INSTITUTIONAL BIOSAFETY COMMITTEE CHARTER
UNIVERSITY OF MARYLAND
JUNE 1996
Revised and approved February 2016

Article I. Introduction

The UMD Institutional Biosafety Committee (IBC) is required by Section IV-B-1 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, November 2013, which states that "Each institution conducting or sponsoring recombinant or synthetic nucleic acid molecule research which is covered by the *NIH Guidelines* is responsible for ensuring that the research is conducted in full conformity with the provisions of the *NIH Guidelines*. In order to fulfill this responsibility, the institution shall: ... establish an Institutional Biosafety Committee..." The policy of the committee is to work cooperatively with researchers, faculty and staff while assuring compliance with the *NIH Guidelines*.

Article II. Responsibilities

The responsibilities of the IBC are derived from those listed in the *NIH Guidelines*. The IBC will:

1. Review recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* and approving those research projects that are found to conform to the *NIH Guidelines*. The IBC may not authorize initiation of experiments that are not explicitly covered by the *NIH Guidelines* until NIH (with the advice of the Recombinant DNA Advisory Committee when required) establishes the containment requirement.

A. Experiments that require NIH and IBC approval prior to initiation – Sections III-A and III-B. The IBC will review the registration and make the determination that it requires NIH and IBC approval before initiation. If necessary, a registration packet will be submitted to the Recombinant DNA Advisory Committee (RAC).

B. Experiments that require IBC & IRB approval and RAC review prior to research participant enrollment – Section III-C. The IBC will review and approve all registrations involving the transfer of rDNA or synthetic nucleic acid molecules to human subjects at a convened meeting, and will determine whether RAC review is also required.

C. Experiments that require IBC approval before initiation – Section III-D. The Biosafety Officer (BSO) will review the registration and make the determination that it requires IBC approval before initiation. The IBC will review all registrations in this category at a convened meeting.

D. Experiments that require IBC notice simultaneous with initiation – Section III-E. The BSO will review the registration and make the determination that it requires notification of the IBC, and will inform

the PI that the registration has been reviewed and the containment level that is required. The BSO will submit the registration at the next IBC meeting for review and comment. At this time, the committee may change the conditions of the approval if it feels this to be necessary.

E. Experiments that are exempt from the NIH Guidelines – Section III-F. The BSO will review the registration and make the determination that it is exempt, and will inform the Principal Investigator (PI) that the registration has been reviewed and the containment level that should be used. The IBC will not review exempt experiments.

2. Notify the PI of the results of the IBC's review and approval. For research registrations that are approved pending minor changes, the BSO will follow up with the PI to ensure such changes are made and will add the registration to the following month's meeting agenda to discuss and document final approval.

3. Lower containment levels for certain experiments as specified in Section III-D-2-a of the *NIH Guidelines*.

4. Set containment levels that are not set by the *NIH Guidelines*.

5. Periodically review recombinant DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*. Research that is subject to the *NIH Guidelines* will be reviewed every four years.

6. Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.

7. Report any significant problems with or violations of the *NIH Guidelines* and any significant research related accidents or illnesses to the appropriate institutional official and to the NIH Office of Biotechnology Activities (OBA) within 30 days. Laboratory incidents shall first be reported to the Principal Investigator in the lab in which the incident occurred. The PI shall immediately notify the BSO, who will report the incident to the IBC. The IBC shall decide, based on the requirements of the NIH Guidelines, whether the incident requires reporting to OBA. Prior to sending to OBA, the incident report will be provided to the PI in whose lab the incident occurred for his/her comments. The final report will be sent to OBA jointly by the IBC Chair and the BSO.

8. Forward public comments made on IBC actions, and the IBC's response, to NIH OBA.

9. Perform such other functions as may be delegated to the IBC, including review of non-recombinant human pathogens and Select Agents and Toxins according to the current edition of the NIH/CDC publication *Biosafety in Microbiological and Biomedical Laboratories*.

A. Risk Groups 2 and 3 Pathogens. The IBC will review, approve, and assign containment for all registrations involving non-recombinant Risk Group 2 or Risk Group 3 human pathogens at a convened meeting.

B. **Select Agents and Toxins**. The IBC will review and approve all registrations of Select Agents and Toxins at a convened meeting.

C. Off-Campus Research. The IBC will review research sponsored by the University but conducted off-campus. The researcher will submit an explanation of the research and a copy of any IBC

approval (s) from the off-campus entity to the Biosafety Office. The Biosafety Officer (or designee) will review the research and provide all documentation to the IBC Chair. The Chair and BSO shall determine if the information provided is sufficient to allow administrative approval, or if full committee review is needed. When approved, the BSO will provide any necessary documentation to the researcher. Submissions will be categorized as "Off-Campus Research (OCR)" and records maintained by the Biosafety Office. OCR approvals shall be reported to the full committee at a convened meeting.

D. Dual Use Research of Concern. The Institutional Biosafety Committee (IBC) serves as University of Maryland's Institutional Review Entity (IRE) beginning September, 24 2015. This committee is charged with addressing the University's responsibilities to the *United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern* (DURC Policy) as well as any requests by the appropriate USG funding agency. The membership of the IBC is comprised predominantly of faculty from various disciplines engaged in research involving recombinant DNA who have received specific training in dual use research of concern. The IBC along with the Institutional Contact for Dual Use Research (ICDUR) serve on the institution's behalf ensuring compliance with the DURC Policy.

Article III. Membership

1. The IBC is comprised of no fewer than five (5) members so selected that they collectively have experience and expertise in recombinant DNA technology. The committee will include, but is not limited to:
    a. Two members who are not affiliated with the institution (apart from their membership on the IBC).
    b. One representative of the laboratory technical staff.
    c. At least one representative of the University of Maryland Institutional Animal Care and Use Committee, or an individual with expertise in animal containment principles,
    d. One individual with expertise in plant, plant pathogen, or plant pest containment principles.
    e. The Biosafety Officer.
2. Members are recommended by the IBC Chair to the Vice President for Research, who makes the appointment. The term of appointment is three (3) years, which is renewable.
3. The IBC Chair is appointed by the Vice President for Research.
4. Ad hoc members with appropriate expertise will be added to the committee and will attend meetings at which Dual Use Research of Concern is reviewed.

Article IV. Management

1. IBC meetings shall be scheduled at least monthly. Meetings may be canceled if there is no business to be conducted.
2. The review of all registrations shall take place at convened meetings at which a quorum of the members of the IBC is present. A quorum is defined as no fewer than five (5) members present.
3. A convened meeting shall be conducted in person, or via conference call.
4. The BSO shall serve as Executive Secretary and shall be responsible for preparation of the meeting minutes.

5. The *Biosafety Manual for University of Maryland* is incorporated into this charter by reference.
6. The BSO shall assign an approval number to each registration for tracking purposes. A separate registration will not be needed for each grant proposal unless a different host/vector/insert system will be used.
7. In the event that a member of the IBC submits a registration for review, she/he will be recused during the discussion and voting process for the registration. Additionally, an IBC member who is a collaborator or personal relative of a researcher whose registration is reviewed by the IBC will not be present during the discussion and voting process.
8. When official requests are made for meeting minutes or other IBC documents, the IBC contact will receive the request and meet with the UMD legal office to determine the information that will be redacted. The legal office will answer the request and send the final documents.
9. Research registrations must list the *funded* principal investigator as PI. Registrations of work being conducted by a private company connected with the university must list someone at the University as responsible, such as the chair or institute director.