

# IBC Registration

One of the most important functions of the IBC is to assess that facilities, procedures, practices and training of research personnel are in compliance with the requirements of the NIH Guidelines.

Experiments involving the following must be registered with the IBC:

- Pathogens affecting humans, animals or plants;
- Materials potentially containing human pathogens (e.g., unfixed human specimens, human blood);
- Recombinant DNA molecules including virus vectors (for more information see Recombinant DNA Categories);
- Human cell lines that are not well-characterized or require Biosafety Level 2 containment (refer to cell line part of “containment categories for commonly used agents”)
- De novo generation of transgenic animals (using recombinant DNA technology to add foreign DNA or subtract a portion of the animal's genome)
- Generation of de novo transgenic animals: Defined as the addition of foreign DNA or subtraction of a portion of the animal genome using recombinant DNA technology. Examples of recombinant DNA technology used to generate transgenic animals include (1) Direct microinjection of a chosen gene construct from another member of the same species or from a different species into a pronucleus of a fertilized ovum; (2) Insertion of the desired DNA sequence by homologous recombination into a culture of embryonic stem cells; (3) Use of a plasmid or virus to transfer genetic material into germ cells.
- Generation of transgenic plants. Contact the Biosafety Officer (jives@safety.rochester.edu).

All research involving the use of recombinant molecules or biohazards requires a minimum of Biosafety Level 1 containment.

Animal Subjects: All research involving the use of recombinant molecules or biohazards in whole animals requires both UCAR and IBC approval.

Human Subjects: Complete instructions for any research involving the introduction of recombinant molecules or biohazards into human subjects are available on the policies and procedures **involving human participants page**.

**UR Proposal Sign-Off Form:** Sign-off on the biosafety line of the ORPA form titled "UR Proposal Sign-Off Form" may be obtained through any of the following:

- Biosafety Officer at Environmental Safety (300 East River Road, Room 23)
- ORPA office (Hylan 518)

This sign-off indicates that the Principal Investigator has identified recombinant materials and biohazards that will be used and has judged what biosafety level is appropriate. Sign-off at this point does NOT constitute a risk assessment nor does it give or imply IBC approval.

### **ORPA Sign-off form**

Note that Biosafety level 4 research is NOT conducted at the University of Rochester. There are no laboratories with adequate containment features for such work.

## **IBC Registration Instructions**

The IBC registration has been changed to a 2-part process in order to streamline the information submitted at grant approval time.

### **Part 1: Laboratory Registration**

Each Principal Investigator must register their laboratory and any biological in their possession that falls under the IBC “registration umbrella”. The Laboratory Registration provides a base for the IBC to approve individual grants or projects. The Laboratory Registration is completed once and is reviewed and updated (if necessary) on an annual basis. Also, if applicable, laboratory registrations of senior Principal Investigators may be used by junior Principal Investigators of the same laboratory.

**Don't forget to maintain a current copy of your Laboratory Registration on your computer for future modification. Contact the IBC at [pbardeen@safety.rochester.edu](mailto:pbardeen@safety.rochester.edu) if you have misplaced yours.**

Please submit the completed Laboratory Registration as a PDF or Word e-mail attachment to [pbardeen@safety.rochester.edu](mailto:pbardeen@safety.rochester.edu) **AND** as a paper copy to the IBC (FAX: 274-0001 or MAIL: RC Box 278878).

- PDF version of the Laboratory Registration Form
- Word version of the Laboratory Registration Form

### **Part 2: Grant or Project Registration**

All grants and projects that involve biologicals falling under the IBC “registration umbrella” must be reviewed and approved by the IBC. If you are planning on using a Mammalian Virus Vector, you must also complete the vector registration.

Grant or Project Registrations will **NOT** be accepted by the IBC for review **UNLESS** a Laboratory Registration has been submitted and reviewed within the last year.

**Don't forget to maintain a current copy of your Grant or Project Registration on your computer for future modification. Contact the IBC at [pbardeen@safety.rochester.edu](mailto:pbardeen@safety.rochester.edu) if you have misplaced yours.**

Please submit the Grant or Project Registration as a PDF or Word e-mail attachment to [pbardeen@safety.rochester.edu](mailto:pbardeen@safety.rochester.edu) **AND** as a paper copy to the IBC (FAX: 274-0001 or MAIL: RC Box 278878).

