



UML Compliance News

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“Science may set limits to knowledge, but should not set limits to imagination.”

Bertrand Russell (1872-1970)
British author, mathematician,
& philosopher

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Research Application Review Forms Online

Please refer to the Institutional Compliance website www.uml.edu/ora/institutionalcompliance *every time* you intend to submit a form for IACUC, IBC, or IRB review. Forms are continuously being improved and updated, based on feedback from the faculty who are using them. Discard **all** old forms that you may have saved on your computer as they will no longer be accepted. We have received wonderful suggestions for improvements that have been implemented. Feedback about the changes to the application and review process has been very positive!

In the upcoming year, the Compliance Office hopes to offer additional training to make the compliance, application, and review process even easier. (See page 3, Compliance Office Updates.) Our goal is to reach those groups who may not be aware of human subject, animal, or bio-hazardous material-related regulations. The hope is that everyone will understand better what is regulated, when they need to submit applications, and how to spend less time on writing applications. The end goal is that applications are written better initially, easier to understand, and can be approved after one review!

Track changes troubles?

The application forms on the website are all protected, fill-able word documents to ensure that the information necessary for review is consistent. However, the forms have led to some problems with removing the editing marks. Try the following setting changes to avoid these problems:

- 1) Open and save the document to your computer so you are not working in the “read only” mode.
- 2) Turn the “track changes” tool off. With the document saved and open, go to “Tools”, “Options”, and then change all of the track changes options to “none” and change the balloons to “never”.
- 3) Make sure that you are working on the document saved to your computer, rather than from the browser. To guarantee this, go to the Control Panel and select “File Types”. Scroll down to select “DOC” and click on “Advanced” and uncheck the box that indicates the browser window. Click “ok” after this change is made and then close.

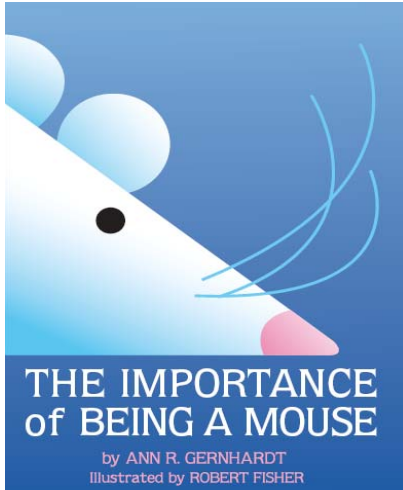
If these steps do not alleviate the problem, please call ext. 3452 for more assistance!

Training Certification

Training certification is required for all researchers, students, staff and committee members who are involved in animal or human subject research. Human subject research training is available online from two sites: citiprogram.org or cme.cancer.gov/c01/intro_01.htm. A certificate of completion must be submitted to the IRB before

application approval is granted.

For animal researchers, the online Lab Animal Welfare Course training, previously available at researchtraining.org, is being transitioned to citiprogram.org in May 2007. Animal researchers are also required to take the IACUC Health and Safety Training. Contact the Institutional Compliance Office to schedule this training.



The Importance of Being a Mouse!

Are you a researcher that uses animal models to advance science? Have you ever been asked to speak to your child's class about the work you do? This new children's book available from the Foundation for Biomedical Research explains the importance of animal research in a way that children can easily understand. It explains the role animals play in the advancement of science and medicine and why animal models are

necessary to test and understand how experimental applications work before they are tested in humans. The book is a great way to share with children the various ways animals are used in research and the importance of such research. You can find a pdf version of it, written by Ann Gernhardt and illustrated by Robert Fisher, at: <http://www.fbresearch.org/Education/pdf/importance.pdf>

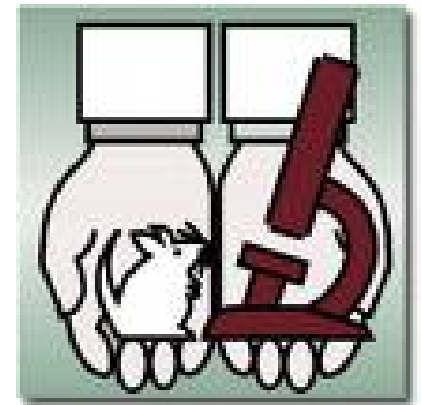
IRB Exempt Status Determination Really Means...

Research that qualifies for review under the Exempt Status does **NOT** mean that the research is exempt from IRB review. It simply means that the research being conducted with human subjects fits a category that poses minimal risk to subjects, no identifying information is collected, and no vulnerable populations are included. **Only the IRB can make the determination** that your project is exempt and an Application for Review Under Exempt Status form must be filed with the IRB just like any other research involving human subjects!

Facts About Animal Research

Scientists place a high priority on reducing the number of animals needed, replacing animals with alternative models, and refining procedures to ensure the most humane treatment possible using the fewest number of animals to yield valid results. Some types of testing can be completed using non-animal procedures. Regulations established by the USDA and the Animal Welfare Act sets high standards of care for research animals. However, medical advancements and innovations often require the use of animal models to test applications in whole living systems. Animal systems provide invaluable and irreplaceable insights into human systems.

The majority of animals used in biomedical research do not experience significant pain or distress. According to the 2000 USDA Annual Report, 63% of animals experienced only slight or momentary pain, such as an injection. The IACUC oversees all of these types of research to ensure that animals are treated humanely and



that pain and distress are minimized.

About 17-23 million animals are used in the U.S. for research every year. About 95% of these are rats and mice specifically bred for research purposes.

Economists estimate that the increase in life expectancy from the 1970s and 1980s was worth \$57 trillion to Americans. The value and improvements in the prevention and treatment of cardiovascular diseases alone is about \$31 trillion. A \$56 million research program on testicular cancer yielded a 91% cure rate and annual savings of \$166 million.

