

Purpose & Charter

UMBI Institutional Biosafety Committee (IBC)

University of Maryland Biotechnology Institute

September 26, 2008

What is the Institutional Biosafety Committee (IBC)?

The Institutional Biosafety Committee (IBC) is a formal committee responsible for reviewing and approving recombinant DNA research and biohazard projects.

Purpose: The purpose of the University of Maryland Biotechnology Institute (UMBI) Institutional Biosafety Committee (IBC) is to provide advice and recommendations to research personnel for the purposes of conducting safe operations revolving around biomedical research and development while ensuring compliance with local, state and federal requirements. The IBC carries out these functions pursuant to requirements set forth by the National Institutes of Health, *NIH Guidelines For Research Involving Recombinant DNA Molecules* (<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>). The IBC will perform risk assessments in order to develop biosafety policies and procedures and to set containment levels that ensure the safety of UMBI's employees and the surrounding community. The IBC also periodically reviews previously approved research projects for changes which would necessitate increasing or decreasing the biosafety level. Once a project has been approved, an approval letter is sent to the principal investigator; this letter lists the project's IBC approval number(s), containment levels set by the IBC, project title(s), and any additional requirements.

Membership: The President, with assistance of the IBC Chair, recruits and nominates Institutional Biosafety Committee members. A Biosafety Officer is a permanent member and will serve as an administrative resource. Committee members will be drawn from the UMBI research programs and non-affiliated institutions to meet the requirements of the *NIH Guidelines*. These members will advise the organization on matters related to development of safe operational policies and procedures and approve appropriate research projects. At least two members shall not be affiliated with UMBI and will represent the interest of the surrounding community with respect to health and protection of the environment. By virtue of members' participation in the work of the committee, it is expected that the policies developed and recommended to the University, once approved by the President, will be accepted as binding. Members will serve on the committee for two years. Non-affiliated members will be compensated for their time and efforts to the committee. This includes parking fees, lunch, etc.

Chairperson: The Chair is appointed by the President. The chairperson may administratively approve research protocols without membership majority vote, if IBC voting members do not request committee discussion within ten business days after

the protocol is circulated for review. Approved protocols will be included in the minutes of the next IBC meeting.

Quorum: A quorum shall exist by or upon a majority of the voting members.

Meetings: Meetings will be scheduled not less than bi-annually or at the call of the chairperson. Robert's Rules of Order shall prevail at the meetings. All meetings shall be face to face and /or videoconference.

Sub-committees: The Institutional Biosafety Committee has authority to appoint subcommittees and ad hoc committees of subject matter experts to address specific issues.

Annual Review and Changes to this Charter: This charter will be reviewed annually. It may be modified or amended by approval of a majority of the voting members.

Functions and Tasks

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The University of Maryland Biotechnology Institute obtains funding from the National Institutes of Health for research activities. In accordance with Section IV-B-2 of the *NIH Guidelines For Research Involving Recombinant DNA Molecules (NIH Guidelines)*, an Institutional Biosafety Committee (IBC) must be formed.

The purpose of the IBC at UMBI is to: 1) provide a safe working environment for its employees, and 2) to comply with government laws and guidelines for the use of recombinant DNA. The overall management oversight of the IBC will be provided by the UMBI Office of Research, Innovation and Commercialization.

The information below describes only the functioning of the UMBI IBC and is not an exhaustive discussion of all requirements of the *Guidelines*. An internet link to the entire text of the *NIH Guidelines* is provided in Section 1, Purpose & Charter.

A. Membership and Procedures

1. The IBC will be comprised of at least five members who collectively have experience in recombinant DNA technology and the capability to assess the safety of recombinant DNA protocols.
 - a. At least two members will be unaffiliated with UMBI except for their memberships on the IBC. Affiliated persons are employees, vendors and consultants who are paid to perform duties or provide services in addition to IBC membership.
 - b. Further information on expertise required for members based on the character of recombinant DNA work is contained in Section IV-B-2-a-(1) of the *NIH Guidelines*.
 - c. The IBC must include persons with expertise in recombinant DNA technology, biosafety, and physical containment and include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment. At least one member of the laboratory technical staff must be included.
2. The IBC shall file an annual report with NIH/OBA which includes a roster of all IBC members (including short CVs) and clearly indicating the Chair, contact person and other members by expertise in accordance with Section IV-B-2-(a)-3 of the *NIH Guidelines*.
3. No IBC member may be involved, except to provide requested information, in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

4. All IBC meeting minutes, protocols, and documents submitted to or received from public funding organizations must be maintained on file and made available to the public in accordance with Section IV-B-2-(a)-7 of the *NIH Guidelines*, if requested.

