must complete biosafety training prior to work with biologicals. In addition, anyone working on a non-exempt rDNA project must complete rDNA Research Training. This training can be completed through a live session provided by EHS, or by a web-based training. Biosafety Training is required every two years, and rDNA Research Training is required every three years. Records are maintained for three years.

#### 13. UBC Authority

If an imminent hazard is identified, EHS will act to mitigate the imminent hazard and then advise the Research Office and the UBC Chair. EHS and the UBC will work with the Research Office to ensure the hazard or compliance issue is addressed before operations are reinstated. In the event of an issue that is not of immediate concern from a safety or regulatory compliance perspective, the issue will be reported to the Research Office by EHS or the UBC Chair and the Vice Provost or his designee will act to address the issue.

#### 14. Record Retention

UBC meeting minutes and documents will be maintained for three years. Recombinant DNA registration forms will be maintained for three years or until a project is completed, whichever is longer. Lab inspection reports and training records will be maintained for three years.

#### 14. Charter Revisions

The UBC charter will be reviewed and updated by the committee. The committee will vote to approve any changes to the charter.

Registration #: \_\_\_\_\_



**University of Delaware**  
**Department of Environmental Health & Safety**  
**Recombinant DNA Registration**



**Directions:** Please complete this form to register recombinant DNA research with the University Biosafety Committee (UBC) as required by the most current "Guidelines for Research Involving Recombinant DNA Molecules" (NIH *Guidelines*) and University Policy 7-19.

*Submit a separate form for each project. A copy of the current Guidelines is available at the EHS web site: <http://www.udel.edu/ehs/>. For questions, please contact the Biosafety Officer at 831-8475.*

**Section I- to be completed for all projects**

Principal Investigator:	
Department:	
Address:	
Phone Number:	Fax:
Email:	
Labs to be used:	
<i>For exempt work:</i> General Work Description:	
<i>For non-exempt (covered) work:</i> Project Title:	
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 UBC, 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 the Biosafety Officer and the UBC of any adverse events, including research-related accidents and illnesses. The Principal Investigator certifies that the work description is accurate. Any work performed which is not approved under this permit may be subject to the loss of grant funds. This registration must be updated annually.

Signature of Investigator:

Date:

## **Section II- to be completed for all projects**

Check the appropriate registration category for experiments covered by the NIH Guidelines:

*All categories are defined in the NIH Guidelines*

### **A. Experiments which are exempt and do not require registration.**

Examples include rDNA that is: not in organisms and viruses; entirely DNA segments from a single nonchromosomal or viral DNA source; entirely 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; entirely from a eukaryotic host when propagated only in that host or a closely related strain of the same species; entirely segments from different species that exchange DNA by known physiological processes; or not a significant risk to health or the environment.

*If work is exempt, attach a description of the recombinant DNA procedures to be performed.*

### **B. Experiments that Require IBC Approval, Recombinant DNA Advisory Committee Review, and NIH Director Approval Before Initiation.**

Deliberate transfer of a drug resistance trait to a microorganism that is not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture

### **C. Experiments that Require NIH/ORDA and IBC Approval Before Initiation.**

Cloning of toxin molecules with LD<sub>50</sub> of less than 100 nanograms per kilogram body weight

### **D. Experiments that Require IBC Approval, Human Subjects Approval, and NIH/ORDA Registration Before Initiation. Submit completed Appendix M, I-V from the NIH *Guidelines* along with this document.**

Deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (human gene transfer)

### **E. Experiments that Require IBC Approval Before Initiation**

- 1. Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems
- 2. Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic Host-Vector Systems
- 3. Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in

tissue culture systems

- 4. Experiments involving recombinant DNA in animals or transgenic whole animals
- 5. Experiments involving whole plants, to include exotic infectious agents that may impact ecosystems, transmissible exotic infectious agents in the presence of their specific arthropod vectors, sequences encoding vertebrate toxins introduced into plants or associated organisms, or microbial pathogens of insects/animals associated with plants if microorganism may impact ecosystem
- 6. Experiments involving more than 10 liters of culture