“Real integrity is doing the right thing, knowing that nobody's going to know whether you did it or not”

Oprah Winfrey

About the Institutional Biosafety Committee

The UML IBC has begun actively overseeing research that involves infectious agents, rDNA, and other potentially hazardous biological materials. The policies and procedures are online and apply to all research *and* teaching activities at UML that involve the use of such materials. The overall purpose of IBC oversight is to 1) ensure that these materials are used safely and responsibly, 2) understand where such materials are used in case of an emergency so response personnel can be prepared, 3) ensure materials are used in well-controlled areas, and 4) meet regulatory guidelines. Most materials simply require that a registration form be completed and filed with the IBC to identify what, where, and how the materials will be used. Select Agents and human or non-human primate source materials are included as materials that require registration for use.

The biohazard symbol (at the right) was developed by Charles Baldwin, an environmental-health engineer at Dow Chemical in 1966. Look for this symbol to indicate areas that have biohazardous materials in use.



Compliance Office Updates

The Institutional Compliance Director encourages you to call and schedule times for us to meet with your Department or students about compliance oversight committees or related issues. Sometimes meeting in person works better to communicate information and resolve compliance problems. It is a good opportunity for us to hear various problems or questions that researchers might have about compliance and provides a worthwhile dialogue for everyone. Contact us at any time to ask questions if you are unsure of whether your project needs to be reviewed by a compliance committee. It is always better to get verification that you are in compliance with UML Policies and Procedures *before* a research project begins! For example:

- ◆ **Did you know** that conducting funded research without the proper committee approval could put the entire institution at risk of losing federal funding?
- ◆ **Did you know** that some publications will not accept human subject research for publication unless you have IRB approval?

New Program Areas

To improve compliance at UML, several additional compliance-related programs will soon be included in the Institutional Compliance Office oversight. It is also hoped that a Compliance Hotline will be

established sometime in the future. Outreach efforts will be organized to raise awareness about these new programs and regulatory requirements. The following paragraphs provide a little more information about each of these new initiatives:

The ***Responsible Conduct in Research*** program is sponsored by the Office of Research Integrity and is designed to support PHS regulations. The program offers guidance to institutional officials who have responsibilities related to allegations of scientific misconduct involving biomedical or behavioral research. The program will focus on responsible conduct in research and raising awareness about best practices and good citizenship in research.

Export and Technology Controls is a program sponsored by the U.S. State, Commerce, and Treasury Departments that enforces the export regulations. Export controls are U.S. laws that regulate the distribution of controlled technology, information, equipment, software or services to foreign nationals and foreign countries. Publicly available technology, technology which arises during or as a result of fundamental research, technology that is educational, technology included in certain patent applications, and publicly available software are *not* sub-

ject to the regulations. However, there are some areas that faculty should be aware of when working with researchers from other countries or traveling to other countries. This includes working with foreign nationals and maintaining control of personal computers and equipment if working outside the U.S. A compliance plan is being developed and academic administrators will be informed of the export control laws and issues relevant to UML in cooperation with the Office of Research Administration.

The research oversight committee members have identified the need for a ***Protocol Writing Workshop***. Faculty and staff who serve on these committees are spending a lot of time reviewing applications that are sometimes unclear or incomplete and, as a result, require more than one review. This workshop will be for researchers who submit applications to the IACUC, IBC, or IRB. It will include information about what the reviewers are looking for, how to complete the application form, how the review process works, and writing applications so that one review is sufficient. The hope is to streamline the process for everyone involved. Coming soon!

Need Help?

If you are unsure of whether a project needs IRB, IBC, or IACUC review, please contact the Institutional Compliance Office. The Compliance Director can answer your questions (or try to find the answer) and provide guidance to take the appropriate action. If it is a human subject research question, the IRB Administrator can also help to advise you.

Some of the regulations *are* confusing so please do not hesitate to call and ask for guidance. We sometimes confer with peers at other institutions to determine how best to advise the PI to submit the paperwork. Every situation is different! Also, some projects may require review by more than one research oversight committee and we can help you coordinate your applications.

Human Subject Research /S...

Briefly, any of the following types of studies are human subject research and require IRB review:

- ◆ Studies that utilize human test subjects for any devices, products, drugs, or materials.
- ◆ Studies that collect data through intervention or interaction with individuals.
- ◆ Studies using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- ◆ Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study.
- ◆ Studies that produce generalizable knowledge about categories or classes subjects from individually identifiable information.
- ◆ Studies that use human beings to evaluate environmental alterations.



Additional Resources

UMass Lowell, Office of Institutional Compliance
200 Dugan Hall
www.uml.edu/ora/institutionalcompliance

USDA: Office for Human Research Protections (OHRP) <http://www.hhs.gov/ohrp/>

OHRP decision chart for determining whether a project is human subjects research www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm

OHRP guidance by topic <http://www.hhs.gov/ohrp/policy/index.html#topics>

Export Control information is available at <http://www.bis.doc.gov/licensing/exportingbasics.htm>

The **Office of Research Integrity**, Responsible Conduct in Research information is available at <http://ori.dhhs.gov/education/>

CITI training certification is available at <https://www.citiprogram.org/>

Proposal Submissions and Internal Processing Forms-

When you submit a proposal and indicate that the research involves human subjects, animals, or biohazardous materials on the Internal Processing Forms, it will trigger a notice to the Compliance Office that you may also be submitting an application to the appropriate research oversight committee. If you have questions as to whether you should indicate “yes” to any of these on the Internal Processing Form, please call Elaine Major at ext. 3452 for guidance. It is important that you contact the Compliance Office when you receive funding notification so we can either advise you of the appropriate steps to take for submitting applications to an oversight committee or close the file.