Drexel University and Drexel University College of Medicine
University Biosafety Committee (UBSC)
Policies and Procedures
September 28, 2009

I. Objectives

The University Biosafety Committee (UBSC) is a University-wide group Committee responsible for reviewing and approving recombinant DNA research and research involving the use of biological substances, toxins and cytotoxic carcinogens. The UBSC has overall oversight responsibility for the Biosafety Program at Drexel University College of Medicine (DUCOM) and Drexel University (DU). The committee operates in accordance with the National Institutes of Health (NIH) Guidelines and the Center for Disease Control and Prevention (CDC). It also periodically reviews previously approved research projects for changes which would necessitate increasing or decreasing the Biological Safety Levels. Once a project has been approved, an approval letter is sent to the principal investigator; this letter lists the project's UBSC approval number(s), containment levels set by the UBSC, project titles, and any additional requirements.

Specifically, the UBSC evaluates research projects that use recombinant DNA, agents that are infectious to humans, animals and plants, other potentially infectious materials such as select agents and biological toxins, human materials including blood, cells, unfixed human tissues and other body fluids, xenotransplants; however, it will NOT review clinical trials involving gene transfer. At present the UBSC does not have the required expertise to review recombinant DNA studies involving plants.

The UBSC coordinates its application procedures with Department of Safety and Health (DSH), in order to ensure that research personnel have adequate occupational health monitoring, training on safe work practices, exposure control emergencies and use of personal protective equipment (PPE). The UBSC carries out these functions as guided and regulated by the federal Office of Biotechnology Activities (OBA), CDC guidelines entitled Biosafety in Microbiological and Biomedical Laboratories (BMBL) and federal Occupational Health & Safety Administration (OSHA) and institutional guidelines, policies and procedures.

The UBSC is composed of faculty investigators from both campuses with expertise in recombinant DNA and biohazards research, as well as two community members, a Biosafety Officer and a recombinant DNA Officer in accordance with the NIH guidelines
(**http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf**.)

In conjunction with the Office of Regulatory Research Compliance (ORRC) and DSH, the UBSC oversees the Biosafety Program for laboratory research with recombinant DNA and biohazards on the DU and DUCOM laboratories. This includes the review

and approval of all new research involving recombinant DNA and biohazards; continued review of approved research projects; review of laboratory inspection reports; investigation of complaints and concerns, and review of training and a medical surveillance programs. The Vice Provost for Research Compliance is the Responsible Official under the University's registration with the CDC/ USDA Select Agents Program. The University's Select Agents Program in conjunction with DSH manages the permits, inventory, security, facility containment and safety operations of all select agents.

II. Policies

The DU/DUCOM UBSC has the charge of reviewing and approving the biological safety of all DU's and DUCOM's basic and clinical research activities involving recombinant DNA, microorganisms, viruses, and biological toxins. Research use of human biological samples such as blood, blood products, sera, secretions, excretions, swabs and tissue samples are also reviewed by the UBSC. Prior to the commencement of any project involving the use of such material, the Principal Investigator (PI) must take the following steps:

PLEASE NOTE: (The UBSC will NOT review human gene transfer studies and recombinant DNA studies involving plants).

1. Review the applicable guidelines and regulations and become familiar with the biological safety procedures and requirements. Appropriate places to review these guidelines are listed below.

   A. DU/DUCOM Policies and procedures and Laboratory Safety Manual posted on **http://www.research.drexel.edu/compliance/biosafety/default.aspx**.

   B. Obtain DSH training and certification, in order to ensure that research personnel have adequate occupational health monitoring, training on safe work practices, use of recombinant DNA material and select agent training, exposure control emergencies and use of PPE. Online training is provided at the following website: **http://www.drexelsafetyandhealth.com/index.asp?page=training.asp**.

   C. The National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA Molecules* **http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_GdInes_Ink_2002z.pdf**.

   D. The Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) publication entitled *Biosafety in Microbiological and Biomedical Labs* **http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm**.