B. IBC Functions

1. The IBC will meet on at least a bi-annual basis and at other times to be scheduled by the IBC Chair based on research need.
2. The major function of the IBC will be to review recombinant DNA protocols relevant to publicly-funded and/or human gene therapy research, and protocols involving pathogens, and Select Agents and Toxins. The registration form will be filled out by the relevant principal investigator and submitted to the Chair of the IBC. Timing of the submission with respect to commencement of work and various levels of approval required are discussed below under C. Levels of Review.
3. Review of protocols by the IBC will include, at a minimum; 1) independent assessment of the Biosafety Level required by the NIH Guidelines for the proposed research, 2) assessment of the facilities, procedures, practices and training and expertise of all personnel who will be working under the protocol, and 3) ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements of the NIH Guidelines.
4. The IBC may pre-review protocols either in person through meetings or by circulation of the protocol to members. In the latter case, the IBC shall seek documentation of individual member approval. This may be accomplished by any convenient means (e.g. email, sign-off sheet, etc.) as deemed appropriate by the IBC Chair.
5. Approval of protocols will be by a simple majority of members in attendance at a convened face-to-face and/or videoconference meeting. The IBC Chair must ensure that all decisions are scientifically defensible and that dissenting opinions are carefully weighed.
6. The IBC will notify principal investigators of the results of protocol review in a timely manner.
7. Existing protocols will be reviewed on at least an annual basis to ensure their accuracy and relevance. Such protocols will be reauthorized, remanded to the principal investigator for further information, or cancelled.
8. The IBC Chair will ensure that notification and reporting of research related injuries and illness is carried out in accordance with Section IV-b-2-b(7) of the NIH Guidelines. The IBC also retains responsibility for adopting emergency plans covering accidental spills and personal contamination resulting from recombinant DNA research.
9. Experiments which have not been explicitly covered by the NIH Guidelines may not be authorized by the IBC until NIH establishes containment levels.
10. The IBC is responsible for continuous assessment of recombinant DNA research at UMBI to ensure that any newly applicable requirements of the NIH Guidelines are implemented.
11. When the IBC has formal business to conduct, such as approving proposed research, it must be convened in a manner that is interactive and accessible and that allows for the preparation of written meeting proceedings. This is in keeping with the provisions of the NIH Guidelines that

encourage institutions to accommodate public attendance at meetings (Section IV-B-2-a-(6)) and that speak to the preparation of minutes (Section N-B-2-a-(7)).

12. With respect to the review of proposed recombinant DNA research, the NIH Guidelines cite a number of matters that the IBC should consider as appropriate. These matters are described in Section II-A-3 and Section III of the *NIH Guidelines* and include:
 - Agent characteristics (e.g. virulence, pathogenicity, environmental stability)
 - Types of manipulations planned
 - Source(s) of the inserted DNA sequences (e.g., species)
 - Nature of the inserted DNA sequences (e.g., structural gene, oncogene)
 - Host(s) and vector(s) to be used
 - Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced
 - Containment conditions to be implemented
 - Applicable section of the *NIH Guidelines* (e.g., Section III-D-1, Section III-E-1, etc.)

C. Levels of Review

1. Increasing levels of review and approval are required for recombinant DNA (R-DNA) experiments as they increase in biohazard and/or as they progress toward the clinic. These are not fully discussed here but are described in Sections III-A through III-C of the *NIH Guidelines*. The hierarchy of approvals beyond the IBC refers to clinical applications and includes the Institutional Review Board (IRB) of the clinical facility, the NIH/OBA, the NIH Recombinant DNA Advisory Committee (RAC) and the NIH Director. The IBC will initiate these reviews as needed.
2. Internal review falls into three categories; 1) protocols requiring IBC review/approval before initiation, 2) experiments requiring IBC review/approval concurrent with initiation, and 3) protocols that the IBC registers, but that the NIH considers to be exempt experiments. Sections III-D through III-F of the *NIH Guidelines* should be consulted for a more complete discussion.

a. Approval before initiation

- Transfer of drug resistance trait to microorganisms that are not known to acquire the trait naturally.
- Cloning of toxin molecules with LD₅₀ of less than 100 μ g per kilogram body weight.
- Deliberate transfer of R-DNA or DNA or RNA derived from R-DNA into human research participants.
- Use of BSL-2 or higher host-vector systems.
- Cloning of DNA from risk group 2 or greater agents or restricted agents into lower prokaryotic or eukaryotic host-vector systems.
- Use of risk group 2 or higher infectious DNA/RNA viruses (wild-type or defective) in presence of helper virus in tissue culture.
- Experiments involving whole vertebrate or invertebrate animals or plants.
- R-DNA involving or generating transgenic animals.
- Experiments involving ≥ 10 liters of culture.

b. Submission/review concurrent to initiation

- R-DNA molecules $\leq 2/3$ of a eukaryotic viral genome of any Eukaryotic virus.

