The University of Kentucky
Institutional Biosafety Committee

By-laws
Revised February 23, 2015

1. **Definitions**
   In construing these By-Laws the following words shall have the meaning herein given, unless a contrary intention clearly appears.

   a. **Biohazard**: (adapted from IOS/IEC Guide 51:1999) potential source of harm from biological agents; includes infectious agents and recombinant or synthetic nucleic acid molecules.
   b. **Biological Safety Officer (BSO)**: an individual appointed by an institution who has expertise in the biohazards encountered in the organization and is competent to advise top management and staff on biorisk management issues. The NIH Guidelines require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at BL-3 or BL-4. The duties of the BSO are described in section IV-B-3 of the NIH Guidelines.
   c. **Biorisk**: (adapted from OHSAS 18001:2007) combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence (in terms of accidental infection, toxicity or allergy or unauthorized access, loss, theft, misuse, diversion or release of biological agents or valuable biological materials) of such an exposure.
   d. **Committee on Safety and Environmental Health**: The Committee on Safety and Environmental Health exercises advisory and other stated responsibilities for the Biological, Chemical, Environmental, Fire, Accident, Industrial Hygiene, Occupational Health, and Radiation Safety programs of the University. The roles of the Committee and its various subcommittees relate to fire, accident, and other general safety matters and to the acquisition, safe use and disposition of radioactive and other hazardous materials. The Committee functions within the context of established external regulations, University policies, and recognized standards for the safe conduct of operations.
   e. **Dual Use Research of Concern (DURC):** On September 24, 2014 the United States Government (USG) issued the USG Policy for Institutional Oversight of Life Sciences Dual Use research of Concern (DURC. This policy is complementary to the USG Policy for Oversight of Life Sciences DURC which was released on March 29, 2012. The institutional policy requires that institutions strengthen their review and oversight of life sciences research project that could meet the current definition of DURC.
      Dual use research is defined by the USG as "research conducted for legitimate purposes that generate knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes". Dual use research of concern is a subset of this broader category. DURC is defined as "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security".
   f. **Institutional Biosafety Committee (IBC):** The IBC is subcommittee of the Committee on Safety and Environmental Health which
      i. Meets the requirements for membership specified in Section IV-B-2 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules November 2013 (NIH Guidelines)
      ii. Reviews, approves, and oversees projects in accordance with the responsibilities of the Institutional Biosafety Committee (defined in Section IV-B-2 of the NIH Guidelines).
   g. **Institution**: Specified in these by-laws as the University of Kentucky.

h. **National Institutes of Health (NIH):** One of the world's foremost medical research institutions and the preeminent federal funder of medical research in the U.S. The NIH, comprised of 27 separate Institutes and Centers, is one of eight health agencies within the Public Health Service, which is an agency within the U.S. Department of Health and Human Services. The goal of NIH research is to acquire knowledge to help prevent, detect, diagnose, and treat disease and disability. The NIH mission is to uncover knowledge that will lead to better health for everyone.

i. **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines):** A document created in 1976 that outlines principles for the safe conduct of research employing recombinant or synthetic nucleic acid molecules technology. The NIH Guidelines detail practices and procedures for the containment of various forms of recombinant or synthetic nucleic acid molecules research, for the proper conduct of research involving genetically modified plants and animals, and for the safe conduct of human gene transfer research. As a "living" document, it is periodically revised to keep pace with the changing state of science.

   i.

j. **President**: president of the University of Kentucky

k. **Recombinant and Synthetic Nucleic Acid Molecules:** In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:

   i. molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;

   ii. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or

   iii. molecules that result from the replication of those described in (i) or (ii) above.

   Additionally, synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the *NIH Guidelines.*

   Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the *NIH Guidelines* unless the transposon itself contains recombinant DNA.

l. **Select Agents and Toxins:** biological agents and toxins deemed by the Secretary of Health and Human Services and listed in 42 CFR 73.3 which have the potential to pose a severe threat to public health and safety

2. **Name**

   The name of this Committee shall be the University of Kentucky Institutional Biosafety Committee.

3. **Location**

   The Committee shall be located in Lexington, Kentucky. The mailing address shall be:

   Chairperson
   Institutional Biosafety Committee
   Department of Biological Safety
   505 Oldham Court
   Lexington, KY 40502

4. **Purpose and Authority**

   The Institutional Biosafety Committee and its Chairperson(s) are appointed by the President of the University.