   E. The CDC/United States Department of Agriculture (USDA) Select Agent Program **http://www.selectagents.gov/**.

F. 32 CFR Part 626 Biological Defense Safety Program **and** 32 CFR Part 627 Biological Defense Safety Program, Technical Safety Requirements (DA Pamphlet 385-69).

G. The annual Occupational Safety and Health Administration (OSHA) *Bloodborne Pathogen Standard* **http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051&p_text_version=FALSE**.

H. The Occupational Safety and Health Administration (OSHA) *Occupational Exposure to Hazardous Chemicals in Laboratories*

2. Perform a risk assessment of the agents and procedures to determine potential safety and environmental hazards. See CDC guidance on performing the risk assessment at **http://www.cdc.gov/od/ohs/biosfty/bmbl5/Biological%20Risk%20Assessment%20Section%202_%20Final%20Document.pdf**.

3. Develop laboratory specific Standard Operating Procedures (SOPs) based on the risk assessment, guidelines and regulations

III. Training

To obtain web-based online safety training in the areas listed below go to: **http://www.drexelsafetyandhealth.com/index.asp?page=training.asp**

List of training courses available on the above website:

1. Student Orientation Training: College of Medicine, College of Nursing & Health Professions, School of Public Health
2. Packaging and Shipping of Biomedical Materials*****
3. Research Personnel Laboratory Safety Training******
4. Facilities Personnel SPCC Training
5. Clinical Practice Group Training*******

* Required training for shipping research specimens.

** Provides laboratory equipment training for DU and DUCOM personnel in addition to DU personnel BBP training.

*** Specific BBP training for DUCOM faculty and staff (REQUIRED TRAININGS MUST BE DONE ANNUALLY).

For other training requests, please contact the Department of Health and Safety. (215) 895-5919.

Web-based Training for using select agents

https://apps.research.drexel.edu/train/login.asp.

Web-based Training to work with Recombinant DNA Material

https://apps.research.drexel.edu/train/login.asp.

IV. Type of Research Registered or Reviewed by the UBSC

Experiments involving the following must be registered with the UBSC:

- Pathogens affecting humans, animals or plants;

- Materials potentially containing human pathogens (e.g., unfixed human specimens, human blood);
- Recombinant DNA molecules including viral vectors;
- Human cell lines that are not well-characterized or require Biosafety Level 2 containment;
- De novo generation of transgenic animals (using recombinant DNA technology to add foreign DNA or subtract a portion of the animal's genome). Examples of recombinant DNA technology include (1) Direct microinjection of a chosen gene construct from another member of the same species or a different species into the pronucleus of a fertilized ovum; (2) Insertion of the desired DNA sequence by homologous recombination into an in vitro culture of embryonic stems and cells; (3) Use of a plasmid or virus to transfer the genetic material into germ cells;
- De novo generation of transgenic plants (Not permitted at the present time);
- Introduction of recombinant DNA (plasmids) or gene transfer vectors (including viral vectors) into human subjects (sent to Western Institutional Review Board Biosafety Committee);
- Introduction of genetically engineered micro-organisms or infectious agents into human subjects including live vaccines if they are experimental in nature and/or not FDA-approved for use in the specific study population. (sent to Western Institutional Review Board Biosafety Committee);
- The analysis of, or experimentation, with sera, blood products, or other human specimens (secretions, excretions and tissue) in DU/DUCOM research laboratories or those labs that are NOT accredited with the College of American Pathologists (CAP) or with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
- Research protocols involving the use of toxins (select agents), chemical carcinogens, hazardous chemicals and cytotoxic drugs and
- Research protocols involving the use of hazardous chemical, biological and carcinogenic agents in animals.

Note: For details on the experiments covered by NIH guidelines go to Section III of NIH Guidelines:
http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf.
Copies of these guidelines are also available at the Office of Regulatory Research Compliance.