- R-DNA-modified arthropods or small animals associated with plants or with arthropods or small animals with R-DNA-modified microorganisms associated with them if the R-DNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems.
- Experiments involving transgenic rodents in which the animal's genome has been altered by stable introduction of R-DNA into the germ-line.

c. Exempt, but IBC-registered experiments

- Experiments not in organisms or viruses.
- DNA segments from a single non-chromosomal or viral source or synthetic equivalents.
- DNA consisting entirely of segments from one prokaryotic or eukaryotic source. Includes plasmids/viruses normally propagated in the relevant host.
- DNA from different species which are natural DNA exchangers.
- Those that meet the definition of no "significant risk" in Section III-F-6 of the *NIH Guidelines*.

D. Responsibilities of Principal Investigators

1. Ensure full compliance with all applicable sections of the *NIH Guidelines* and with the policies stated in the UMBI Biosafety Manual and Bloodborne Exposure Control Plan.
2. Complete and submit protocols using the "UMBI IBC Registration of Human Materials, Human or Animal Pathogens & R-DNA form" for R-DNA experiments requiring review before and concurrent with initiation.
3. Complete and submit protocols using the "UMBI IBC Registration of Human Materials, Human or Animal Pathogens & R-DNA" form for R-DNA experiments claimed as exempt from the *Guidelines*.
4. Remain in communication with and provide information to the IBC as requested throughout the review/approval process.
5. Report all significant problems, violations or research related accidents and illnesses to the Chair of the IBC.
6. Be adequately trained in biosafety and good microbiological techniques.
7. Make protocols describing work, potential biohazards and precautions available to all employees who will work under the protocols.
8. Ensure that employees are adequately trained in biosafety, safe work practices, emergency procedures, and medical requirements and provisions.
9. Supervise the safety performance of employees and correct work errors and conditions which may compromise biosafety or result in release of R-DNA materials.
10. Ensure the integrity of physical containment equipment (e.g. biosafety cabinets) and biological containment (purity, genotypic/phenotypic characteristics).

UMBI IBC Registration Instructions

UMBI procedures require all Principal Investigators register their research with human materials, potential pathogens, recombinant DNA, or select agents with the UMBI Institutional Biosafety Committee (IBC). The form "UMBI IBC Registration of Human Materials, Human or Animal Pathogens & R-DNA" is available at the UMBI website

<http://www.umbi.umd.edu/research-development/compliance/path-human-tissue-rdna.php>

Human Materials Registration: Human material(s) to be registered include human tissue samples, blood, serum, plasma, internal body fluids (semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid) and any body fluid that is visibly contaminated with blood) from patients, volunteers, or cadavers as well as human-derived tissue culture cells. Common laboratory cell lines including HEK293 and HeLa are not exempt and must be registered. Also included are unfixed tissues or organs from a human (living or dead), HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV- or HCV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV or HCV.

Pathogens or Potential Pathogens Registration: Potential pathogen(s) to be registered include all bacterial, viral, fungal, parasitic microorganisms with a potential for vertical or horizontal transmission. Host-specific viruses and viral vectors commonly used for gene transfer must also be registered. This includes, but is not limited to, adenovirus, MuLV, and other commercially available or investigator-generated modified lentiviral and retroviral-based vectors.

Recombinant DNA Registration: Recombinant DNA to be registered includes all research involving the use or manipulation of recombinant DNA. Recombinant DNA research is defined by the *NIH Guidelines* [Section IB] as either molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or DNA molecules that result from the replication of molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. Recombinant DNA experiments considered "exempt" as defined within the *NIH Guidelines* must also be registered.

Select Agent Registration: Select agent(s) are listed by the HHS Centers for Disease Control and Prevention (CDC) and the USDA Animal Plant Health Inspection Service (APHIS). These materials are considered: Non-overlap select agents and toxins; High consequence livestock pathogens and toxins (overlap agents); or USDA high consequence livestock pathogens and toxins (non-overlap agents and toxins). Laboratories intending to obtain select agents must be registered with CDC or APHIS through the UMBI Responsible Official and adopt the UMBI Security Policy. Contact the research compliance officer gilpin@umbi.umd.edu for more information.

Laboratory Animal and Human Subjects Registration: Research with laboratory animals must be coordinated with the UMBI Animal Care and Use Committee. Research with human tissue may require coordination with the UMBI Institutional Review Board. The IACUC protocol submission forms are available at the UMBI website <http://www.umbi.umd.edu/research-development/compliance/vertebrate-animal-iacuc.php>

Research with human subject must be registered with the UMBI Institutional Review Board. The IRB protocol submission forms are available at the UMBI website <http://www.umbi.umd.edu/research-development/compliance/human-subjects.php>