

## **Institutional Biosafety Committee (IBC) Policy on Conduct of Meetings in Open Session**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to provide information on IBC meetings and that they are to be conducted in an open session, unless otherwise noted.
- 2.0 Scope:** This policy applies to all members of 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:**
- University of Wisconsin-Madison, Office of Biological Safety (OBS) - Institutional Biosafety Committee (IBC) Handbook.
  - U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Membership and Procedures, Section IV-B-2-a-(6).
- 4.0 Definitions:** Not Applicable.
- 5.0 Role(s) and Responsibilities:** Not Applicable.
- 6.0 Policy:** All business conducted in IBC meetings, including the review of research protocols, shall be publicly noticed and conducted in open session, except that the following matters may be discussed in closed session as permitted or required by the Wisconsin Open Meetings law:
- a. Review of research protocols and related matters involving USDA/CDC Select Agents.
  - b. Discussion of investigatory and personnel matters prior to their conclusion.
  - c. Review of protocols and related materials that contain proprietary information as established by the investigator.
  - d. Conferring with legal counsel.

**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  
Professor Susan West, IBC Chair

Date  
06/23/2010

## **Institutional Biosafety Committee (IBC) Policy on Access to IBC Meeting Minutes and Other Records**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to provide information regarding access to IBC meetings minutes and other records.
- 2.0 Scope:** This policy applies to all members of 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:**
- University of Wisconsin-Madison, Office of Biological Safety (OBS) - Institutional Biosafety Committee (IBC) Handbook.
  - U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Membership and Procedures, Section IV-B-2-a-(7).
- 4.0 Definitions:** Not Applicable.
- 5.0 Role(s) and Responsibilities:** Not Applicable.
- 6.0 Policy:** All documents maintained by the University of Wisconsin-Madison Institutional Biosafety Committee (IBC), including minutes from IBC meetings, research protocols, and IBC correspondence with funding agencies and regulatory agencies are considered public records under the Wisconsin Public Records law, and are available for copying or inspection by any interested member of the public upon request. The IBC will follow the procedures established by the Wisconsin Public Records law for responding to requests for IBC documents, and will redact information from IBC documents provided to the public only to the degree necessary to address significant security, privacy, or proprietary concerns.
- 7.0 Document Revision:**

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

Signature  
Professor Susan West, IBC Chair

Date  
06/23/2010

## **Institutional Biosafety Committee (IBC) Policy on Receipt and Transmission of Public Comments**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to provide information regarding receipt and transmission of public comments.
- 2.0 Scope:** This policy applies to all members of 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:**
- University of Wisconsin-Madison, Office of Biological Safety (OBS) - Institutional Biosafety Committee (IBC) Handbook.
  - U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Membership and Procedures, Section IV-B-2-a-(7).
- 4.0 Definitions:** Not Applicable.
- 5.0 Role(s) and Responsibilities:** Not Applicable.
- 6.0 Policy:** The University of Wisconsin-Madison Institutional Biosafety Committee (IBC) encourages members of the public to submit comments to the IBC regarding any matter under the purview of the IBC. Upon receipt of any such comments, the IBC will prepare a response that will be approved by a vote of the IBC, and forward the public comments and IBC response to the U.S Department of Health and Human Services, National Institutes of Health (NIH) Office of Biotechnology Activities.

**7.0 Document Revision:**

Revision History		
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2		

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

Signature  
Professor Susan West, IBC Chair

Date  
06/23/2010

## **Institutional Biosafety Committee (IBC) Policy on Registration of Transgenic Animals**

**1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to provide information on registration of transgenic animals.

**2.0 Policy:** The University of Wisconsin-Madison Institutional Biosafety Committee (IBC) policy on registration of transgenic animals is as follows:

Per the U.S Department of Health and Human Services, National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules, all research at UW-Madison facilities involving transgenic animals must be registered with the UW-Madison IBC by inclusion on an approved biosafety protocol. It is the responsibility of the University of Wisconsin-Madison Principal Investigator (PI) of an applicable project to ensure that such animal research is appropriately registered, including research that may be simultaneously covered on an approved UW-Madison IACUC animal care protocol.

Transgenic animal research that requires IBC approval at the UW-Madison, or notice simultaneous with initiation, may be found in sections III-D, III-E and III-F of the NIH Guidelines.

### **3.0 Definitions:**

**Animal:** Any vertebrate, mollusk, arthropod, annelid, sponge or jellyfish as covered under the NIH guidelines.

### **4.0 Related Documents:**

- University of Wisconsin-Madison, Office of Biological Safety (OBS) - Institutional Biosafety Committee (IBC) Handbook. ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu))
- U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, current version and/or any subsequent revisions.



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy on Registration of Transgenic Animals

Document Number: IBC-POL-004

Revision: Amendment

Date Approved: February 04, 2015

Effective Date: February 04, 2015

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**5.0 Document Revision:**

Revision History		
Revision Number	Revision Date	Description of Revision
1	01/07/2015	Updated NIH guidelines, updated formatting, updated IBC chair, removed experimental details

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

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Signature

Date

Professor Kristen Bernard, IBC Chair

02/25/2015



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## **Institutional Biosafety Committee (IBC) Policy on Reporting of Potential Exposures and Releases of Recombinant DNA Material to the NIH OBA**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to define the internal reporting system for releases of and exposures to recombinant DNA and/or any other biohazardous material that is biological in nature as well as the mechanism, criteria, and timeline for reporting such incidents to the National Institutes of Health Office of Biotechnology Activities (NIH/OBA).
- 2.0 Scope:** This policy applies to all University of Wisconsin-Madison personnel who are associated with an incident involving the release of recombinant DNA materials or that have been potentially exposed to recombinant DNA and/or biohazardous materials.
- 3.0 Related Documents/Resources**
- University of Wisconsin-Madison, Office of Biological Safety (OBS) - First Report of Exposure or Release form.
  - UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook.
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook.
  - U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules.
  - 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**
- **Release of recombinant DNA materials:** A discharge of recombinant DNA materials outside the primary containment barrier due to failure in the containment system, an accidental spill, or occupational exposure.
  - **Exposure:** Skin, eye, mucous membrane, or parenteral contact with potentially biohazardous and/or recombinant DNA materials.
- 5.0 Roles and Responsibilities**
- **UW-Madison Principle Investigator (PI), designee, or other personnel having knowledge of a release or potential exposure:** report any release or exposure using the UW-Madison, OBS - First Report of Exposure or Release form.
  - **UW-Madison PI or designee:** provide regular training regarding reporting procedure.
  - **UW-Madison Biological Safety Officer (BSO) or designee:** Assess incident to determine whether it needs to be reported to the NIH/OBA and in what timeframe. Communicate with Occupational Health Officer to ensure that proper medical care is provided, if necessary. Follow up with personnel involved in incident and determine



## Institutional Biosafety Committee - Office of Biological Safety

Title: IBC Policy on Reporting of Potential Exposures and Releases of Recombinant DNA Material to the NIH OBA

Document Number: IBC-POL-005

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what steps should be taken, if any, to help prevent a similar situation from occurring in the future. The BSO will also communicate potential exposures and releases of recombinant DNA material to the IBC Chair prior to the next convened IBC meeting, as applicable.

**6.0 Policy:** Any potential exposure to, or release of recombinant DNA materials and/or biohazardous materials shall be reported using the UW-Madison, OBS - First Report of Exposure or Release form within 24 hours of the incident.

Potential exposures and releases include but are not limited to:

Needle sticks, animal bites, aerosol exposures, exposures to pathogenic and recombinant non-pathogenic organisms, other incidents potentially resulting in disease, as well as spills outside primary containment and potential releases to the environment. Unauthorized releases of transgenic animals or plants should also be reported on this form.

Anyone can submit the form, although it is preferred that a PI, lab manager or other senior lab member report the incident. When submitted, this report form provides the Office of Biological Safety and the Occupational Health Program with information to ensure proper actions have been taken, including appropriate medical care, as applicable.

The Biological Safety Officer or designee will determine whether the incident should be reported to the NIH and in what timeframe. All incidents that are reported to the NIH/OBA will also be reported to the IBC at the next convened meeting. In cases where incidents are reported to the NIH/OBA in an expedited fashion (see below) and the next convened IBC meeting does not occur within that timeframe, the IBC Chair will be notified.

**Timeframe for reporting of potential exposure or release:**

- Any significant problems, violations of the NIH Guidelines, or any significant research-related accidents shall be reported to the NIH/OBA, and other appropriate authorities (if applicable) within 30 days.
- Spills and accidents in a BSL-2 or BSL-3 facility resulting in an overt exposure to organisms containing recombinant DNA molecules will be immediately reported to the NIH/OBA.
- Any serious adverse event that is fatal or life-threatening, that is unexpected, and associated with the use of the gene transfer product must be reported to the NIH OBA as soon as possible, but not later than 7 calendar days after the sponsor's initial receipt of the information (i.e., at the same time the event must be reported to the FDA).
- Serious adverse events that are unexpected and associated with the use of the gene transfer product, but are not fatal or life-threatening, must be reported to the NIH OBA as soon as possible, but not later than 15 calendar days after the sponsor's initial receipt of the information (i.e., at the same time the event must be reported to the FDA).



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy on Reporting of Potential Exposures and Releases  
of Recombinant DNA Material to the NIH OBA

Document Number: IBC-POL-005

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

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Signature  
Professor Susan West, IBC Chair

Date  
06/23/2010



## **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 least 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		
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1		
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*Original signed & dated Policies are retained by the Office of Biological Safety*

Signature  
Professor Susan West, IBC Chair

Date  
06/23/2010



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy on Review of Research Protocols

Document Number: IBC-POL-006

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Date Approved: 06/02/2010

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## **Institutional Biosafety Committee (IBC) Policy on Principle Investigator/Research Service and Core Unit Registration Responsibilities**

**1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to define that there are a number of research service and core units affiliated with the University of Wisconsin-Madison that are engaged in certain biological activities covered by human subjects protocols, animal care and use protocols, and/or performed on a fee-for-service basis. These activities may involve materials and/or animals which have been exposed to hazardous materials or recombinant DNA. Activities may also include administering recombinant DNA to human subjects. This policy is intended to help ensure that the work is performed in a safe manner and is covered in a Biological Materials and Recombinant DNA Protocol (Biosafety Protocol).

**2.0 Scope:** This policy applies to all University of Wisconsin-Madison Principle Investigators (PI's) that have animal care and use protocols involving research with recombinant DNA or potentially hazardous materials, and/or PIs whose research that involves the deliberate transfer of recombinant DNA into human subjects.

This policy also applies to all UW-Madison PIs that have animal care and use protocols involving research with recombinant DNA or potentially hazardous materials, and/or PIs whose research that involves the deliberate transfer of recombinant DNA into human subjects.

### **3.0 Related Documents/Resources**

- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook.
- UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook.
- U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules.

**4.0 Definitions:** Not Applicable.

- **Research Service Units:** Pathology/Necropsy, Flow Cytometry, Animal Care and/or Research Units, GMP facilities, etc.

### **5.0 Roles and Responsibilities:**

- **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:** Biosafety Protocols serve two main purposes. The first purpose is to provide an accurate description of the research methods and materials so that risks associated with the work can be accurately assessed and mitigated. The second is to provide a registration for recombinant materials in accordance with the NIH Guidelines.

Because research service and core units often lack the expertise to accurately assess risk associated with materials supplied to them by a PI, the PI must provide the service unit with any appropriate safety information along with any relevant training. Furthermore, any recombinant materials must be accounted for on the protocol of the PI for which the work is being performed. All work that is associated with a specific project must be accounted for on the biosafety protocol corresponding to the PI that is facilitating the work.

Service units incur inherent risks associated with the services they provide. These risks include, but are not limited to, zoonotic diseases, aerosol generating activities, and exposure to chemical, radioactive, or biological agents. UW-Madison research service units must account for risks associated with the work they perform in an “umbrella” biosafety protocol that describes the work they do and hazards they are likely to encounter through the service they provide. Research service units also must include steps taken to mitigate risks, including training, engineering controls (e.g. biosafety cabinets) and personal protective equipment.

**7.0 Document Revision:**

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

Signature

Professor Susan West, IBC Chair

Date

01/12/2011

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## **Institutional Biosafety Committee (IBC) Policy on Shared Use of Biosafety Level 2 Facilities**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to define recommendations for researchers who conduct activities under Biosafety Level 1 (BSL-1) containment, were assigned to work in a multi-room laboratory or animal suite where work is conducted by others under Biosafety Level 2 (BSL-2) containment.
- 2.0 Scope:** This policy applies to all University of Wisconsin-Madison Principle Investigators (PI's) who conduct activities under BSL-1 containment and have been assigned to work in a multi-room laboratory or animal suite where work is conducted by others under BSL-2 containment [i.e., UW-Madison, Wisconsin Institutes for Medical Research (WIMR) facility].
- 3.0 Related Documents/Resources**
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook.
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control (BRC) Handbook.
  - UW-Madison Environment Health and Safety (EH&S) Laboratory Safety Guide.
  - 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:** Not Applicable.
- 6.0 Policy:** This policy statement was adopted to address situations where researchers who conduct activities under BSL-1 containment were assigned to work in a multi-room laboratory or animal suite where work is conducted by others under BSL-2 containment.

The IBC requires that all researchers who utilize multi-room laboratories or animal suites where both BSL-1 and BSL-2 activities are performed must comply with BSL-2 procedures as described in the 5th and later editions of Biosafety in Microbiological and Biomedical Laboratories, published by the Centers for Disease Control and Prevention. Additionally, appropriate signage indicating the BSL-2 level must be clearly posted on all doors of the research or animal care suite of rooms and indicating that entrance to the research or animal care suite is restricted to "Authorized Personnel Only". Biosafety signs listing the agent(s) and the responsible Principal Investigators must be posted in a common area within the suite

of rooms. Biosafety manuals and protocols should be available in a common location for all users of the research suite. All workers within the suite should be informed of the risks associated with the infectious agents or hazardous materials that are used. It is expected that the Principal Investigators who are assigned to a multi-room laboratory or animal suite will work together co-operatively to insure the safety of all workers, including custodial and animal care staff.

## 7.0 Document Revision:

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

Signature  
Professor Susan West, IBC Chair

Date  
01/12/2011

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## **Institutional Biosafety Committee (IBC) Policy on UW-Madison New IBC Member Training**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to define recommendations for UW-Madison new IBC member training.
- 2.0 Scope:** This policy applies to the University of Wisconsin-Madison Biosafety Committee members.
- 3.0 Related Documents/Resources**
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook.
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control (BRC) Handbook.
  - UW-Madison, Office of Biological Safety - IBC Member Orientation Training Document (BIO-TRN-009).
  - 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:** Not Applicable.
- 6.0 Policy:** This policy was adopted to define recommendations for UW-Madison new IBC member training.

The IBC approved the “UW-Madison New IBC Member Training” on December 1, 2010. The training document can also be found under the UW-Madison, Office of Biological Safety - IBC Member Orientation Training Document (BIO-TRN-009). The IBC voted to require IBC New Member Training of all new IBC members (i.e. all members joining the IBC on or after July 1, 2010), in addition to requiring all IBC members to take the three biological safety training modules required of all PIs and their staff.

Note: The current required courses provided by the Office of Biological Safety, include (1) Biosafety 101-Risk Assessment, (2) Biosafety 104-Safe Use of Sharps, & (3) Biosafety 201-NIH Guidelines; please go to **Learn@UW** to self register for these and other online courses. This computer-based training is available for UW-Madison faculty, staff, and students, as applicable, to take at their convenience.

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

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Signature  
Professor Susan West, IBC Chair

Date  
03/02/2011

## **Institutional Biosafety Committee (IBC) Policy for Compulsory Biosafety Training**

- 1.0 Purpose:** The purpose of this University of Wisconsin-Madison Institutional Biosafety Committee (IBC) policy is to define recommendations for the UW-Madison IBC to 1) require a compulsory training program in which all personnel working with biohazardous materials and/or recombinant or synthetic nucleic acid must take and pass specific biosafety training modules, 2) allow the UW-Madison IBC to withhold protocol approval if required biosafety training courses are not completed by actively working personnel listed on a Biosafety protocol, and 3) to require biosafety refresher training for UW-Madison personnel, specifically for personnel listed in UW-Madison Biological Materials and Recombinant DNA Protocol (Biosafety protocol).
- 2.0 Scope:** This policy applies to all members of the UW-Madison IBC, UW-Madison Office of Biological Safety (OBS), UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, along with any additional personnel listed on the Biosafety protocol, as applicable.
- 3.0 Related Documents/Resources**
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control (BRC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, School of Medicine and Public Health, Mandatory Biological Safety Training and Incident Reporting Requirements ([www2.medicine.wisc.edu/home/department-announcements/new-mandatory-biological-safety-training-incident-reporting-requirements](http://www2.medicine.wisc.edu/home/department-announcements/new-mandatory-biological-safety-training-incident-reporting-requirements)).
  - U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules, current version and/or any subsequent revisions.
  - 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), current version and/or any subsequent revisions.
- 4.0 Definitions:** Not Applicable.
- 5.0 Roles and Responsibilities:**
- Principal Investigators will be responsible for verifying that all laboratory personnel listed in their biosafety protocols have completed the training modules as required by the UW-Madison IBC (see below).
- 6.0 Policy:** This policy is adopted to define initial and refresher biosafety training requirements for UW-Madison personnel, specifically for personnel listed in a UW-Madison Biosafety protocol.

UW-Madison IBC Policy 4.1.17 (see IBC Handbook) requires an initial compulsory training program in which all personnel working with biohazardous materials and/or recombinant or synthetic nucleic acid must take and pass specific biosafety training modules. To enhance the safety knowledge of personnel, the UW-Madison IBC will require a refresher training every five years for all personnel who are actively working on projects covered by a Biosafety protocol. The refresher training will be made available by the OBS. These training will cover topics included in the initial biological safety training mandated by IBC Policy 4.1.17 and will include additional topics at the discretion of the IBC and OBS.

Principal Investigators will be responsible for verifying that all new or current members of a laboratory are added/ listed on the biosafety protocols as soon as possible; information on adding laboratory personnel to an active Biosafety protocol can be found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)), under the Protocol tab. All personnel listed in the biosafety protocol must complete training prior to or within a reasonable amount of time of beginning research in the laboratory. Active biosafety protocols may be suspended and new/renewal applications may not be processed if the Principal Investigator and all listed personnel have not completed the training.

Also, as indicated above, the UW-Madison IBC has the right to withhold protocol approval if mandatory biosafety training are not completed by actively working personnel listed on a Biosafety protocol.

The required training course topics will include, but not limited to, the following information:

- Risk assessment and biosecurity (e.g. risk groups, biological safety levels, etc.)
- Personal protective equipment
- Biohazardous waste disposal
- Decontamination and sterilization
- Sharps handling
- Use of biosafety cabinets and other engineering controls
- Hazard communication
- Mixed hazard safety (including biological, chemical, and physical)
- Emergency response (including spill and exposure procedures)
- *NIH Guidelines for Research Involving Recombinant DNA Molecules* regulatory information
- *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* recommended practices
- Other topics as deemed useful and/or necessary by the IBC and OBS

The training will be presented by the OBS in a format which is accessible to trainees. At the time of this policy implementation, the required trainings are presented as three courses offered online through UW-Madison at **Learn@UW**.

- (1) Biosafety 101: Building Biosafety into Your Research - Risk Assessment
- (2) Biosafety 104: Building Biosafety into Your Research - Safe Use of Sharps
- (3) Biosafety 201: NIH Guidelines



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy for Compulsory Biosafety Training

Document Number: IBC-POL-010

Revision: New

Date Approved: 03/06/2013

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Record of these trainings will be made accessible by the OBS and information on completion of the required courses should also be retained by trainees. At the time of this policy implementation, individuals with a UW NetID can access their own and their staff's biosafety training record online by using the UW-Madison Graduate School Lookup Utility tool. A link to the Lookup tool can be accessed on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)), under the Training tab or by going directly through the Graduate School website.

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

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Signature

Professor Susan West, IBC Chair

Date

03/06/2013





## **Institutional Biosafety Committee (IBC) Policy For Principal Investigator On A Biosafety Protocol**

**1.0 Purpose:** The purpose of this University of Wisconsin-Madison Institutional Biosafety Committee (IBC) policy is to define roles, responsibilities for a Principal Investigator (PI) on a biosafety protocol.

**2.0 Scope:** This policy applies to all UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, along with applicable employees and staff of external agencies having agreements with UW-Madison, all members of the UW-Madison IBC, and UW-Madison Office of Biological Safety (OBS).

**3.0 Related Documents/Resources:**

- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
- U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, current version and/or any subsequent revisions.
- 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), current version and/or any subsequent revisions.

**4.0 Definitions:**

**Principal Investigator (PI):** The term Principal Investigator identifies the individual who is responsible for a research project. This responsibility includes leadership of the scientific/technical aspects, training of laboratory personnel and adherence to NIH Guidelines, UW-Madison IBC policies and rules and regulations of all applicable governing entities. The PI must understand, adhere to, and sign the UW-Madison IBC assurance statement.

**5.0 Roles and Responsibilities:**

Roles and responsibilities of PIs are defined by the UW-Madison IBC, NIH Guidelines, and other applicable regulations or local, state, and federal guidelines. The PI shall sign and adhere to the assurance statement for their research conducted within the UW-Madison IBC oversight.

**6.0 Policy:**

The IBC defines a PI for biological safety protocols as University of Wisconsin-Madison tenure track faculty.

Circumstances may occur where a non-tenure track researcher or researcher from an external agency may request to be a PI for the purposes of the biological safety protocol. This is requested of the IBC by filling out the attached form. These requests are subject to IBC approval. These persons may include (but are not limited to):





**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy For Principal Investigator On A Biosafety Protocol

Document Number: IBC-POL-011

Revision: Amendment

Date Approved: 11/04/2015

1. Emeritus faculty or academic staff (with the approval of the dean and director) including but not limited to titles: Scientist, Research Instructor, Lecturer, Faculty Associate, etc.
2. Employees of external agencies with which UW-Madison has a formal agreement to provide biosafety/IBC services.

The completion and approval of the form pertains solely to the ability to serve as Principal Investigator on a biosafety protocol. Submission of the form to the Institutional Biosafety Committee (IBC) does not replace the formal campus designation process to serve as a Principal Investigator on an extramural grant proposal, nor does it grant you any of the benefits of campus-designated PI status.

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

---

Signature  
Professor Kristen Bernard, IBC Chair

---

Date  
12/22/2015



## University of Wisconsin-Madison Request for Principal Investigator (PI) On a Biological Safety Protocol: UW Personnel

The completion and approval of this form pertains solely to your ability to serve as Principal Investigator on a biosafety protocol. Submission of this form to the Institutional Biosafety Committee (IBC) does not replace the formal campus designation process to serve as a Principal Investigator on an extramural grant proposal, nor does it grant you any of the benefits of campus-designated PI status.

**PI Name:**

**Title:**

**Highest Degree Earned:**

**Year:**

**Department/Center:**

**College/School:**

**Funding Source:**

**Justification:** Please indicate reasons below and provide written explanation.

Faculty position pending resolution of visa.

Emeritus faculty appointment.

Served as PI on previous grant. Grant being submitted for competitive renewal.

Necessary for technical and administrative direction of project including fiscal responsibility.

Other

**Explanation:**

PI Signature \_\_\_\_\_

Date \_\_\_\_\_

Chair/Director Signature \_\_\_\_\_

Date \_\_\_\_\_

Dean Signature \_\_\_\_\_

Date \_\_\_\_\_



## **University of Wisconsin-Madison Request for Principal Investigator (PI) On a Biological Safety Protocol: Non-UW Entity**

The completion and approval of this form pertains solely to your ability to serve as Principal Investigator on a biosafety protocol. Submission of this form to the Institutional Biosafety Committee (IBC) does not replace the formal campus designation process to serve as a Principal Investigator on an extramural grant proposal, nor does it grant you any of the benefits of campus-designated PI status.

**PI Name:**

**Title:**

**Highest Degree Earned:  
Year:**

**Entity name & Location:**

**UW Affiliation:**

**Funding Source:**

**Entity:**

**If you are not affiliated with UW-Madison, a letter from your employing entity granting permission and stating responsibility must accompany this request.**

**Justification:** Please indicate reasons below and provide written explanation.

Served as PI on previous grant. Grant being submitted for competitive renewal.

Necessary for technical and administrative direction of project including fiscal responsibility.