V. UBSC Meetings

The UBSC meets once per month generally on the third Tuesday of each month. Principal Investigators or his/her representatives are encouraged to attend the meeting to answer questions raised by the committee, but they cannot be present during the discussion and voting. The ORRC publishes a calendar on its website **http://www.research.drexel.edu/compliance/biosafety/default.aspx**.) of scheduled meetings for the academic year and will notify the investigator when the investigator's protocols are reviewed. The calendar will also list the deadline dates for each of the monthly meetings.

VI. Standard Review Process

A. Experiments Exempt from UBSC Review

The following recombinant DNA molecules are exempt form the NIH Guidelines and registration; therefore, UBSC review or registration is not required. Experiments than can be considered exempt do not present a significant risk to the health or the environment such as:

1. Those that are not in organisms or viruses.
2. Those that consist entirely of DNA segment from a single non-chromosomal or non-viral DNA source, though one or more of the segments may be synthetic equivalent.
3. Those that consist entirely of DNA from a prokaryotic host including the indigenous plasmids or viruses when prolonged only in the host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
4. Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers is available in the NIH Guidelines for recombinant DNA (Appendices A-I through A-VI, exemptions Under Section III-F-5-Sublists of Natural Exchangers).

B. Submission of Registration or Protocols for Review

Only DU and DUCOM faculty (instructor or above) are permitted to submit applications for the use of biohazards and recombinant DNA materials in research. Postdoctoral fellows and visiting faculty may only submit the application under the sponsorship of faculty member of DU or DUCOM. All individuals named on the application must receive immunizations and training specific to the biohazard materials used, as appropriate, prior to the approval of the UBSC application. Documentation or training must be on file in the DSH and ORRC. DSH will forward the confirmation of training to ORRC. According to OSHA regulations, these trainings MUST be done annually.

The UBSC application consists of the following essential elements:

1. The Office of Research Transmittal Form
2. UBSC Application form for use of human samples
3. UBSC Application and registration form for the use of Recombinant DNA material
4. Animal Addendum
5. Chemical Addendum
6. The technical portion of the grant proposal or contract, if applicable that proposes the use of human samples or animals

NOTE: The Office of Research Transmittal Form and UBSC application for use of human samples could be part of the IRB application. In that case the ORRC will forward these forms to UBSC and you need to apply for registration separately. Registration to obtain human samples is a "one time" registration for that particular human sample. Multiple human samples can be registered on the same application if obtained for the same study. There is no deadline for submission.

Review levels may vary depending upon the risk level. Registrations for the use of human samples will generally be reviewed as expedited unless the risk level is higher than level 2. In that case, a full board UBSC application/registration is required.

C. Pre-review Process

All complete UBSC applications arriving on time (see calendar for submission dates) will be assigned to a pre-review team by the chair or Vice Chair of the UBSC or the Vice Provost for Research Compliance. The ORRC Biosafety Coordinator will prepare the pre-review packages and send them to the designated reviewers. The pre-review members will be identified as either a primary reviewer (P) or a secondary reviewer (S) on the cover sheet of each application.

The pre-review team will receive the entire application/registration (UBSC form and all other applicable documents such as UBSC protocol, or the technical portion of the grant).

The review process is a team effort. The steps and responsibilities of the pre-review processes are:

1. The primary reviewer is responsible for gathering the comments from the secondary reviewer and combining the comments into a single list of recommendations. The primary reviewer will provide the comments to the Principal Investigator via e-mail.
2. The investigator will make appropriate changes and submits an electronic version of the revised form and responses within the due date for review by the UBSC.

D. UBSC Review and Review Actions

Revised applications will be sent to each member of the committee for full committee review.

