UMBC

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IBC Charter
Institutional Biosafety Committee
University of Maryland Baltimore County
September 2016

Purpose:

The University of Maryland, Baltimore County (UMBC) Institutional Biosafety Committee (IBC) will review and approve or disapprove research with recombinant or synthetic nucleic acid (NA) molecules conducted and biohazardous materials used at or sponsored by UMBC for compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic NA Molecules (NIH Guidelines). The IBC will also review and approve or disapprove research conducted with microorganisms pathogenic to humans, plants, or animals in accordance with the publication Biosafety in Microbiological and Biomedical Laboratories 5th edition and their compliance with the NIH Guidelines. ALL research subject to IBC oversight requires IBC approval. The source of the funding does not alter this requirement. The IBC will provide recommendations to the Vice President for Research (VPR) for the development of University policies and procedures that will promote safe conduct of biomedical research and compliance with local, state and federal regulations.

The IBC will coordinate its protocol review processes with Institutional Review Board (IRB) review when a protocol requires review by both committees. Similarly, the IBC will coordinate its review processes with UMBC Institutional Animal Care and Use Committees (IACUC) review when review by both committees is required. When an IRB or IACUC protocol also requires review by the IBC, the work described in the protocol may not commence until both committees have approved the research.

Membership:

The VPR, with assistance from the IBC, recruits and nominates IBC members. All Biosafety Officer (BSO) responsibilities will be represented by UMBC Environmental Safety and Health (ESH); an ESH staff person is a permanent member of the IBC. Committee members will be drawn from UMBC's department and non-affiliated institutions to meet the requirements of the NIH Guidelines. At least two members shall be persons who are not affiliated with UMBC; those members will represent the interest of the community with respect to health and protection of the environment. Members will serve on the IBC for three year terms, and may be reappointed to successive terms. The VPR may remove a member for cause in the event of excessive absence or unavailability due to other responsibilities.

Chairperson:

The VPR, with assistance from the IBC, recruits and appoints the chairperson of the IBC from the membership. The chairperson will be a person affiliated with UMBC. The Chair directs the IBC in accordance with institutional and federal requirements. S/he works closely with IBC members, the VPR, ESH, ORPC and investigators to ensure that research and

other activities involving regulated or potentially biohazardous materials are conducted safely and in accordance with all applicable federal, state, and Institutional regulations, policies, and procedures. The chair calls the meeting and directs the meeting deliberations, requests motions and seconds, and closes the meeting once it has concluded business, approves the agenda for the convened meeting of the IBC and assigns subcommittees as needed to review an issue prior to official committee decisions made at the convened meeting.

IBC Responsibilities:

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

- Review recombinant or synthetic NA molecules research conducted and biohazardous materials used at or sponsored by UMBC for compliance with the NIH Guidelines, approving those research projects that are found to conform to the NIH Guidelines.
- Notify the Principal Investigator (PI) of the results of the IBC's review and approval or disapproval.
- Lower containment levels for certain experiments as specified in Section III-D-2-a of the NIH Guidelines.
- Set containment levels that are not set by the NIH Guidelines.
- Periodically (typically annually) review recombinant or synthetic nucleic acid molecule research conducted at UMBC for compliance with the NIH Guidelines.
- Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research.
- 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 NIH Office of Biotechnology Activities (OBA) in accordance with the NIH Guidelines, unless the IBC determines that a report has already been filed by the PI.

The IBC may not authorize initiation of experiments that are not explicitly covered by the NIH Guidelines until NIH (with the advice of the RAC [Recombinant Advisory Committee] when required) establishes the containment requirement.

Principal Investigator Responsibilities:

The Principal Investigator (PI), who conduct research involving recombinant or synthetic NA molecules and biohazards, should make the initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines and the most recent edition of the BMBL (Biosafety in Microbiological and Biomedical Laboratories). In addition, the PI

- should select the appropriate microbiological practices and laboratory techniques to be used for the research
- must submit an application form to the IBC and follow committee approval before any work begins
- needs to ensure that all staff listed have access to the currently approved protocol and have read the protocol before beginning work.
- should ensure that the staff listed on the protocol have sufficient knowledge and are sufficiently trained and documented to safely perform the responsibilities for which they have been assigned.

- should ensures that the protocol participants fully understand the steps necessary following any spills or potential exposures with the agents described in the protocol.
- should immediately report any suspected confirmed BSL-2 research-related illnesses as well as reporting any accidents, significant problems with or violation of the NIH Guidelines to UMBC ESH immediately and report to the spills or accidents that fall under the UMBC ESH process.

The PI also provides reports of the progress of the study including:

- Progress reports
- Adverse events or incident reports
- Modifications
- Changes to research team
- Premature closure/suspension of activities
- Final study closure or renewal of research activities.

Principal Investigators are responsible for complying with applicable policies and procedures of other compliance committees, such as the Institutional Review Board and the Institutional Animal Care and Use Committee.

IBC Procedures:

1. All administrative functions of the IBC will be handled, in conjunction with the Environmental Safety and Health, by the Office for Research Protections and Compliance. All recombinant or synthetic NA work, work involving the use of microorganisms pathogenic to humans, plants, or animals will be registered through ORPC.

2. Recombinant or synthetic nucleic acid molecule research will be reviewed as follows:

Experiments that require NIH and IBC approval prior to initiation- Section III A and III-B.

> The BSO will review the registration and determine if it requires NIH and IBC approval before initiation. A registration packet will be submitted to the Recombinant DNA Advisory Committee (RAC) and the IBC. The IBC will review and approve all registrations in this category at a convened meeting.

Experiments that require IBC and IRB approval and RAC review prior to research participant enrollment -III-C.

> The BSO with coordination with the IRB will review the registration and determine if it requires RAC review and IBC approval prior to initiation. The IBC will review and approve or disapprove all registrations in this category at a convened meeting.

Experiments that require IBC approval before initiation- Section III-D.

> The BSO will review the registration and determine if it requires IBC approval before initiation. The IBC will review and approve or disapprove all registrations in this category at a convened meeting.

Experiments that require IBC notice simultaneous with initiation- Section III-E.

The BSO will review the registration and determine if 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.

Experiments that are exempt from the NIH Guidelines - Section III-F.

The BSO will review the registration and determine if it is exempt, and will inform the PI that the registration has been reviewed and the containment level that should be used. The IBC will not review exempt experiments. (The IBC should receive details about this research)

3. Work involving the use of microorganisms pathogenic to humans, plants, or animals will be reviewed as follows:

Risk Group 2

The BSO will review registrations involving non-recombinant Risk Group (RG) 2 pathogens and notify the PI of the containment level required. The IBC will review the protocol.

Risk Group 3

Research with RG 3 pathogens is currently not permitted at UMBC.

Risk Group 4

Research with RG 4 pathogens is currently not permitted at UMBC.

Select Agents

Biological select agents and toxins (BSAT). The IBC and ESH will review and approve or disapprove all registrations of Biological select agents and toxins (BSAT) at a convened meeting and reviewed by the Institutional Official.

Quorum:

A minimum of 5 members must be present at IBC meetings in order to conduct business. If the quorum does not include at least one member who is not affiliated with UMBC, the chairperson may defer action on items in order to permit their consideration with community input.

Meetings:

Meetings will be held quarterly or at the call of the Chairperson.

Sub-committees:

The IBC has the 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 voting members of the IBC, subject to approval of the VPR.

Adopted: June 10, 2015
September 14, 2016