- PDF version of the Grant or Project Registration Form
- Word version of the Grant or Project Registration Form

**Experiments requiring BSL-1 containment:** Submission of IBC grant or project registration paperwork is simultaneous or prior to initiation of such experiments.

**Experiments requiring BSL-2 containment:** IBC approval is obtained PRIOR to initiation of such experiments.

**Experiments involving whole animals:** IBC approval is obtained PRIOR to initiation of such experiments.

#### **Mentored Project – IBC Registration Form**

- This form is to be used only for mentored awards for research already declared by the Principal Investigator by the Institutional Biosafety Committee.
- Any deviations from the original declarations must be noted on the form.

Please contact Patty Bardeen with any questions. (X52402)

- PDF version of the Mentored Project IBC Registration Form
- Word version of the Mentored Project IBC Registration Form

#### **Mammalian Virus Vectors:**

Please provide the information as requested and relevant to your Mammalian Virus Vector. The Mammalian Virus Vector registration is a **supplemental requirement** to provide the IBC with information necessary for determining appropriate biosafety precautions for your particular viral construct(s).

Virus vector registrations will NOT be reviewed by the IBC UNLESS a Grant or Project Registration accompanies it; and a current Laboratory Registration is on file.

**Don't forget to maintain a current copy of your Mammalian Virus Vector on your computer for future modification. Contact the IBC at [pbardeen@safety.rochester.edu](mailto:pbardeen@safety.rochester.edu) if you have misplaced yours.**

Please submit the Mammalian Virus Vector Registration as a PDF or Word e-mail attachment to [pbardeen@safety.rochester.edu](mailto:pbardeen@safety.rochester.edu) **AND** as a paper copy to the IBC (FAX: 274-0001 or MAIL: RC Box 278878).

Please see the **General Information about Mammalian Virus Vectors** section of the IBC web pages for additional information.

Selected portion of the NIH Guidelines that may be useful in completing this registration form:

- Appendix B - for risk groups of DNA sources and vectors
- Section II - on risk assessment and containment considerations
- Section III - for description of experiments covered by NIH Guidelines
- Appendix G - for lab practices at various physical containment levels
- Appendix Q - on physical and biological containment for rDNA with animals
- Complete NIH Guidelines Table of Content

- PDF version of the Mammalian Virus Vector Registration Form
- Word version of the Mammalian Virus Vector Registration

### **Changes to the Grant or Project Registration:**

Changes involving the biologicals used in your grant or project must be communicated to the IBC. Please contact Patty Bardeen at x5-2402 for the appropriate form (pbardeen@safety.rochester.edu).

### **IBC Review/Approval and Meetings:**

The IBC meets twice per month to discuss and approve Laboratory Registrations and Grant or Project Registrations. Please remember that Grant or Project Registrations will NOT be accepted by the IBC for review UNLESS a Laboratory Registration has been submitted and reviewed within the last year.

Principal Investigators will be contacted of their approval in writing, along with an IBC approval number.

**NOTE:** This IBC approval number will be required for UCAR approval.

The meetings are open to the public. Please contact the IBC Program Coordinator at pbardeen@safety.rochester.edu for the meeting schedule and agenda. Registration documents **MUST** be submitted at least 7 days before the scheduled meeting date.

### **Additional Investigator Responsibilities**

Investigators must ensure that laboratory personnel complete federally (OHSA) mandated laboratory safety training. The University's Research Laboratory Safety Training is a 3 hour session and is offered periodically. This training is also offered in a web-based format to accommodate busy schedules. Please access this link for the classroom training schedule and the web-based program.

- Laboratory Safety Training

Investigators may also want to contact the following departments for additional responsibilities.

- University Committee on Animal Resources (UCAR)
- Research Subjects Review Board (RSRB)
  - If using primary human cells, please be aware you may need RSRB approval.
- Office of Research and Project Administration (ORPA)

This page last updated 5/9/08. Disclaimer