1. The primary reviewer is responsible for presenting the application at the meeting. If the primary reviewer cannot attend the meeting, he /she must submit their comment to secondary reviewer ask the secondary reviewer to present the protocol.
2. After discussions are complete, the investigator may be asked to appear before the committee to answer any questions the committee may have and the investigator leaves the room before the vote is taken.
3. Committee Actions:

a. Approve the protocol: If the members vote to approve a protocol at the meeting, the ORRC will prepare an approval letter for the Chair's signature. A copy of the approval notice will be sent to the Principal Investigator within five working days.
b. Table the protocol for substantive change: This action indicates that there considerable safety issues and the approval is not without substantial revisions. The investigator will receive a letter within seven (7) days describing the reasons for tabling the study and outlining the necessary revisions for reconsideration by the UBSC. The pre-review panel may confer with the investigator to review committee concerns and issues. A revised copy of the protocol must be submitted within 90 days for review by the committee. ***The investigator must also submit a point-by-point response in a cover letter.*** Tabled protocols require full board review at a convened meeting before it can be approved.
c. Defer approval of protocols with pending minor changes: If UBSC votes to defer approval pending changes, the ORRC will communicate those changes to the investigator within five (5) working days via e-mail or fax. The investigator will submit the changes to the protocol and form in a point-by-point response on a cover letter to the ORRC. The ORRC will forward the response to the Chair for approval. The Chair may ask the pre-reviewers, or the whole committee, to evaluate the acceptability of the revisions.
d. Ad-Hoc approval: When pending conditions are met and upon review by the Chair, the Chair may approve the protocol and the ORRC will prepare the approval letter for Chair's signature and the ORRC will send the approval letter to the investigator.

E. Amendments

Any proposed modifications to an approved protocol must be approved by the UBSC prior to implementation. This includes, but is not limited to changes to procedures, or addition or deletion of laboratory personnel. Investigators requesting for changes must submit a letter to the Chair of the UBSC describing in detail the proposed modifications, justification for the proposed changes and any effects that the modifications may have on the safety of laboratory personnel; if the amendment involves the use of new biohazards, the investigator should also submit the appropriate sections of the protocol/registration review forms. **The chair may decide that the amendment represents significant procedural changes that require the submission of a new UBSC protocol.** Alternatively, the Chair of the UBSC, on an Ad-Hoc basis, may approve the proposed changes amendments; depending upon the nature of the proposed changes, the Chair may request co-review by additional members of the UBSC to render a decision to approve the protocol as amended.

F. Continuing or Periodic Review

All activities involving recombinant DNA and other biohazards (except human pathological samples) must be reviewed annually. To this end, each principal investigator of an approved protocol will receive a request to complete a Continuing/Periodic Review Form each year 60 and 30 days prior to the anniversary date of the initial UBSC approval. This form solicits information regarding whether there have been any changes to the protocol, changes in the personnel, changes in the laboratory locations, etc. **The completed form must be retuned to the ORRC no later than two weeks prior to the anniversary dated. Otherwise, the protocol will be administratively inactivated.**

The forms that have been submitted will be reviewed by the UBSC at its monthly meetings. If there are no problems, the committee may vote to allow the protocol to remain active for another year. If problems are observed or suggested, further investigation by the UBSC may be necessary and although rare, suspension or termination of the protocol may be required. The investigator will be notified in writing the outcome of the UBSC's review of the periodic/continuing review.

G. Renewal

Generally, UBSC protocols are approved for three years. To renew a protocol beyond three years for which there has been no change to the protocol a pre-review is not required and the application should be submitted to ORRC for full review and approval.

H. Electronic Voting on Protocol Approval

At the discretion of the Chair, the committee may use the audiovisual form to assemble a meeting to approve or make modifications to the protocol. Protocols not involving recombinant DNA, but those protocols that can receive expedited review, the Chair at his/her discretion may be sent electronically to committee members for their review and electronic vote.

I. Exceptions to Standard Review Process – Expedited Review

1. **Identical to a Previously Approved protocol**

   The Chair or Vice Chair can approve a protocol based upon the fact that a protocol is identical in type, amounts, and usage of biohazards to the previously approved protocol by the same investigator. The approval period will have the same termination date as the original protocol. This approval is reported and voted on at the next UBSC meeting.

2. **Protocols Meeting Expedited Review Criteria**

   The Chair or Vice Chair can approve a protocol based upon the fact a protocol meets certain criteria for expedited review (applicable to the certain recombinant DNA/bloodborne pathogen category).