**F. Experiments that Require IBC Notice Simultaneous with Initiation**

- 1. Formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus in tissue culture with no helper virus
- 2. Recombinant DNA modified plants that are noxious weeds or can interbreed with noxious weeds. Plants associated with recombinant DNA modified non-exotic microorganisms which have the potential for serious impact on ecosystems. Recombinant DNA modified arthropods or small animals associated with plants if these materials have no serious impact on ecosystems
- 3. Experiments involving recombinant DNA modified whole plants or organisms (if not included in Category E5 above)
- 4. Generation of transgenic rodents where genome is altered by stable introduction of rDNA into germ line, if it requires only BSL1 containment

**Section III- to be completed for covered (non-exempt) projects only**

1. Names of individuals participating in project, with job title:
2. Source(s) of DNA/RNA sequences (include genus, species, gene name and abbreviation):
3. Is a vector required? <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> If yes, identify specific phage, plasmid, or virus: Virus vector: Adenovirus <input type="checkbox"/> Retrovirus <input type="checkbox"/> Other <input type="checkbox"/> Defective: <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> Replication competent: <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> If viral vector, what percent of the viral genome remains?
4. If the recombinant contains viral DNA, does the insert represent more than 2/3 of the viral genome? <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/>
5. Is a helper virus required? <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/> If yes, specify:
6. What is the biological activity of the gene product or sequence inserted?
7. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA? <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/>
8. Host strain for propagation of the recombinant (give genus, species, and parent strain):

<p>9. Target recipient of recombinant DNA (indicate species or cell lines used):</p> <p>Animals: _____ Tissue Culture: _____</p> <p>Plant cells: _____ Plants: _____</p> <p>Gene therapy: _____</p> <p>Specify target host(s) - human, animal species: _____</p>
<p>10. Proposed biosafety level for project (check one): 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/></p>
<p>11. Have all personnel involved in this project been trained to the appropriate biosafety level?  <b>Yes</b> <input type="checkbox"/> <b>No</b> <input type="checkbox"/></p>
<p>12. Dual Use Research- Check any categories below that apply to your project:</p> <p><input type="checkbox"/> Renders a useful vaccine ineffective</p> <p><input type="checkbox"/> Adds antibiotic resistance affecting response to a clinically useful drug</p> <p><input type="checkbox"/> Enhances pathogen virulence</p> <p><input type="checkbox"/> Increases pathogen transmissibility</p> <p><input type="checkbox"/> Widens a pathogen's host range</p> <p><input type="checkbox"/> Enables a pathogen to evade diagnostic or detection modalities</p> <p><input type="checkbox"/> Weaponization (e.g. environmental stabilization of pathogens)</p> <p><input type="checkbox"/> None of the above</p>
<p>13. <b>Be sure to attach a description of the recombinant DNA procedures to this form.</b> Include the following items: nature and purpose of the project; outline the procedures and techniques; risk to personnel; practices/equipment/facilities to protect the personnel; methods to inactivate and dispose of the agents. Sufficient detail must be provided to understand the project and review the rDNA procedures.</p>

**Section IV- For UBC Use Only**

<p><input type="checkbox"/> Project/work exempt from recombinant DNA NIH <i>Guidelines</i>.  <b>(Make sure Work Description is attached).</b></p>
<p><input type="checkbox"/> Project/work requires registration according to NIH <i>Guidelines</i>. The PI and staff can safely perform this work with the training, work practices, and lab facilities listed.</p>
<p>The following signatures indicate provisional approval by the University Biosafety Committee for this project involving recombinant DNA technology. The work is to be performed according to NIH requirements. Final approval for projects that are NOT exempt from the NIH <i>Guidelines</i> will not be granted until after review by the entire UBC at the next meeting. Non-exempt work covered under this approval cannot begin until final approval is received.</p> <p><b>UBC Member Conducting Review</b></p> <p>Print Name: _____</p> <p>Signature: _____</p>

Date:

**Biosafety Officer**

Print Name:

Signature:

Date:

Expiration date:

Final UBC approval date:

UBC Representative Signature:

UBC Comments: