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BioSide Lines

FOSTERING SAFE WORK & LABORATORY PRACTICES THROUGH TRAINING & EDUCATION

Guidelines for rDNA Animal Research

As an institution receiving research funds from the National Institutes of Health (NIH), UW-Madison is subject to the NIH *Guidelines for Research Involving Recombinant DNA Molecules*. The primary purpose of the [NIH Guidelines](#) is to specify practices for constructing and handling recombinant DNA (rDNA) molecules, and organisms and viruses containing rDNA molecules.

Much attention is often placed on research involving distinctly or potentially infectious, pathogenic or otherwise biohazardous agents. However, special care and evaluation are also necessary for establishing the applicability of the NIH *Guidelines* to animal experiments. Specifically, all research at UW-Madison facilities involving trans-

genic animals must be registered with the UW-Madison Institutional Biosafety Committee (IBC) by inclusion on an approved biosafety protocol, unless explicitly exempt from the NIH *Guidelines*.

It is the responsibility of the 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. Additionally, PIs should sufficiently describe their rDNA animal research activities on biosafety protocols to allow for an assessment of pertinent sections of the NIH *Guidelines*. To assist in this assessment, the NIH Office of Biotechnology Activities (OBA) has published a useful criteria table

which can be accessed at: <http://oba.od.nih.gov/oba/ibc/FAQs/Animal%20Experiments%20Covered%20under%20the%20NIH%20Guidelines.pdf>.

Each biosafety protocol is unique, frequently encompassing complex research elements. Please contact OBS for assistance in determining how the NIH *Guidelines* apply to your research.



BIO-NEWS

IBC MEMBER UPDATE

The UW-Madison IBC is pleased to announce the addition of the following new members: Christina Hull, Heidi Kaeppler, Allen Laughon, Anthony Lucchesi and Brenda Ogle. We also extend our sincere appreciation to exiting member Susan Paskewitz for her dedicated efforts while serving on the committee.

DISINFECTION & DISPOSAL:

EH&S Animal Tissue Disposal Service

The use of laboratory animals in research and instruction is both federally and institutionally regulated,

and this oversight also extends to the disposal of animals, their bedding and wastes, particularly when potentially contaminated with biological and/or chemical hazards. The goal of such regulations is to protect the public and environment from unnecessary exposures to harmful materials.

Indirect hazards occur when research animals are intentionally exposed to biological agents, chemicals and/or radioactive materials, which then may contaminate animal bedding, equipment, waste products and the atmosphere around cages. The biosafety protocol approval process requires PIs to identify these agents and communicate guidance to protect lab personnel and animal care staff.

The UW-Madison Environment, Health & Safety Department (EH&S) provides an Animal Tissue Disposal Service (ATDS) for laboratory animal carcasses and tissues. Animal carcasses and tissues that are properly packaged will be picked up

on Wednesday and Friday mornings, then transported to the EH&S incinerator. Most animal tissues can be disposed of by this service; however, additional precautions are necessary for biohazardous animal waste to limit unnecessary handling, transportation and exposure risks to uninformed waste handlers.

◆ **The EH&S Animal Tissue Disposal Service CANNOT dispose of:**

- ◆ Animal tissue and carcasses containing radioactive materials
- ◆ Human tissue, blood or body fluids; any bulk blood or fluids
- ◆ Laboratory chemicals, chemical waste or chemically contaminated labware
- ◆ Labware or glassware
- ◆ Microbiological cultures and stocks
- ◆ Surgical instruments or animal handling equipment
- ◆ Waste collection containers for needles and other sharps

Biohazardous animal waste includes bedding, carcasses and tissues from animals known or suspected to carry infectious microorganisms, whether experimentally or naturally infected. At UW-Madison, this specifically includes animal waste from BL2 and BL3 research activities. On-site decontamination (e.g., autoclaving or chemical disinfection) is generally required for animal bedding from BL2 and BL3 facilities.

Animal carcasses and tissues from BL3 facilities require autoclaving prior to pickup by EH&S for incineration.

EH&S is only licensed to process animal carcasses and tissues. Soiled bedding may be disposed of in regular trash; however, biohazardous bedding must be decontaminated prior to such disposal. Disposal of biohazardous bedding via the EH&S Animal Tissue Disposal Service requires prior approval from OBS.

PIs and lab personnel working with biohazardous animals must follow the decontamination and disposal procedures described in their approved biosafety protocols. EH&S will assist in evaluating your biohazardous waste disposal options, such as autoclaving, chemical disinfection, incineration or temporary on-site storage. Caustic digestion is also available through the Wisconsin Veterinary Diagnostic Lab (WVDL), a process that destroys bacterial, viral and prion contaminants. Contact the WVDL at 262-5432 for details.

