



## **Institutional Biosafety Committee (IBC) Policy for Suspension of Previously Approved Research**

**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.



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

Title: IBC Policy for Suspension of Previously Approved Research of Research Under a Biosafety Protocol Document Number: IBC-POL-015

Revision: Amendment

Date Approved: March 04, 2015

Effective Date: March 04, 2015

- 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

Professor Kristen Bernard, IBC Chair

Date