Other



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy For Principal Investigator On A Biosafety Protocol

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Revision: Amendment

Date Approved: 11/04/2015

**Explanation:**

PI Title\_\_\_\_\_

PI Signature\_\_\_\_\_ Date\_\_\_\_\_

Title\_\_\_\_\_ (e.g. department director)

Signature\_\_\_\_\_ Date\_\_\_\_\_

Title\_\_\_\_\_ (e.g. Chief Executive Officer)

Signature\_\_\_\_\_ Date\_\_\_\_\_

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**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy For Principal Investigator On A Biosafety Protocol

Document Number: IBC-POL-011

Revision: Amendment

Date Approved: 11/04/2015

**University of Wisconsin-Madison  
IBC Approval for Principal Investigator (PI)  
On a Biological Safety Protocol**

The completion and approval of this form pertains solely to your ability to serve as Principal Investigator on a biosafety protocol. Submission of this form to the Institutional Biosafety Committee (IBC) does not replace the formal campus designation process to serve as a Principal Investigator on an extramural grant proposal, nor does it grant you any of the benefits of campus-designated PI status.

**PI Name:**

**Title:**

**IBC Decision:**

**Date:**

**Contingencies:**

**Justification:**

Signature IBC Chair \_\_\_\_\_ Date \_\_\_\_\_

Printed Date:-----

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The Current version of this Policy is retained at the Office of Biological Safety and posted to biosafety.wisc.edu

**Printed copies may not be relied upon as current, active IBC policy**



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy For Principal Investigator On A Biosafety Protocol

Document Number: IBC-POL-011

Revision: Amendment

Date Approved: 11/04/2015

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**7.0 Document Revision:**

Revision History		
Revision Number	Revision Date	Description of Revision
1	11/04/2015	Clarification regarding PI status solely for biosafety protocol and not otherwise, updated formatting.

## **Institutional Biosafety Committee (IBC) Policy on Reporting of Laboratory-Acquired Infections to State and Local Public Health Authorities**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to affirm UW-Madison's commitment to investigate suspected or confirmed instances of laboratory-acquired infections and to report such instances to the proper entities. This policy also describes the process by which laboratory-acquired infections are to be investigated and reported, as required by state and federal regulations.
- 2.0 Scope:** This policy applies to all University of Wisconsin-Madison employees who are associated with and/or are aware of any confirmed or suspected cases of laboratory-acquired infections occurring in a UW-Madison employee, visitor, or student.
- 3.0 Related Documents/Resources**
- Wisconsin Statute and Department of Health Services, Ch. DHS 145 of the Wisconsin Administrative Code, Control of Communicable Diseases ([https://docs.legis.wisconsin.gov/code/admin\\_code/dhs/145](https://docs.legis.wisconsin.gov/code/admin_code/dhs/145)).
  - University of Wisconsin-Madison, Office of Biological Safety (OBS) - First Report of Exposure or Release form, found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules, current version and/or any subsequent revisions.
  - 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), current version and/or any subsequent revisions.

### **4.0 Definitions**

**Laboratory-Acquired Infection:** Any human infection with a pathogen capable of causing disease that is suspected or proven to have been acquired through laboratory or laboratory-related activities, regardless whether it is symptomatic or asymptomatic in nature.

**Select Agent:** Bacteria, viruses, and toxins, which have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products, classified as Select Agents and toxins by the Centers for Disease Control and the USDA Animal and Plant Health Inspection Service (<http://www.selectagents.gov/index.html>).



## 5.0 Roles and Responsibilities

**UW-Madison Principle Investigator (PI), designee, or other personnel:** Investigators and others who have knowledge of confirmed or suspected cases of any laboratory-acquired infection occurring in a UW-Madison employee, visitor or student are to report such infection as soon as possible, using the UW-Madison, OBS - First Report of Exposure or Release form, on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)). Confirmed or suspected cases of any laboratory-acquired infection with a Select Agent or Toxin should immediately be reported by telephone to the UW-Madison Responsible Official or an Alternate Responsible Official.

**UW-Madison Biological Safety Officer (BSO) or designee:** The BSO will assess applicable information to determine validity of any confirmed or suspected laboratory-acquired infection or communicable disease. The Biological Safety Officer will report any confirmed or suspected communicable disease to University Health Services.

**UW-Madison Responsible Official or an Alternate Responsible Official:** The RO/ARO will report any confirmed or suspected communicable disease caused by a Select Agent directly to the Wisconsin Division of Public Health and Public Health Madison Dane County per select agent program policy. The RO/ARO will also concurrently notify University Health Services of such disease.

**UW-Madison University Health Services (UHS):** UHS will assess applicable information to determine validity of any confirmed or suspected communicable disease. UHS will gather information required to complete a case investigation and notify the appropriate state or local public health agency. UW-Madison will assist state and local health public health agencies with the investigation of diseases that are suspected to be laboratory acquired.

**Health Care Provider or Clinical Laboratory:** Health care providers or clinical diagnostic laboratories shall report any communicable disease they diagnose to the patient's local public health agency as required by Wisconsin State Statute and Ch. DHS 145 of the Wisconsin Administrative Code.

See also Appendix A for contact information for the above groups, as applicable.

**6.0 Policy:** UW-Madison will investigate any confirmed or suspected laboratory-acquired infections that occur in employees, visitors, or students and report any communicable disease within the prescribed time period as required by Wisconsin Statute and Wisconsin Administrative Code. In the case where the event involves a Select Agent, the Responsible Official or an Alternate Responsible Official will report the event directly to public health authorities.





**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy on Reporting of Lab-Acquired Infections to State and

Local Public Health Authorities

Document Number: IBC-POL-012

Revision: New

Date Approved: 06/05/2013

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

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Signature	Date
Professor Susan West, IBC Chair	06/05/2013

**Appendix A**

**Contacts for reporting of laboratory-acquired infections:**

- UW-Madison Biological Safety Officer
  - Phone: 608-263-2037
- UW-Madison Responsible Official/Alternate Responsible Official
  - Phone: 608-890-3468
- University Health Services, Epidemiologist
  - Phone: 608-262-6720
  - Pager: 608-376-6403
- University Health Services, After Hours
  - Director on Call: 608-265-5600, Option 6
- Public Health Madison Dane County (PHMDC)
  - Communicable Disease Reporting: 608-243-0336
  - 24/7 Emergency Page: 608-376-6403

## **Institutional Biosafety Committee (IBC) Policy on Vaccinia Vaccination and Waiver Form**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to ensure that researchers working with vaccinia virus receive information about vaccinia vaccination and to provide a copy of the vaccinia vaccination form that must be completed by all such researchers.
- 2.0 Scope:** This policy applies to all members of the UW-Madison IBC, UW-Madison Office of Biological Safety (OBS), UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, along with any additional personnel listed on the Biosafety protocol, as applicable.
- 3.0 Related Documents/Resources**
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Occupational Health Program, Document Control System, Considerations for use of Vaccinia virus (VACV) Guidance Document (OH-GUI-018).
  - UW-Madison, Occupational Health Program, Document Control System, Vaccinia Exposure Medical Response Guidance for the University of Wisconsin- Madison (OH-GUI-036).
  - UW-Madison, Occupational Health Program, Document Control System, Monkeypox Exposure Medical Response Guidance for the University of Wisconsin- Madison (OH-GUI-043).
  - UW-Madison, Occupational Health Program, medical response plans for infectious agents used in research on campus. The plans can be accessed on the UW-Madison Occupational Health Program webpage at: [www.ehs.wisc.edu/occ-resources.htm](http://www.ehs.wisc.edu/occ-resources.htm) (EH&S Home > Occupational Health > Resources > Medical Response Plans).
  - U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Emergency Preparedness and Response website, Smallpox (<http://emergency.cdc.gov/agent/smallpox/>).
  - 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), current version and/or any subsequent revisions.
  - U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules, current version and/or any subsequent revisions.
  - [Virology](#), Risks Associated with Vaccinia in the Laboratory, Science Direct, [Volume 385, Issue 1](#), 1 March 2009, Pages 1–4 ([www.sciencedirect.com/science/article/pii/S0042682208007976](http://www.sciencedirect.com/science/article/pii/S0042682208007976)).

**4.0 Definitions:** Not Applicable.

**5.0 Roles and Responsibilities:** Not Applicable.

**6.0 Policy:** This policy requires researchers who conduct activities with vaccinia virus to consider IBC recommendations for vaccinia vaccination and to complete the vaccinia vaccination form (attached).

Additional information regarding vaccinia virus can be found in the UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)), Policy and Procedure No. 4.1.13, *Precautions for Work with Poxviruses that Infect Humans*; see also *Virology, Risks Associated with Vaccinia in the Laboratory*, Science Direct, Volume 385, Issue 1, 1 March 2009, Pages 1–4.