The IBC is a sub-committee of the Committee on Safety and Environmental Health, mandated by UK Administrative Regulation 6.9. The Chairperson(s) of the Institutional Biosafety Committee is(are) automatically a member(s) of the Committee on Safety and Environmental Health.

The IBC is charged to carry out the functions required under National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules including policy and procedure recommendations; compliance reviews; investigation of potential violations of the Guidelines; individual research project approval; and the certification that facilities, procedures, and practices and the training and expertise of the personnel involved have been reviewed and approved. The IBC is also required by UK Administrative Regulation 6.9 to serve as an advisory committee on the use of infectious agents to include: policy and procedure recommendations and individual research project approval. The IBC maintains confidentiality as appropriate. The IBC also reviews research as required by USG policy for DURC per the University of Kentucky Institutional Biosafety Committee Proposed Plan for Compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (available on request from the Institutional Biosafety Officer).

The IBC is responsible for reviewing recombinant or synthetic nucleic acid molecule and biohazardous research conducted at or sponsored by the institution, regardless of funding source or location of research, for compliance with the NIH Guidelines as specified in Section III, Experiments Covered by the NIH and other appropriate guidelines and University policies, and approving those research projects that are found to conform to the Guidelines, UK policies, and other federal, state, and local regulations regarding biological safety. This review shall include:

(i) Independent assessment of the containment levels required by the NIH and other appropriate guidelines for the proposed research;

(ii) Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecules and biohazardous research; and

(iii) Ensuring compliance with all surveillance, data reporting, reporting of significant incidents, problems, and violations, and adverse event reporting requirements required by the NIH and other appropriate guidelines. Establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecules and/or biohazardous research and that ensure compliance with NIH guidelines in Section IV-B-1f, Section IV-B-2.

To ensure compliance with the NIH Guidelines when the Institution participates in or sponsors recombinant or synthetic nucleic acid molecules research involving human subjects the institution must ensure that: (i) the Institutional Biosafety Committee has adequate expertise and training (using ad hoc consultants as deemed necessary) and (ii) all aspects of Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Subjects (Points to Consider) , have been appropriately addressed by the Principal Investigator prior to submission to NIH/OBA.

5. Membership Provisions

a. Composition and Appointment

The Committee is appointed by the President of the University and has membership as follows:

i. <u>Membership</u>

The Institutional Biosafety Committee must be comprised of no fewer than six Members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecules technology and the capability to assess the safety of Recombinant or synthetic nucleic acid molecules research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the Institution (apart from their membership on the Institutional Biosafety Committee) and shall represent the interest of the

surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community).

ii. Special Members

1. At least one individual with expertise in plant, plant pathogen, or plant pest containment principles (who is a member of the Institutional Biosafety Committee) shall be appointed if the institution conducts recombinant or synthetic nucleic acid molecules research that requires Institutional Biosafety Committee approval in accordance with Appendix P, Physical and Biological Containment for Recombinant or synthetic nucleic acid molecules Research Involving Plants.
2. At least one individual with expertise in animal containment principles (who is a member of the Institutional Biosafety Committee) shall be appointed if the institution conducts recombinant or synthetic nucleic acid molecules research that requires Institutional Biosafety Committee approval in accordance with Appendix Q, Physical and Biological Containment for Recombinant or synthetic nucleic acid molecules Research Involving Animals.
3. Other appropriate individuals with expertise in such fields as human gene therapy trials shall also be appointed or consulted to ensure adequate expertise for review of submitted protocols.

iii. The Chairperson of the Committee

The Chairperson of the Committee shall be a tenured member of the University of Kentucky faculty.

iv. Ex-Officio Members

These shall include the Biosafety Officer, a veterinarian of the University of Kentucky and others if the Institutional Biosafety Committee deems it necessary and they shall have full voting privileges.
The presence of an UK Department of Laboratory Animal Research (DLAR) Veterinarian on the committee satisfies the requirement to have at least one individual committee member with animal expertise and facilitates collaboration between the IBC and the Institutional Animal Care and Use Committee (IACUC).

v. Non-voting Members

Administrators or other members of the University community may participate in the IBC deliberations as non-voting members, as deemed desirable or necessary.

