

## **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 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**

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**7.0 Document Revision:**

Revision History		
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1		
2		

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

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Signature

Professor Susan West, IBC Chair

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Date