Also please see information pertaining to vaccinia under the UW-Madison, Occupational Health Program (OHP), “Considerations for use of Vaccinia virus (VACV) Guidance Document” (OH-GUI-018), Vaccinia Exposure Medical Response Guidance for the University of Wisconsin- Madison (OH-GUI-036), and OHP Medical Response Plans for Infectious Agents used in Research on Campus, accessed on the OHP webpage at: [www.ehs.wisc.edu/occ-resources.htm](http://www.ehs.wisc.edu/occ-resources.htm) (EH&S Home > Occupational Health > Resources > Medical Response Plans).

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

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Signature  
Professor Susan West, IBC Chair

Date  
06/05/2013



Attachment 1

Vaccinia Vaccination Form
University of Wisconsin-Madison

Form with fields: Employee Name, Employee ID#, PI, SC#, Protocol Title, Protocol Description, and a description of the vaccinia virus protocol.

Please read the information below and check the appropriate boxes.

The research described in this protocol uses the vaccinia virus or an attenuated form of the vaccinia virus. The consequences of exposure to either high doses of virus or an unusual route of exposure that may be associated with a lab-acquired infection are largely unknown.

The vaccinia virus is the "live virus" used in the Vaccinia Vaccine for smallpox. The vaccinia virus is related to the smallpox virus. The Vaccinia Vaccine has been used in the past to vaccinate against smallpox. Worldwide use of the Vaccinia Vaccine has eliminated smallpox. Vaccination with the Vaccinia Vaccine may confer immunity to accidental exposure to the vaccinia virus or an attenuated form of the vaccinia virus.

Other details:

- List of five bullet points describing the disease Vaccinia, its symptoms, transmission, and the safety of the ACAM2000 vaccine.

- Three checkboxes with statements regarding the user's understanding of the University of Wisconsin-Madison Institutional Biosafety Committee Policy for Personnel Working with Pox Viruses, the risks of inadvertent exposure, and the immunity conferred by the ACAM2000 vaccine.

Printed Date:

Page 3 of 6

Paper copies may be outdated and should not be relied upon as current, active IBC policy

The Current version of this Policy is retained at the Office of Biological Safety and posted to biosafety.wisc.edu

I understand that the vaccine site must be properly cared for to avoid autoinoculation of other sites on my body with the vaccinia virus and/or inoculation of other individuals with the vaccinia virus.

I understand that vaccination with the Vaccinia Vaccine (ACAM2000) may cause side effects including:

**Normal and Typically Mild Reactions** (go away without treatment):

- The arm receiving the vaccination may be sore and red where the vaccine was given.
- The lymph nodes in the armpits may become large and sore.
- The vaccinated person may run a low fever.
- One out of 3 people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.

**Serious Reactions** (250-500 of every 1 million people vaccinated for the first time; not life-threatening but serious):

- Inadvertent self inoculation. This is an accidental spreading of the vaccinia virus caused by touching the vaccination site and then touching another part of the body or another person. It usually occurs on the genitals or face, including the eyes, where it can damage sight or lead to blindness. Washing hands with soap and water after touching the vaccine site will help prevent this inadvertent inoculation.
- A widespread vaccinia rash (generalized vaccinia). The virus spreads from the vaccination site through the blood. Sores break out on parts of the body away from the vaccination site.
- A toxic or allergic rash in response to the vaccine that can take various forms (erythema multiforme).

**Rare reactions** (14-52 of every 1 million people vaccinated for the first time; life threatening):

- Eczema vaccinatum. Serious skin rashes caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis.
- Progressive vaccinia (or vaccinia necrosum). Ongoing infection of skin with tissue destruction frequently leading to death.
- Postvaccinial encephalitis (inflammation of the brain).
- Myocarditis or pericarditis

I understand that vaccination with the Vaccinia Vaccine (ACAM2000) should not be used in the following circumstances:

- I have active eczema or a history of eczema or atopic dermatitis, or Darier's disease.
- I have other acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, varicella zoster, severe acne, or other open rashes or wounds), until the condition resolves.
- I am pregnant or intend to become pregnant within 4 weeks of vaccination or am breast-feeding.
- I am immunodeficient or immunocompromised (by disease or therapy), including HIV infection.
- I have a current moderate or severe acute illness.
- I am less than 18 years of age.
- I am undergoing topical steroid therapy for inflammatory eye diseases or undergoing therapy with systemic steroids (potential immune suppression increases risk for vaccinia-related complications).
- I have a history of allergy or serious reaction to prior vaccinia vaccination or any of the vaccine's components.
- I have known cardiac disease (e.g., previous heart attack, angina, CHF, cardiomyopathy, stroke or TIA) or have three or more known risk factors for cardiac disease (e.g., hypertension, hypercholesterolemia, diabetes, first degree relative with onset of cardiac complications prior to age 50, smoker).
- I have close household contacts with one or more of the conditions listed above.



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy on Vaccinia Vaccination and Waiver Form

Document Number: IBC-POL-013

Revision: New

Date Approved: 06/05/2013

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**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy on Vaccinia Vaccination and Waiver Form

Document Number: IBC-POL-013

Revision: New

Date Approved: 06/05/2013

- I have read the above facts and elect to receive the Vaccinia Vaccine (ACAM2000).
- I have received an evaluation via the UW-Madison Occupational Health Service.
- I have been vaccinated with a vaccinia vaccine within the last ten years.  
Date of Vaccination: \_\_\_\_\_
- I have read the above facts and decline the Vaccinia Vaccine (ACAM2000) at this time.  
I understand that I may change my mind and receive the vaccine.
- I have read the above facts and elect to not participate in this research project.

Employee Signature: \_\_\_\_\_

Date: \_\_\_\_\_

References: CDC Website <http://emergency.cdc.gov/agent/smallpox/>

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## **Institutional Biosafety Committee (IBC) Policy on Dengue Virus and Laboratory Information Acknowledgment Form**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to ensure that researchers working with dengue virus receive information about the risks of working with this virus and also to provide a copy of the laboratory acknowledgment form for personnel working with this virus.
- 2.0 Scope:** This policy applies to all members of the UW-Madison IBC, UW-Madison Office of Biological Safety (OBS), UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, along with any additional personnel listed on the Biosafety protocol, as applicable.
- 3.0 Related Documents/Resources**
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Occupational Health Program, Document Control System, *Dengue Exposure Medical Response Guidance for the University of Wisconsin- Madison* (OH-GUI-033).
  - UW-Madison, Occupational Health Program, medical response plans for infectious agents used in research on campus – “*Dengue Exposure Medical Response Guidance for the University of Wisconsin- Madison*”. The plans can be accessed on the UW-Madison Occupational Health Program webpage at: [www.ehs.wisc.edu/occ-resources.htm](http://www.ehs.wisc.edu/occ-resources.htm) (EH&S Home > Occupational Health > Resources > Medical Response Plans).
  - U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Dengue ([www.cdc.gov/24-7/protectingPeople/dengue/index.html](http://www.cdc.gov/24-7/protectingPeople/dengue/index.html); [wwwnc.cdc.gov/eid/article/13/2/06-0539\\_article.htm](http://wwwnc.cdc.gov/eid/article/13/2/06-0539_article.htm)).
  - 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), current version and/or any subsequent revisions.
  - U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules, current version and/or any subsequent revisions.
- 4.0 Definitions:** Not Applicable.
- 5.0 Roles and Responsibilities:** Not Applicable.



**6.0 Policy:** This policy requires researchers who conduct activities with dengue virus to consider IBC recommendations for work with the virus and to complete the “Understanding the Risks of Working with Dengue Virus” acknowledgment form (attached).

Also please see information pertaining to dengue under the UW-Madison, Occupational Health Program (OHP), “*Dengue Exposure Medical Response Guidance for the University of Wisconsin- Madison*” (OH-GUI-033) and OHP Medical Response Plans for Infectious Agents used in Research on Campus, accessed on the OHP webpage at: [www.ehs.wisc.edu/occ-resources.htm](http://www.ehs.wisc.edu/occ-resources.htm) (EH&S Home > Occupational Health > Resources > Medical Response Plans).

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

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Signature  
Professor Susan West, IBC Chair

Date  
06/05/2013

## Attachment 1

### Understanding the Risks of Working with Dengue Virus - University of Wisconsin-Madison

Dengue fever and dengue hemorrhagic fever are diseases caused by four closely related dengue viruses or strains. The research program led by principal investigator \_\_\_\_\_ involves the use of dengue viruses. Prior to working with dengue virus or dengue infected animals or tissues, lab members need to have their titer checked for previous dengue exposure.