   - For BL-1 experiments that employ E coli K12-derived plasmid vectors, phages and DNA sequences which are not derived

from pathogenic viruses or organisms. If the recombinant DNA aspects of the protocol can be safely carried out in BL-1 containment, but the cell lines or body fluids are derived from humans. Under these conditions the experiment would require BL-2 containment. A certified biosafety cabinet is required for such experiments.

- For experiments that do not involve the use of recombinant DNA but utilize human cell lines, tissues or body fluids under the guidelines recommended for universal precautions. These experiments must be carried out in BL-2 containment but approval can be expedited provided the proposed experiments do not involve recombinant DNA or BL-2 or higher and do not employ any known pathogens.
- Experiments involving generating transgenic animals that can be performed at BL-1 containment.
- If an application receives a preliminary recommendation as a BSL1 application and/or if the application involves only human materials, the application may be expedited.
- In expedited review, the application is circulated to the USBC Chair, the BioSafety Officer, and another voting member for review. These three (3) persons review the protocol in depth and vote on appropriate biosafety containment and any additional practices/procedures. Should the application require BSL2 containment (with the exception of human), the application will be brought to the full committee for review. Otherwise, the expedited review group will approve the application at the approved BSL on behalf of the committee. The UBSC will be placed on the agenda and voted at the next convened meeting of any expedited applications.

- The expedited review process pertains to protocols that only involve biohazards and may not be used for recombinant DNA research that is not exempt.

VII. Termination or Inactivation of Protocol/Registration

Protocols are approved for three (3) years. A protocol may be terminated or inactivated by the principal investigator at any time during this approval period by notifying the UBSC in writing or, as part of the continuing/periodic review process by completing the appropriate section on the continuing/periodic review form. A protocol may be administratively inactivated by the UBSC if the principal investigator fails to submit the continuing/periodic review form as required by the annual continuing review process or safety concerns.

VIII. UBSC Inspections

The UBSC in conjunction with DSH inspect laboratories where biohazards are known to be used. Investigators are sent, in advance, an Inspection Checklist

that they should complete to assist the inspection team at the time of inspection. After inspection, a report is prepared listing the deficiencies and a timetable for the correction of deficiencies. The principal investigator is responsible for correcting the deficiencies and training of laboratory staff. Failure to take corrective actions will be reported to the UBSC and the UBSC may take appropriate action including the suspension or termination of the approved protocol.

IX. Office of Regulatory Research Compliance

The role of the ORRC is to ensure the effective functioning of the UBSC and to aid the Institutional/Responsible official. The ORRC is responsible for providing information and update guidelines issued by the NIH Office of Biosafety Administration. All documents associated with the UBSC, i.e., minutes, protocols, membership roster and annual reports to the agencies are maintained at ORRC. The ORRC coordinator can be reached by calling (215) 255-7857 or by e-mail at **mf23@drexel.edu**.

X. Department of Safety and Heath

The DSH is responsible for the development and implementation of polices and procedures designed to create a safe workplace environment that is conducive to learning and research. DSH's goal is develop compliance programs that meet and/or exceed regulatory standards and to promote standardized practices for all campuses that reduce the overall risk of injury to human health or the environment. DSH is the central training site and it provides a variety of training sessions to University departments and personnel. Education is an integral part of any effective safety and health program. Its purpose is to inform employees of standardized practices and procedures that have been developed to protect the health and well being of employees, students, and visitors throughout all of our campuses. DSH training is mandatory for research protocol approval and some trainings are required annually. The DSH exists to serve University Departments and personnel. We offer a wide array of services designed to reduce the regulatory burden placed on Investigators and Practice Managers and assist University Departments and personnel in meeting their regulatory obligations. The DSH will routinely inspect all University areas including Research Laboratories and Clinical Departments in an effort to recognize and correct potentially hazardous situations as they arise. This proactive approach is necessary to limit the liability of our institution and to reduce the risk of injury and/or illness of our employees, students and visitors. For further information contact DSH at (215) 895-5919.