vi. Alternate Members

Former IBC members may serve as alternate members, with full voting privileges, and substitute for a current member with similar expertise. These are the only substitute representatives permitted.

vii. Community Observers

When possible and consistent with the protection of privacy and proprietary interests, the Institution is encouraged to open its IBC meetings to the public. In the event of exchange of proprietary or personnel information, community observers may be asked to leave the room. Minutes of the IBC meetings are available to the public upon request.

b. Eligibility

In order to ensure the competence necessary to review and approve recombinant or synthetic nucleic acid molecules activities, the Institutional Biosafety Committee will include:

i. Persons with expertise in recombinant or synthetic nucleic acid molecules technology, biological safety, and physical containment;
ii. 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
iii. At least one member representing the laboratory technical staff.

c. **Terms of Office**
The regular members shall have staggered three-year terms so as to insure institutional memory.

d. **Resignation**
A member may resign at any time upon written notice to the President (copy to the Committee Chairperson) at least 15 days prior to the effective date.

Upon resignation, the director of Environmental Health and Safety shall recommend a replacement, pending approval by the IBC Chairperson and the President.

e. **Removal**
A member shall be removed only for good cause and only by the President upon the recommendation of a majority of the membership of the Committee. Good causes may include:

i. Change in eligibility status.
ii. Insufficient attendance at the Committee meetings.
iii. Insufficient diligent participation in the other required activities of the Committee including, for example, timely review of applications for authorization to use biohazards

f. **Special Provisions**

i. No member may appoint a designee to participate in the deliberations of the Committee meetings in the absence of a member except as described in "Alternative Members" (section 5-a-vi).
ii. No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) 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.
iii. Each member shall agree to and sign a confidentiality /non-disclosure agreement, to be in effect the entire term of the member's tenure on the IBC plus an additional two years.
iv. If a faculty member changes job duties such that the majority of his/her time is spent on administrative oversight of other faculty members, this member may either:
    1. Change to "non-voting" status and continue to review and participate in the discussions of protocols but abstain from voting
    2. Resign from the IBC

6. **Organization**

a. **Officers**
A tenured faculty member is appointed by the President to be Chairperson of the Committee. The Institutional Biosafety Officer or his designee shall serve as the ex-officio chairperson.

b. **Ad Hoc Committees**

To ensure the Institutional Biosafety Committee has adequate expertise and training, the Committee may designate an ad hoc committee subject to the following provisions:

i. With consent of the Committee, the Chairperson shall appoint the members of all ad hoc committees and shall designate the ad hoc committee chairperson. All members need not be members of the Institutional Biosafety Committee.
ii. Ad hoc committees shall have no separate substantive powers or authority for actions or decisions not ultimately subject to the approval of the Committee.
iii. A quorum for the transaction of ad hoc committee business shall consist of a simple majority of its members unless otherwise directed by the Committee.
iv. The ad hoc committee may also call upon ad hoc consultants as deemed necessary.

7. Duties of the Officers

a. Chairperson(s)

One chairperson or two co-chairs shall preside at all meeting of the Committee. He/she shall appoint membership of all sub-committees or ad hoc committees and shall designate the chairperson of said committees. He/she may assign such additional duties to other members of the Committee as deemed necessary to assist him/her in the conduct of the work of the Committee and which are not inconsistent or conflicting with the duties prescribed for those officers as indicated by these bylaws.

The chair or co-chairs will keep or cause to be kept in the Biological Safety Office a file of approved minutes of all meetings of the Committee. Records shall be retained electronically for 10 years.

b. Biosafety Officer

The Biological Safety Officer's duties include, but are not be limited to:

i. Periodic inspections to ensure that laboratory standards are rigorously followed.
ii. Reporting to the Institutional Biosafety Committee and the institution's research compliance official of any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware.
iii. Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecules research.
iv. Providing advice on laboratory security.
v. Providing technical advice to Principal Investigators and the Institutional Biosafety Committee on research safety procedures.

8. Meetings

The Committee shall meet at least quarterly upon due notice by the Chairperson, to conduct the business of the Committee. The Chairperson shall advise the members of the time and place of the meeting. In the absence of a meeting call from the Chairperson, and if pending business of the Committee needs to be resolved, a meeting can be called by any three of the regularly appointed members of the Committee or by the Director of Environmental Health and Safety or the Biological Safety Officer.

a. Time and Place of Meeting

Meeting shall be held at such time and place as shall be specified in the call of the meetings.

b. Notice of Meetings

Each member of the Committee shall be notified in writing or via e-mail of all regularly-scheduled meetings at least one week prior to the date of the meeting. Notification of meetings scheduled on short notice shall be via e-mail and /or couriered written notice.