The main symptoms of dengue fever are high fever, severe headache, severe pain behind the eyes, joint pain, muscle and bone pain, rash, and mild bleeding (e.g., nose or gums bleed, easy bruising). There is no specific medication for treatment of a dengue infection. Persons who think they have dengue should use analgesics (pain relievers) containing acetaminophen and avoid those containing aspirin. They should also rest, drink plenty of fluids, and consult a physician. If they feel worse (e.g., develop vomiting and severe abdominal pain) in the first 24 hours after the fever declines, they should go immediately to the hospital for evaluation.

Dengue hemorrhagic fever is a more severe form of dengue infection, which can be fatal. Dengue hemorrhagic fever is characterized by a fever that lasts from 2 to 7 days, with general signs and symptoms consistent with dengue fever. After the fever declines, additional symptoms may develop including persistent vomiting, severe abdominal pain, and difficulty breathing. As with dengue fever, there is no specific medication for dengue hemorrhagic fever. It may, however, be effectively treated by fluid replacement therapy if an early clinical diagnosis is made. Management often requires hospitalization.

The risk of laboratory-acquired infection with dengue virus is low when proper BSL-2 practices are followed. However, individuals who were previously infected with a dengue strain have a greater risk of more severe disease upon secondary infection with a different strain. Because of the potential seriousness of dengue hemorrhagic fever, persons who work with the dengue virus who have also tested positive for dengue infection should be particularly aware of the symptoms of dengue disease and associated risks. **Currently we do not have available a test that can distinguish between different serotypes.**

If an incident occurs which causes you to believe you have been exposed to dengue virus in the lab, or if you experience signs or symptoms of the disease, you should immediately inform your supervisor, seek medical attention, and follow any other procedures applicable to the lab in which you work.

**By signing below, I acknowledge that (1) I have read and understand the information above; (2) I have had the opportunity to discuss any questions or concerns with the PI or with my own physician; and (3) I may direct any future questions or concerns to the PI, to staff in the UW-Madison Occupational Health Program or Office of Biological Safety, to UW medical personnel who can be accessed free of charge through University Health Service at (608) 265-5600, or to my own physician.**



**Institutional Biosafety Committee - Office of Biological Safety**

Title: IBC Policy on Dengue Virus and Information Form

Document Number: IBC-POL-014

Revision: New

Date Approved: 06/05/2013

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Signature of Lab Member

Printed Name

Date

Printed Date:

Page 4 of 4

**Paper copies may be outdated and should not be relied upon as current, active IBC policy**

The Current version of this Policy is retained at the Office of Biological Safety and posted to [biosafety.wisc.edu](http://biosafety.wisc.edu)



## **Institutional Biosafety Committee (IBC) Policy for Suspension/Reinstatement and Revocation/Reapplication of Research Under a Biosafety Protocol**

**1.0 Purpose:** The purpose of this University of Wisconsin-Madison Institutional Biosafety Committee (IBC) policy is to define the situations in which the IBC, or its chair or vice Chair, is authorized to suspend previously approved research.

### **2.0 Policy:**

#### **IBC Policy on Suspension of Previously Approved Research**

- A. UW-Madison upholds the fundamental principle that conducting work with recombinant DNA, infectious agents, and other material that may be toxic to living organisms is a privilege and not a right.
- B. The UW-Madison Institutional Biosafety Committee has the authority to suspend previously approved research when the IBC determines that the research:
  - 1) is not being conducted in accordance with the approved protocol, the IBC's requirements, federal or state laws or regulations, or institutional policies applicable to biological research; or
  - 2) creates an unexpected serious potential threat to safety, health, or the environment.
- C. The IBC chair may suspend previously approved research before a determination is made by the full IBC if the IBC chair concludes that the suspension must be done immediately to protect safety, health, or the environment. If the IBC chair is unavailable, the IBC vice chair may exercise this authority.
- D. The IBC recognizes that isolated instances of non-compliance can occur as the result of simple and minor oversight and error with no intent to circumvent applicable requirements. This policy is not intended to eliminate the ability or responsibility of an investigator to immediately report and correct a simple or minor oversight or error, but is intended to address serious compliance and safety, health or environmental issues that, in the determination of the IBC, go beyond simple and minor oversight.

#### **IBC Procedures for Suspension of Previously Approved Research**

##### **A. Suspension by the IBC**

- 1) The IBC may be involved in suspending research either by acting alone to suspend, or by reviewing a Chair or Vice-Chair's decision to suspend.
- 2) In suspending research, the IBC should consider the following:



- a) What additional measures could be imposed to satisfy the IBC that the research can be conducted safely and/or in compliance of regulations
  - b) How to ensure safety and appropriate containment during the period of suspension
  - c) Reporting obligations to NIH or other agencies
  - d) If necessary, whether the protocol could be assigned to a different PI in order to allow the research to continue. (This would require a protocol amendment).
- 3) The IBC may impose contingencies that must be met in order for the suspension to be lifted.
  - 4) Where possible, the PI should have the opportunity to address the committee during the discussion (to be held in closed session) about the potential suspension.
  - 5) If it is determined that the decision to suspend and imposition of contingencies cannot be resolved in one IBC meeting, the Office of Biosafety should assign a case manager to ensure that the process moves forward in a timely manner.
  - 6) If the IBC suspends authorization of previously approved research, it will promptly notify the investigator, and report the suspension to the investigator's department chair, the Associate Dean for Research in the School/College, the Associate Vice Chancellor for Research Policy, and the Responsible Official of the Select Agent program, where appropriate. This notification should include the basis for the suspension and any contingencies that must be met in order for the suspension to be lifted.
- B. Suspension by the Chair**
- 1) If the chair (or vice-chair if the chair is not available) suspends research, s/he will promptly notify the investigator of the basis for the suspension, and report the suspension to the investigator's department chair, the Associate Dean for Research in the School/College, the Associate Vice Chancellor for Research Policy, and the Responsible Official of the Select Agent program, where appropriate.
- C. IBC Review of Chair's Immediate Suspension**
- 1) If the IBC Chair or vice-chair suspends research, the chair's decision and rationale underlying it will be scheduled for discussion at the next full meeting of the IBC. The IBC, following the processes and recommendations set forth in Section A, will determine whether to continue



or lift the suspension, and any conditions that must be met in order for the suspension to be lifted. The IBC will notify the investigator, his/her department chair, and the Associate Dean for Research of the School or College promptly of its decision.

- D. A PI may request that the IBC reconsider its decision to suspend research based on the existence of relevant new information not previously shared with the IBC.

**3.0 Related Documents/Resources:**

- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
- UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Policy for PI Request for Reconsideration Process (IBC-Policy-016).
- U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, current version and/or any subsequent revisions.
- 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), current version and/or any subsequent revisions.

Revision History		
Revision Number	Revision Date	Description of Revision
1	02/05/2015	Clarification from Legal Services updating policy content; new IBC chair signature; new format to form; title change

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

Signature	Date
Professor Kristen Bernard, IBC Chair	03/04/2015

## **Institutional Biosafety Committee (IBC) Policy on Principal Investigators' Requests for Reconsideration Process**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to define the procedure for a Principal Investigator to request reconsideration of an IBC decision on IBC biological protocol assessment, IBC Dual Use Research of Concern (DURC) analysis, and IBC DURC reports.
- 2.0 Scope:** This policy applies to all members of the UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, UW-Madison IBC, UW-Madison Office of Biological Safety (OBS), along with applicable employees and staff of Morgridge Institute for Research (MIR) and WiCell.
- 3.0 Related Documents/Resources**
- UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
  - 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), current version and/or any subsequent revisions.
  - U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant DNA Molecules, current version and/or any subsequent revisions.
  - U.S. Office of Science Policy – National Institutes of Health, Office of Biotechnology Activities, Dual Use Research (<http://oba.od.nih.gov/biosecurity/biosecurity.html>).
- 4.0 Definitions:** Not Applicable.
- 5.0 Roles and Responsibilities:** Not Applicable.
- 6.0 Policy:** Principal Investigators may submit a request for reconsideration of an IBC decision based on the existence of relevant new information not previously provided to the IBC. PIs may submit such requests regarding biological safety protocol reviews, DURC analyses, and/or DURC reports. Upon receipt of any such request, the IBC will prepare a response that must be approved by a vote of the IBC, and forward the IBC response to the PI. The PI may request or be requested to attend an IBC meeting in order to discuss the matter. Per regulatory and policy requirements, the IBC's decision on the request for reconsideration will be final.

