Institutional Biosafety Committee (IBC) Policy on Review of Research Protocols

1.0 Purpose: The purpose of this Institutional Biosafety Committee (IBC) policy is to provide information on University of Wisconsin-Madison Biosafety Protocol review process.

2.0 Scope: This policy applies to all University of Wisconsin-Madison personnel who are associated with the review of Biosafety protocols, including the University of Wisconsin-Madison Institutional Biosafety Committee, UW-Madison Office of Biological Safety, UW-Madison Principle Investigators, and UW-Madison employees and staff.

3.0 Related Documents/Resources

- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook
- UW-Madison, Office of Biological Safety - Workflow Standard Operating Procedure (BIO-SOP-001)
- U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules, Sept. 2009
- U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) - Biosafety in Microbiological and Biomedical Laboratories (BMBL), Fifth Edition

4.0 Definitions: Not Applicable.

5.0 Roles and Responsibilities

- **UW-Madison Institutional Biosafety Committee members:** provide expert advice, recommendations, and approval of Biosafety Protocols. Responsibilities defined under NIH Section IV-B-2.
- **UW-Madison Biological Safety Officer (BSO) or designee:** provide expert advice, recommendations, and assist IBC with review and approval of Biosafety Protocols. Responsibilities defined under NIH Section IV-B-2.
- **UW-Madison Principle Investigator (PI), designee, or other personnel:** having knowledge of a Biosafety Protocol and relevant studies. Responsibilities defined under NIH Section IV-B-3.

6.0 Policy: The University of Wisconsin-Madison Institutional Biosafety Committee (IBC) policy on Biosafety protocol review is as follows.

6.1 Membership of the Committee

The UW-Madison Institutional Biosafety Committee (IBC) is composed of faculty, a laboratorian, 2 public members, *ex officio* members, and consultants. The committee typically has 18 voting members; consultants are not voting members, and there is no

provision for designation of alternates to serve when a member cannot attend. Regular members are selected for their expertise in subjects for which the committee will review protocols, as follows, in accordance with NIH Section IV-B-2-a:

- One member with expertise in plant, plant pathogen or plant pest containment principles [NIH Sections IV-B-1-d, IV-B-2-a-(1), and IV-B-4].
- One member with expertise in animal containment principles [NIH Sections IV-B-1e, IV-B-2-a-(1), and IV-B-5].
- One member representing technical laboratory staff [NIH Section IV-B-2-a-(2)]
- Committee shall be composed of at lease five members, includes the UW-Madison Biosafety Officer (BSO) [NIH Section IV-B-2-a-(1)].
- Members sign confidentiality agreements.
- Members with expertise in areas of microbiology including virology, parasitology, bacteriology, and mycology.
- Members with expertise in recombinant techniques involving microbes, plants, and animals.
- Members with expertise in exotic organisms, particularly those regulated by USDA APHIS and VS, for which escape from containment would have significant consequences for the environment.
- Experience in working under Biosafety Level 2 and 3 containment in laboratory and animal facilities.
- Expertise in the areas of biological safety and physical containment.
- Human gene therapy (NIH Sections III-C and IV-B-6).
- Toxicology, to assess occupational risks of hazardous chemicals used to elicit a biological effect.

In accordance with NIH Section IV-B-2-a-(1), at least two members of the committee shall not be affiliated with the institution. They shall represent the interest of the community including health and protection of the environment. It is important that public members do not have a conflict of interest with the research that is conducted at this institution, such as a vested interest with financial gains at stake.

Ex officio members may be selected from the following areas:

- Graduate School, Associate Dean for Research Policy, or designee
- Campus Veterinarian or designee
- Safety Department Director
- Biological Safety Officer (BSO)

*Note: An **ex officio** member is a member of a body (a board, committee, council, etc.) who is part of it by virtue of holding another office.*

Consultants with the following expertise serve on the committee:

- Physical aspects of containment (equipment and ventilation)
- Human subjects
- Occupational health
- Legal affairs

6.2 Appointment Process and Length of Service:

The IBC members are appointed by the UW-Madison Chancellor. The BSO provides an annual update of the roster and recommendations to the Associate Dean for Research Policy. Regular members serve a 3-year term starting at the beginning of the fall term. At the conclusion of a 3-year term, they may elect to continue for an additional 3-year term or to rotate off the committee. The length of service for public members is indeterminate. Ex officio members serve as long as they are in their respective positions. The committee chairperson, a faculty member, usually serves in this capacity for at least 1 year.

6.3 Meeting Procedures and Protocol Reviews

6.3.1 Meeting Procedures

Meeting materials are prepared and distributed by OBS to members and consultants circa two weeks in advance of the meeting. The agenda includes review assignments, with designation of a primary and a secondary reviewer for each protocol. An ad hoc review will be sought by the BSO if a protocol comes before the committee for which relevant expertise is not adequately represented by committee members. Contacting the investigator in advance of the meeting is reasonable and recommended if the reviewer finds that additional information is needed to complete the assessment. It also is acceptable and sometimes necessary to seek the opinion of an expert outside of the committee, which requires written acknowledgement that the information provided in the protocol is to be handled in a confidential manner.

Meetings are conducted according to Robert's Rules of Order. Thus, the IBC cannot act on a protocol without a quorum present, which is defined as one more than half of the voting members. Attendance of meetings by voting members is critical. Committee members may be polled in advance of the meeting to ensure that a quorum will be met; otherwise, the meeting will be canceled. It is recognized, however, that members may not be able to attend every meeting.

