

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:

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
01/12/2011