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

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Signature  
Professor Susan West, IBC Chair

Date  
08/06/2013





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## Institutional Biosafety Committee (IBC) Conflict of Interest Policy

**1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to identify and manage conflicts of interest of the Institutional Biosafety Committee (IBC) members and consultants that may affect or appear to affect their contributions to protocol review, DURC reviews, and the suspension or revocation of laboratory research privileges.

**2.0 Policy:** Except when providing information at the IBC's request, no IBC Member or Consultant may be involved in the review or approval of research in which she or he has a conflict of interest. Except when providing information at the IBC's request, IBC Members with conflicts of interests as defined in Section 4. may not be involved in deliberations or voting in actions to suspend, revoke or reinstate privileges.

### 3.0 Roles and Responsibilities:

- a. The Office of Biological Safety will provide each IBC Member with the IBC Conflict of Interest Policy
- b. When IBC Members or Consultants receive materials before a meeting, they have a responsibility to review such materials with the issue of potential conflicts of interest in mind and to disclose any potential conflict to the Office of Biological Safety or the IBC Chair in advance of the meeting when possible. Early disclosure permits the Office of Biological Safety to ensure a quorum for review and for the IBC Member to be excused from any vote on the protocol.
- c. IBC Members or Consultants are also responsible for disclosing potential conflicts of interest to the IBC when issues arise during the course of a meeting regarding research in which the individual may have a potential conflict of interest.
- d. An IBC member or IBC consultant, or an immediate family member of an IBC member or IBC consultant, must disclose if he/she has a personal relationship that may cause bias or create the appearance of bias by the member or consultant in the review of the project.

### 4.0 Definitions:

- a. **Conflict of Interest:** An IBC Member or Consultant has a conflict of interest with respect to research when:
  - 1) An IBC Member or Consultant, or an immediate family member of the IBC Member or Consultant, has a professional interest as a Principal Investigator, Co-Investigator or Laboratory or Administrative Personnel on the protocol; or
  - 2) An IBC Member or Consultant, or an immediate family member of the IBC Member or Consultant, has an interest that is related to the research and that meets or exceeds one of the following thresholds:
    - o Compensation of \$5,000 or more in a calendar year from a publicly traded or privately held business entity.





## Institutional Biosafety Committee - Office of Biological Safety

Title: IBC Conflict of Interest Policy

Document Number: IBC-POL-017

Revision: New

Date Approved: 07-02-2014

Effective Date: 07-02-2014

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- An ownership interest in a publicly traded business entity valued at \$5,000 or more or a 5% or greater equity interest.
  - Any ownership interest in a privately held business entity regardless of the value.
  - A combination of compensation and ownership interests in a publicly held business entity valued at \$5,000 or more.
  - A leadership position in a business entity (e.g. service as an officer, member of the board of directors, or in any other position of trust, confidence, and responsibility for a business entity, whether or not the investigator receives compensation for such service).
  - Proprietary interest of any value including, but not limited to, a patent, trademark, copyright or licensing agreement, managed by the Wisconsin Alumni Research Foundation (WARF).

- b. **Immediate Family Member** includes an IBC Member or Consultant's spouse and dependent children

### 5.0 Related Documents/Resources

- a. *NIH Guidelines*, Section IV-B-2-a-(4).
- b. UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
- c. UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
- d. U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, current version and/or any subsequent revisions.
- e. 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), Current Edition.

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

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Signature

Date

Professor Susan West, IBC Chair

07/02/2014



## Institutional Biosafety Committee (IBC) Biosafety Cabinet (BSC) Policy

**1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to provide guidance for the UW-Madison research community on the certification and maintenance of some engineering control equipment.

### 2.0 Policy:

#### **Purchasing a BSC or other Workstations**

A contract is maintained by the UW-Madison for the purchase of all types of biological safety cabinets (BSC) and clean air devices (CAD). Before ordering one, consult the Office of Biological Safety (OBS) and Engineering Technical Services for an evaluation, selection and approval of BSC suitability for the intended work and of the available space. To ensure the adequacy of the installed mechanical ventilation and to facilitate coordination with the Physical Plant Remodeling group, exhausted biological safety cabinets (type B1 or B2) must be approved by the Engineering Department, UW Facilities Planning & Management, prior to purchase.

#### **Certification of Biological Safety Cabinets**

Biological Safety Cabinets must be certified when initially purchased and installed. Annual certification is required unless it is waived by OBS, which is considered on a case-by-case basis for low-risk activities. Cabinets are labeled to indicate that they either were certified on a given date or that the equipment must not be used with infectious materials. [Adopted by the IBC, January 1993. See also Biohazard Recognition & Control and the BSL-3 Laboratory Design].

**A BSC or CAD should not be moved or disassembled without prior approval from OBS or EH&S - BSC Program. All BSCs after being moved, must be recertified by EH&S - BSC Program.**

#### **Maintenance**

To function adequately, the cabinet airflow must be closely regulated and the HEPA filters must be certified. All biological safety cabinets should be certified annually. **Annual certification is required for work at Biosafety Level 2 (BSL2) and BSL3. Annual risk assessment through OBS is required for work at BSL1 to determine certification needs.** It is highly recommended that all BSL1 BSCs are annually certified. Certification services are available for a fee through Engineering and Technical Services at Environment, Health & Safety (EH&S).

**All BSC, CAD service, maintenance and certification must be either approved by or provided by EH&S - BSC Program.**

All BSCs must be either surface or gas decontaminated prior to being moved from one space to another. Before a unit is removed from the lab for maintenance, opened up for maintenance or repair, relocated, or disposed, laboratory staff are responsible for arranging surface or gas

decontamination with Engineering and Technical Services. Gas decontamination is always required prior to disposal of a BSC. Gas decontamination must be done by trained personnel; through Engineering and Technical Services. BSCs to be decommissioned must be disposed by campus metal recycler. BSCs should not be sent to UW-Madison's Surplus With a Purpose (SWAP) to be sold. Prior to the disposal or removal from campus the Principal Investigator must determine if the BSC is listed by Property Control as an inventory (capital) asset by their department. If so, the BSC must be removed from the inventory list. The Department's Property Administrator will be able to help with the list and inventory removal.

### **Drip Pan Maintenance**

Beneath the BSC work surface is a drip pan to collect large spills. This area ought to be routinely checked for cleanliness and, if a major spill has occurred, appropriately cleaned and disinfected.

### **Waivers:**

A certification waiver may be requested through OBS for BSCs where low-risk work is performed. They are issued by risk assessment through OBS on an annual basis where every three years certification of a waived unit is required.

For new BSCs, certifications may be extended up to six months to align all building certifications for the same period of time. This extension must be approved by OBS.

## **3.0 Roles and Responsibilities:**

**Principal Investigator:** Update OBS with any research activities or changes to research activities, day-to-day maintenance, proper use of equipment, surface decontamination, training staff on proper use of equipment, request of: BSC purchase, waiver, gas decontamination.

**EH&S - BSC Program: Select, evaluate and approve purchases of BSCs/CADs. Provide the service, maintenance, decontamination and certification for all BSCs/CADs.**

**OBS:** Laboratory risk assessment, waiver approvals.

**OBS Animal Safety:** Animal facility risk assessment.

## **4.0 Definitions:**

**Annual:** For the cabinet certification program, annual is defined as 12 months of time. For new BSCs, certifications may be extended up to six months to align all building certifications for the same period of time. This extension must be approved by OBS.

**Biological Safety Cabinet (BSC) Types:** Three kinds of biological safety cabinets, designated as Class I, II, and III, have been developed to meet varying research and clinical needs. Four varieties of Class II biological safety cabinets are used on campus. All are adequate for manipulations of pathogens in Risk Group 2 (RG2) or RG3.

**Animal transfer stations: are not biological safety cabinets and should never be used for work with potentially hazardous biological or chemical materials.** These devices protect the material in the cabinet but not the worker or the environment. Certification is required annually. Some units are designed to be mobile, and may be moved without recertification.

**Clean air devices and ‘clean benches’: are not biological safety cabinets and should never be used for work with potentially hazardous biological or chemical materials.** These devices protect the material in the cabinet but not the worker or the environment. Annual certification is required for units in animal areas or if used with animals to ensure proper function and quality control of research materials.