Meetings may be audio recorded by OBS staff for the purpose of having an accurate record of the deliberations to assist in preparation of minutes, although there is no requirement that the meetings are recorded.

Reviews of protocols are performed primarily by regular members, who are assigned functions as primary or secondary reviewers. On occasion, an ex officio member who has relevant expertise may be asked to serve as a reviewer. The primary and secondary reviewers prepare an evaluation of the protocol for presentation to the committee at the meeting. If a reviewer cannot attend a meeting, comments on a protocol may be prepared and presented in absentia, whereby the BSO, IBC chair or designee may read their written comments to the committee. In the event both reviews are absent, reviewer's comments may be presented to the committee by the IBC Chair, BSO, or designee. Review by two designated reviewers is desirable but not essential for the committee to act on a protocol.

During review the following procedures usually occur:

1. The primary reviewer gives a brief overview of the protocol, highlighting the objectives, materials, procedures, apparent risks, and containment procedures.
2. The secondary reviewer then presents his/her perspective as it adds to or differs from the primary reviewer's comments.
3. The chair then seeks additional comments from committee members and consultants, and discussion ensues.
4. The chair calls for a motion, followed by a second and by further discussion and consideration of amendments to the motion, if necessary.
5. The vote is then called for those in favor, opposed, and abstaining.

In accordance with NIH Section IV-B-2-b (1), the IBC protocol review shall include:

- Independent assessment of containment levels required by the NIH Guidelines.
- Assessment of the facilities, procedures, practices, training and expertise of personnel involved in rDNA research.
- Ensure all aspects of NIH Appendix M are addressed by the PI (human gene transfer experiments, as applicable).
- Ensure no research participant is enrolled in human gene transfer until the RAC review process has been completed.
- Consider issues raised and recommendations made as a result of the human gene transfer RAC protocol review; consider PI response to RAC recommendations.
- Ensure final IBC approval is granted only after RAC review process is completed.
- Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH guidelines.

Actions by the IBC on a protocol typically involve one or a combination of the following decisions:

- Adopt. The protocol is accepted as provided to the committee.
- Adopt with recommendation(s). The protocol is approved as submitted with no further action required by the investigator.
- Adopt with contingency(s) that require the investigator to take additional steps before the protocol will be approved. Typically, the protocol must be revised to the satisfaction of the BSO and/or the reviewers.
- Table action. The protocol has significant deficiencies that must be addressed before the committee will reconsider it.
- Reject. This action is indicative of significant problems with the protocol.

The BSO and/or reviewers or designee send a memo to the investigator explaining the action taken by the IBC. When a member of the committee has a protocol on the agenda for which s/he is a Principal Investigator (PI) or co-PI, or otherwise has a vested interest in the outcome of the deliberation, the member may remain in the meeting room during the deliberation but may not serve as a reviewer and must abstain from offering comments unless called upon to answer a question or provide clarification. The member must abstain from voting on the motion.

6.3.2 Protocol Reviews

OBS will provide guidance to the investigator in advance of distribution of the protocol to the committee in order to facilitate review. In the event of a PI needing expedited IBC protocol review, the OBS strives to facilitate said IBC review. Although OBS has the discretion to withhold protocols from the agenda if the protocol is deemed not ready for review, this is generally a rare event. Investigators are always welcome to attend the IBC meeting in which their protocol will be discussed. In some cases, the IBC and/or BSO may request that the PI or designee be present for discussion of his or her protocol.

It should be noted that all communications initiated by PIs whose protocols are under consideration by the IBC should be directed to the BSO. PIs should not attempt to contact IBC members regarding their protocol which is under review. This policy is aimed at reducing conflicts of interest or appearances of conflicts of interest between the IBC and PIs whose protocols are under active review. The IBC may however request further information from the PI to facilitate review of the protocol.

IBC reviews of Biosafety protocols focus on the risks of the materials and the mitigating measures, and are very different from grant proposal reviews. The IBC does not judge the merits of the scientific inquiry or ethical considerations.

The following criteria are used when assigning new, updated, renewal, or amended protocols to the IBC for review:

- Experiments falling under NIH guidelines III-A, III-B, III-C, III-D, and III-E (All non-exempt protocols go to the IBC for review).
- Experiments involving microorganisms that are pathogenic to humans and/or animals (Risk Group 2 or higher).
- Experiments involving organisms that could have a significant impact on the environment if accidentally released from the lab (e.g., exotic plants, non-indigenous plant pathogens or regulated insects).
- Protocols involving issues that OBS is not able to resolve.

Examples of amendments that would merit review by the IBC involve addition of the following materials and/or procedures:

- Recombinant procedures subject to NIH Sections III-A, III-B, III-C, III-D and III-E of the Guidelines.
- Extension of the protocol to include administration of biohazardous materials to animals.

6.3.3 Biological Safety Protocols not requiring full review by the IBC.

Protocols not requiring a full IBC review will be reviewed by the Office of Biological Safety (OBS) according to SOP (BIO-SOP-001). Such protocol reviews may include simple administrative amendments, non-recombinant DNA protocols, and protocols which are exempt from the NIH Guidelines. Once the applicable protocol has been reviewed and approved by the OBS, OBS administrative staff will send the protocol approval registration form to the PI. A list of these OBS approved protocols is also provided to the IBC for review and discussion at the monthly IBC meetings, and for IBC committee member approval, as applicable.

7.0 Document Revision:

Revision History		
Revision Number	Revision Date	Description of Revision
1		
2		

Original signed & dated Policies are retained by the Office of Biological Safety

Signature	Date
Professor Susan West, IBC Chair	06/23/2010