

Compliance Considerations When Submitting a Proposal

Proposals submitted to the Office of Grant and Contract Administration (OGCA) are accompanied by the Internal Processing Form (IPF) that includes questions relating to a variety of compliance considerations as listed below:

Human Subjects

(Institutional Review Board – IRB)

Before any research involving human subjects is conducted, the principal investigator must obtain approval from the IRB for sponsored research or from the local review board for unsponsored research. If you check **human subjects** on page 1 of your IPF, the Human Research Protection Office (HRPO) will be notified and you will receive a reminder to submit appropriate paperwork. Note that several sponsors will permit the proposal to be submitted pending human subjects review. This “just in time” policy permits the agency to consider a proposal prior to human subjects review. If funded, human subjects approval is required before funds will be released. Instructions for new protocol submissions can be found at:

<http://www.umass.edu/research/submitting-reporting/submitting-and-reporting-irb>. For assistance call Nancy Swett at 545-3428.

Vertebrate Animals

(Institutional Animal Care and Use Committee – IACUC)

Before any research project that uses vertebrate animals can begin, or animals purchased, the principal investigator must obtain IACUC approval. This applies to both sponsored and unsponsored research. If you check **vertebrate animals** on page 1 of your IPF, OGCA forwards a copy of your proposal to the Compliance Office. You will receive a reminder that you need to submit an animal use protocol for review by the IACUC. Note that PHS “just in time” policy now permits agency review of a proposal prior to IACUC review and approval but IACUC approval is required before funds will be released. Forms and instructions can be found at

<http://www.umass.edu/research/iacuc>. For assistance call Barbara Miller at 545-0668.

Recombinant DNA

(Biological Safety Officer BSO, Institutional Biosafety Committee – IBC)

Projects using rDNA must be registered with the IBC. This applies to both sponsored and unsponsored research. The Biosafety Officer assigns an rDNA review level in accordance with NIH Guidelines. If you check recombinant DNA on page 1 of the IPF OGCA forwards a copy of your proposal to the Compliance Office and you will receive a reminder you will need an rDNA registration approved prior to release of funding. The registration form can be found at

<http://www.umass.edu/research/policy-procedure/rdna>. For assistance call Melinda LeLacheur at 545-5283.

Radioactive Materials

(Radiation Safety Officer RSO, Radioactive Use Committee - RUC)

UMass Amherst maintains a broad scope radioactive materials license issued by the Massachusetts Radiation Control Program (MRCP). Before radioactive materials can be used for a research project the principal investigator must be approved to use the specific radioactive isotope, and work locations must be approved by the RSO before the project begins. If your

project will use very high levels of RAM it will require full RUC review. If you check **Radioactive Materials** on page 1 of the IPF, OGCA forwards a copy of your proposal to the RSO. The RSO will contact you to ensure that you have approval for lab and facilities for your proposed use of radioactive materials. Applications for use of radioactive materials can be obtained at <http://www.ehs.umass.edu/ram1.html>. For assistance call Jeannine Clark at 545-2682.

Biohazardous Substances

(Biological Safety Officer BSO, Institutional Biosafety Committee IBC)

This category includes projects using biohazardous materials (microorganisms or other materials) which may pose a biological hazard for which biosafety level 2 or higher practices, techniques, equipment or facilities are required. All such projects require IBC review and approval prior to receipt of the biohazardous materials. If you check **Biohazardous Substances** on page 1 of the IPF a copy of your proposal will be forwarded to the Compliance office. The BSO will review your proposal and will contact you to assist you in preparing your request for IBC review of your project. If your “biohazard materials” also involve recombinant DNA the rDNA project review process ensures that the IBC reviews your project. For assistance call the BSO at 545-2682.

Carcinogenic Substances

(Biological/Chemical Safety Officer BSO)

If you check **Carcinogenic Substances** on page 1 of the IPF a copy of your proposal will be forwarded to the Compliance Office. The BSO will review your proposal and will assist you in designing measures to ensure the safety of yourself and other personnel who could come into contact with the carcinogens. The BSO will also advise you on appropriate disposal of contaminated materials. If you also checked “Vertebrate Animals” or “Human Subjects” on your IPF your protocol will not be approved by the IACUC or IRB until the committee has received notification from the BSO that any issues surrounding the use of carcinogens have been addressed.

Select Agents

(Biological Safety Officer BSO, Institutional Biosafety Committee IBC)

If you plan to use an agent on the list of Select Biological Agents and Toxins, High Consequence Pathogens or Toxins, or Plant Pathogens, you must check **Select Agents** on page 1 of your IPF. A copy of your proposal will be sent to the Compliance Office and you will receive a request to complete a *Select Agent Registration Form*. This form will be reviewed by the BSO and the IBC. The BSO will consult with you to ensure you and your lab personnel are in compliance with the Patriot Act regulations. Lists of Select Agents and the Select Agents registration form and can be found at <http://www.umass.edu/research/policy-procedure/select-agents>. For more information, contact the BSO at 545-2682 or Hilary Woodcock (for forms) at 577-0387.