The regular date, time and place of the meetings shall be posted on the webpage for the IBC or other suitable site accessible to the public.

c. Rules of Order

All business meetings shall be conducted in accordance with Robert's Rules of Order, newly revised, unless inconsistent with specific provisions of these bylaws.

d. Quorum

At least 6 of the voting members shall constitute a quorum for the transaction of business at any meeting of the Committee as long as relevant expertise is adequately represented to review the protocols involving recombinant or synthetic nucleic acid molecules. No business shall be acted upon by the membership of the Committee at any meeting at which a quorum, as herein defined, is not present and the only motion which the Chairperson shall entertain at such meetings is a motion to adjourn the meeting to a stated time and place. This shall not preclude the Committee from discussing issues of business in the absence of a quorum provided that no action is taken on such items of business. Adequate notice of the time and place of such adjourned meetings shall be made to the membership in accordance with these bylaws.

e. Voting

Each member, including ex-officio members, shall have one vote. Alternative members shall vote for the member they are substituting for.

i. If provisional approval has been voted for a protocol, pending completion of significant documentation, or other significant requirements, final approval may be granted through e-mail polling, with hard copies of the individual votes/e-mails attached to the minutes for that meeting.
ii. If provisional approval has been voted for a protocol, the Committee may delegate to the BSO the determination of completion of minor revisions and the granting of final approval.
iii. Approval is granted only when appropriate containment levels, facilities, procedures and practices and training and expertise of the personnel have been presented in the protocol registration documents.
iv. Members shall change to non-voting status when they move to administrative positions at UK.

f. Appeal of IBC Decision

A principal investigator (PI) who wishes to appeal a decision regarding his/her IBC registration may file an appeal to the IBC by submitting to the Biological Safety Officer, in writing, this intent as well as the reasons the decision should be changed or amended. To be considered at a scheduled IBC meeting, the written appeal must be received at least eight calendar days before that meeting.

g. Open/Closed Meetings

All meetings will be open to the public (per NIH Guideline Section IV B-2-a (6)), EXCEPT:

i. When personnel matters are considered
ii. When protection of privacy and proprietary interests is required
iii. When matters relating to Select Agents are considered

When these exceptions apply, the IBC may go into closed session.

h. Minutes

Shall be kept and will record therein the time and place of holding, the names of Committee members present and absent, a record of votes taken, and any other relevant business of the Committee.

Upon request, minutes shall be made available to the public. Portions which deal with proprietary issues or issues relating to Select Agents may be redacted in compliance with NIH Guidelines or 42CFR 73, 9 CFR 121, or 7 CFR 331. (NIH Guidelines: Section IV-B-a-(7))

i. **Public Comments**
If public comments are made on IBC actions, the IBC shall forward both the public comments and the IBC's response to the Office of Biotechnology Activities. (NIH Guidelines: Section IV-B-2-a-(7)).

9. **Amendment of Bylaws**
These bylaws may be amended at a regularly scheduled meeting by the affirmative vote of a majority of the full membership of the Committee, so long as consistency with all applicable State and Federal regulations regarding biological safety committee constitution and operation is maintained.

10. **Conflict of Interest**
A member with a conflict of interest on an issue will be allowed to participate in the discussion of the issue, but shall not be permitted to make any formal motions or to cast a vote concerning the topic at hand. The member shall be asked to leave the room during any vote affecting the conflict of interest area.

11. **Annual Report**

The IBC shall file an annual report with NIH/OBA each year which includes:

a. A roster of all IBC members, clearly indicating the Chair, contact person, Biological Safety Officer, plant expert, animal expert, human gene therapy expertise, one member of the technical staff and
b. Biographical sketches or CVs of all IBC members (excluding any private, personal information).

Approved by a majority vote of the University of Kentucky Institutional Biosafety Committee on

March 4th, 2015
Date

Thomas Chambers, PhD

Co-chair of the University of Kentucky Institutional Biosafety Committee

Doug Harrison, PhD

Co-Chair of the University of Kentucky Institutional Biosafety Committee

Brandy Nelson, MS

Biological Safety Officer