

Biological Materials and Recombinant DNA Protocol

UNIVERSITY OF WISCONSIN-MADISON

Institutional Biosafety Committee/Office of Biological Safety

<http://www.fpm.wisc.edu/biosafety/>

Office of Biological Safety, 30 East Campus Mall 263-2037,

Return completed form to: FAX 265-8700; or as electronic attachment to biosafety@fpm.wisc.edu

Instructions for Completing Biological Materials and Recombinant DNA Protocol

Biosafety protocols must be submitted to the Office of Biological Safety (OBS) for research activities involving:

- microbiological agents infectious to humans and/or animals; provide a copy of any required federal permit.
- exotic plants, animals, and microbes (e.g., nonindigenous plants or insect pathogens, or biological control agents); provide a copy of any required federal permit.
- potentially infectious materials derived from humans (e.g., established cell lines) and from animals, including their blood, tissues, and cell lines, for which a reasonable potential for transmission of zoonotic agents exists, e.g., wild-trapped animals, pregnant sheep, and rhesus macaques.
- potentially hazardous chemicals administered *in vivo* or *in vitro* to induce a biological outcome (e.g., carcinogens, mutagens, teratogens, drugs, and toxins).
- select agents. CDC and USDA regulate these microbes and toxins due to their threat to public health and agriculture as potential biological weapons. The consolidated list of select agents is available at the OBS website, <http://www2.fpm.wisc.edu/biosafety/resources/docs/HHS-USDA-APHIS-Agents.pdf>
- recombinant DNA molecules and recombinant DNA-containing organisms or cell cultures which are subject to the NIH *Guidelines for Research Involving Recombinant DNA Molecules*. Please contact OBS about requirements for protocols involving human gene therapy trials. (Many rDNA experiments are considered to be *low-risk* yet still are *subject* to the Guidelines.)

This form provides OBS and the Institutional Biosafety Committee a detailed description of the research elements and their management, with emphasis on containment practices, and provides a basis for risk assessment. A single biosafety protocol may cover multiple grant submissions. We recommend that you use a word processor to enter the information. The format is expandable to accommodate the complexity of your project(s). Save an electronic copy so that amendments are easy to make. Do not submit grant proposals or publications.

List the research elements used in your project(s) in Sections IV. Skip sections that do not apply. In Section V, please provide an overview of the project and a detailed description of the practices employed in the management of biohazardous elements; discuss safety aspects of the facility, available containment equipment, personnel practices, and staff training that will ensure safe conduct of the investigation. *Pay close attention to the detailed requests for information.* OBS staff will contact you if information is missing.

Enumerating Details. It is not necessary to provide the details for every permutation of a research element, such as gene constructs or pharmaceutical compounds. Instead, group elements by categories associated with risk and provide at least one specific example. Be sure your biosafety and animal care protocols are consistent in the materials described.

Inventory. List the pathogens and toxins that are stored and not actively used in your current research projects in the appendix at the end of the protocol form.

Funding. The protocol should encompass all potentially hazardous aspects of a research program, whether currently funded or not. Include Material Transfer Agreements. To avoid unnecessary delays, list applications at the time they are submitted, whether funding is awarded or not. When submitting a protocol for renewal, list continuing and pending awards.

PI status. The Principal Investigator and co-PIs must be UW-Madison faculty or staff who have PI status by virtue of their position or by having been granted this status by the Graduate School. Protocols must be signed by the PI, but an electronic submission from a PI's email will suffice.

Expiration Date. Once registered and assigned a safety committee number (SC#), the protocol is valid for three years. OBS will send a reminder to the PI prior to the expiration date and again after the fact if there was no response to the notice.

Minor changes. The protocol, once registered, may be amended. Grant submissions that utilize the materials, locations, and methods of the existing protocol may be added simply by entering this information in Section I of the form (Core Registration Information) and resubmitting this single page. Amendments that add/change locations and/or research elements but do not significantly alter the risk assessment should be entered into the existing protocol using a distinctive font (e.g., bold).

Protocol Renewals. A protocol submitted for 3-year renewal must be comprehensive, describing all research elements and funding sources.

Protocol Processing and Submission Deadlines. Assurances are routinely processed once a month, in conjunction with the IBC meeting which tentatively is scheduled for the first Wednesday of each month. We will try to accommodate requests for expedited processing. Protocols that will be reviewed by the IBC must be submitted to OBS two weeks prior to an IBC meeting. Materials received less than one week (five working days) before a scheduled IBC meeting will not be considered until the following meeting.

Training and research center awards may be submitted by completing section I; list participating Principal Investigators, sign, and send to the OBS.

References

Biohazard Recognition and Control: Guidelines for handling pathogenic microorganisms and disposing biohazardous waste. 1999. Institutional Biosafety Committee, UW-Madison.

Biosafety in Microbiological and Biomedical Laboratories. CDC/NIH. 4th edition, May 1999. <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>

Bloodborne Pathogens: Reference and Training Manual. 1997. University of Wisconsin - Madison. Occupational Health Program, Safety Department. <http://www.fpm.wisc.edu/bbp/>

Chemical Safety and Disposal Guide. 2002. University of Wisconsin - Madison. Chemical & Environmental Safety Program, Safety Department. http://www2.fpm.wisc.edu/chemsafety/table_of_contents2005.htm

Laboratory Standard. 1990. Department of Labor, Occupational Safety and Health Administration. 29 CFR, Part 1910.1450. Fed. Reg. Vol. 55, No. 21.

NIH *Guidelines for Research Involving Recombinant DNA Molecules*. April 2002 and subsequent amendments. National Institutes of Health. <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

National Toxicology Program Chemical Health and Safety Data. http://ntp-server.niehs.nih.gov/Main_Pages/Chem-HS.html

Occupational exposure to bloodborne pathogens; final rule. 1991. Department of Labor, Occupational Safety and Health Administration. 29 CFR, Part 1910.1030. Federal Register 56(235).

Proposed Guidelines for Research Involving the Planned Introduction into the Environment of Organisms with Deliberately Modified Hereditary Traits. 1991. USDA. Federal Register Vol. 56, No. 22.

Recommendations for the Safe Handling of Chemical Carcinogens and Mutagens. 1990. Biological Safety Committee, UW-Madison.

TOXNET, a cluster of databases on toxicology, hazardous chemicals, and related areas. <http://toxnet.nlm.nih.gov/>

Traynor et al. 2001. A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes. Information Systems for Biotechnology. http://www.isb.vt.edu/cfdocs/greenhouse_manual.cfm