**Equipment Labeling:** A label will be placed on the outside front of the cabinet for easy type identification.

<b>A</b>	<b>Represents our standard Class II-A2 (A/A1) biological safety cabinet that recirculates HEPA filtered air back into the laboratory. These are the most commonly used equipment in UW campus laboratories for containment of biological hazards. Certification required annually and provides personal, product and environmental protection.</b>
<b>B</b>	<b>Represents our standard Class II-B (B1 or B2) biological safety cabinet that is hard ducted directly to laboratory exhaust system. HEPA filtered air is exhausted to the outside the building, not back into the laboratory. The Class II- B1 BSC is most often recommended for containment of biological and chemical hazards in UW campus laboratories. Certification required annually and provides personal, product and environmental protection.</b>
<b>C</b>	<b>Represents a clean air device that issued for non-hazardous research procedures. Current equipment includes animal transfer stations, clean benches and bedding dump stations that recirculate HEPA filtered air to the work surface or users breathing zone and back into the laboratory. These are not appropriate for use with biological or chemicals hazards. To ensure proper function and quality control of research materials, certification is required annually for these units in animal areas or units that are used with animals.</b>
<b>D</b>	<b>BSC to be decommissioned. Gas decontamination required by EH&amp;S. BSCs to be decommissioned must be disposed by campus metal recycler. Do not send BSCs to SWAP to be sold. BSC power cord will</b>

**be locked out to prevent unauthorized use. Please contact Property Control to remove equipment from your capital inventory list when decontamination is complete.**

**X** **BSC not in service. BSC is in storage or not certified for use. To put equipment back in service contact EH&S - BSC program at 262-1809. BSC power cord will be locked out to prevent unauthorized use.**

### 5.0 Related Documents/Resources

- a. UW-Madison, Office of Biological Safety - Institutional Biosafety Committee (IBC) Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
- b. UW-Madison, Office of Biological Safety - Biohazard Recognition and Control Handbook; found on the OBS website ([www.biosafety.wisc.edu](http://www.biosafety.wisc.edu)).
- c. U.S. Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, current version and/or any subsequent revisions.
- d. 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), Current Edition.

### 6.0 Document Revision:

Revision History		
Revision Number	Revision Date	Description of Revision
1	01/07/2015	Clarification regarding maintenance and certification, clarification that a BSC or CAD should not be moved or disassembled without prior approval from OBS or EH&S - BSC Program, updated formatting.

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

Signature

Date

Professor Kristen Bernard, IBC Chair

02/25/2015

## **Institutional Biosafety Committee (IBC) Policy on Appropriate Containment for Select Opportunistic and Borderline Pathogens**

- 1.0 Purpose:** The purpose of this Institutional Biosafety Committee (IBC) policy is to require BSL-2 precautions in laboratories working with opportunistic and borderline pathogens which are not known to cause infection in healthy individuals but are known pathogens of persons who have been compromised in various ways including, but not limited to, open wounds, cuts, antibiotic therapy, persons with immune systems rendered deficient.
- 2.0 Scope:** This policy applies to all UW-Madison Principal Investigators (PI), and UW-Madison employees and staff, along with applicable employees and staff of external agencies having agreements with UW-Madison, all members of the UW-Madison IBC, and UW-Madison Office of Biological Safety (OBS).
- 3.0 Related Documents/Resources:**
- UW-Madison, Office of Biological Safety - **Institutional Biosafety Committee (IBC) Handbook**; found on the OBS website ([www.ehs.wisc.edu/biosafety](http://www.ehs.wisc.edu/biosafety)).
  - UW-Madison, Office of Biological Safety - **Biohazard Recognition and Control Handbook**; found on the OBS website ([www.ehs.wisc.edu/biosafety](http://www.ehs.wisc.edu/biosafety)).
  - 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)**, current version and/or any subsequent revisions.
  - U.S. Department of Health and Human Services, **National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**, current version and/or any subsequent revisions. (Organisms are in Appendix B of the guidelines)

**4.0 Definitions:**

**Opportunistic Pathogens:** Organisms which are not known to cause infection in healthy individuals but are known pathogens of persons who have been compromised in various ways including, open wounds, cuts, antibiotic therapy, persons with immune systems rendered deficient via infection, acquired or congenital condition or via therapy (e.g. HIV+, diabetes, complement deficiencies, severe asthma, organ transplant, chemotherapy or long-term steroid treatment) and persons with immunocompromised, immunosuppressed or susceptible immune status (e.g. pregnant women, very young or old, diabetes, individuals on steroid therapy).

**Risk Group 1:** Agents not associated with disease in health adult humans.

**Risk Group 2:** Agents associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.



**Risk Assessment:** A critical exercise focused on the prevention of laboratory acquired infections whereby the facilities, equipment and practices are considered. The assessment may take into account laboratory conditions and engineering controls, as well as expertise of the person handling the agent, available therapies, and immunizations, presence of vectors, quantity (volume and/or titer), economic and environmental effects.

**5.0 Roles and Responsibilities:** Not Applicable.

**6.0 Policy:** Based on risk assessments, the IBC has determined that Biosafety Level 2 (BSL-2) precautions are appropriate for handling the following microorganisms:

**Adeno-associated virus (AAV):** The wildtype virus is generally considered RG1 because it usually requires another virus for replication. BSL-1 laboratory precautions are acceptable for gutted AAV vectors (e.g., missing the *rep* and *cap* genes) unless higher hazard transgenes (e.g., oncogenes) are expressed or high titers and/or large volumes of virus are handled, in which case BSL-2 should be used.

***Aspergillus flavus* and *A. fumigatus*:** May cause opportunistic infections in the immunocompromised individual.

***Bacillus anthracis* (Sterne):** A vaccine strain and is missing an important virulence factor. There are some reports of pathogenicity of this strain in animals. Furthermore, per guidance from CDC, BSL-2 practices will avoid contamination of the lab, which could cause problems in confounding detection of anthrax.

***Bacillus cereus*:** A foodborne pathogen produces toxin and causes cutaneous infections in healthy adults.

***Candida albicans*:** An opportunistic pathogen with significant consequences for individuals with stressed immune systems.

***Clostridium difficile*:** The “new” epidemic strain (B1/NAP-1) of this bacterium has substantial clinical consequences, is usually resistant to some antibiotics such as fluoroquinolones, and can infect healthy adults.

***Enterococcus faecalis* and *E. faecium*:** All vancomycin resistant strains are included. Furthermore, containment will minimize contamination of surfaces in the lab, which is important because this pathogen is extremely hardy in its ability to survive for weeks on environmental surfaces.

***Pneumocystis jiroveci (P. carinii f.sp. hominis)***: Causes opportunistic infections in the immunocompromised individual.

***Pseudomonas aeruginosa***: Causes eye infections, especially in contact lens wearers, chronic respiratory infections among cystic fibrosis patients and may be invasive in persons taking antibiotic therapies.

***Salmonella typhimurium LT2***: There is evidence that this strain may cause disease in healthy adults as well as immunocompromised individuals.

***Stenotrophomonas maltophilia***: Has been implicated in infrequent ocular infections, primarily in patients with ocular compromise. Of particular concern is that treatment is limited by resistance to common antibiotics.

**Additional information:**

Most wet labs will meet the standards for a BSL-2 facility. Some of the practices utilized under BSL-2 containment are:

- Work with microorganisms in the laboratory setting may create situations whereby the normal route of transmission is circumvented. In the lab, the concentration and volume are typically higher than encountered outside of the lab and procedures provide “opportunities” to infect in an abnormal manner such as splash to mucosa or needle stick injury.
- Biohazard signs are posted on the door to the laboratory when work with the microorganism is in progress.
- Individuals who may be exposed are informed of the potential risks to their health posed by the pathogen.
- Exposures are treated with first aid and reported to the PI with medical evaluation as deemed prudent.
- The lab is under negative air pressure relative to the corridor and the lab door is kept closed to maintain negative pressure.
- Many procedures can be conducted at the open lab bench under BSL-2 containment, but activities involving high concentrations and/or large volumes or that generate aerosols need to be avoided or done in containment.
- Use of a biological safety cabinet is preferred but is not required; alternative containment equipment may be acceptable.
- Disinfectants are chosen that are effective against the pathogens handled.
- Submission of a biosafety protocol is required.





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

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Signature	Date
Professor Susan West, IBC Chair	05/07/2014