For ATDS packaging requirements and more information, please see the EH&S Laboratory Safety Guide, Chapter 8 at: www2.fpm.wisc.edu/chemsafety/GUIDE2005/chapter%208.pdf and the UW-Madison Biohazard Recognition & Control guide on the OBS website.

Call EH&S at 265-5000 to request disposal service.

BIOSAFETY PROTOCOL TIPS:

Notes on PI Responsibility

Many PIs choose to combine their pertinent research projects into one biosafety protocol form, a practice OBS encourages in order to streamline the protocol review process. However, these combined research projects often involve a research collaborator (co-PI) or have been delegated to senior lab personnel. As a result, OBS frequently receives questions regarding PI confidentiality, ownership and responsibility of protocols – we have attempted to clarify some of these issues in this article.

PI Signature. The PI's signature on a protocol is always required, as this gives us assurance that they have accepted responsibility for the information submitted. However, protocols received as an email attachment directly from the PI are accepted as an electronic signature equivalent.

PI Status. The PI and co-PI listed on a protocol's first page 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. OBS may request documentation of PI status for staff listed as co-PIs on biosafety protocols.

Protocol Funding. A PI may receive joint funding with a collaborator or member of their lab (e.g., post-doctoral fellowship) for work covered under their protocol. Collaborators under such funding who are not responsible for oversight of the entire protocol (versus a co-PI) can be listed with the funding title on the protocol's first page.

Protocol Confidentiality. To protect PI research confidentiality, PIs must authorize OBS to release copies of their protocol and registration form to a third party (e.g., lab manager, departmental staff, etc.). This can be accomplished by noting these designated individuals on the protocol form or by notifying OBS by email at: biosafety@fpm.wisc.edu.

Please contact OBS with further questions on the protocol administrative process.

POLICY UPDATE: Subthreshold Select Agent Toxins

Principal Investigators (PIs) who utilize biological toxins in their research programs must be aware that certain "Select Agent" toxins are federally regulated by CDC and APHIS, and have specific requirements for use. These regulated toxins include, but are not limited to, staphylococcal enterotoxins, tetrodotoxin, saxitoxin and botulinum neurotoxin.

However, if the total amount of toxin under the control of a PI remains below the specified threshold amount for a specific toxin at all times, the PI is not required to comply with **full** Select Agent registration, security and record-keeping requirements.

UW-Madison policy nonetheless requires that all PIs working with subthreshold amounts of these toxins notify the OBS Select Agent

Compliance Specialist, Rebecca Moritz, and also comply with minimal inventory and security requirements for the toxin samples. In addition, as with all biological toxins, use of subthreshold Select Agent toxins must be described on the PI's biosafety protocol. Please keep in mind that the protocol description should not only include a description of the toxin work, but also include any special handling, disposal and potential spill and exposure response procedures for the specific toxin in use.

Additional information about Select Agent toxins, including permissible subthreshold amounts of each toxin, is available at www.selectagents.gov or through the UW-Madison Select Agent website, under the links tab at: www.fpm.wisc.edu/Safety/SAPProgram.

Please contact Rebecca Moritz, UW-Madison Compliance Specialist, for more information at: 890-3468 or rmoritz@fpm.wisc.edu.



Biosafety Q&A

Use of Controlled Substances in UW-Madison Research Facilities

Although attention should be paid to the safe use of chemicals in all research facilities, there is a class of chemicals that requires special attention for important legal reasons. These are chemicals listed as controlled substances by the Drug Enforcement Administration (DEA). These chemi-

cals have many laboratory uses, but their most common use on campus is in animal research. The UW-Madison Research Animal Resources Center (RARC) publishes a very useful guide to DEA-listed chemicals, available at: www.rarc.wisc.edu/forms/files/lab_notebook/controlled_substances_information.pdf. In addition, some common questions regarding use of DEA-controlled substances on campus and the EH&S response are clarified below.

How do I go about ordering a controlled substance required for my research?

The first step is to register with the Wisconsin Department of Regulation and Licensing (DRL) by filling out and submitting Form #2184 (<http://drl.wi.gov/docview.asp?docid=308&locid=0>). The next step is to register with the DEA by filling out the online application at: www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm.

Are there any special storage requirements for these substances?

Yes, there are physical security requirements outlined by the DRL in Form #2277 (<http://drl.wi.gov/docview.asp?docid=313&locid=0>).

There has been a theft or loss of some of my DEA-controlled material; what should I do?

First, contact UW Police if there is a theft, then notify the DEA by completing the online Form DEA-106 (<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>).

An IACUC inspector told me to dispose of an expired bottle of ketamine; how should I do this?

Contact the regional DEA special agent office for authorization at (414) 336-7370. EH&S can help by determining whether the chemical is suitable for drain disposal; however, only the DEA can approve the final disposal method.

For more information, contact the EH&S Chemical Hygiene Officer, Jeff Zebrowski, at: 890-0993 or jzebrowski@fpm.wisc.edu.



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