



UML Compliance News

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"I decided not to let my past rule my future so I decided to change my present in order to open up my future."
Dr. Ana M. Guzman

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Export News

Efforts are underway to increase awareness on campus of Export Administration Regulations (EAR) and International Traffic and Arms Regulations (ITAR). These regulations do apply to some areas of research conducted at UML and high risk disciplines include engineering, space sciences, computer science, biomedical research with lasers, research with encrypted software, and research with controlled chemicals, biological agents and toxins. There are specific types of materials covered under each of the disciplines that faculty should be aware of and understand how to stay in compliance with the regulations that cover each of these materials.

Faculty briefings will be held this fall to review the regulations, outline steps being taken to implement an export control program, and explain additional requirements for some types of research that may involve foreign nationals.

Additional briefings will be held with UML staff from various departments that may be involved in the implementation process, such as Grants & Contracts, Human Resources, Purchasing, and others to outline roles, establish responsibilities, and identify a contact person.

There are steep fines and penalties for non-compliance with these regulations. Our goal is to increase your understanding of the regulations so that UML maintains compliance with all federal regulations. If you have any questions about export controls, please contact Elaine Major by phone at x3452 or email Elaine_Major@uml.edu.

IACUC Updates

Several new forms have been developed for tracking purposes. These include:

- ◆ Individual Training Proficiency Form
- ◆ Training Session Documentation
- ◆ Controlled Substance Use Logs
- ◆ Census Cards

Updated Policies and procedures are now posted on the website. Major changes include required demonstration of handling and procedure proficiency, forms to document all training conducted and completed, expedited annual review for protocols with no changes, an online training program change to CITI, and use of cell phones in the animal facility.

Any procedures to be conducted should be scheduled by using the log sheet on the procedure room door. Also, remember that it is your responsibility to leave the room as clean as you find it.

Training Dates

- ◆ **Annual IACUC overview:**
Friday, Oct. 17 at 11am in 615 Olsen
- ◆ **New! IRB Clinics:**
Need help developing IRB Applications? Stop by Thursdays between 2-4pm Wannalancit 2nd floor Conference Room Call Elaine at x3452 for more information
- ◆ **Export Controls- Faculty Briefing:**
Wed., Oct 15: 12 to 1:30pm,, Alumni Hall
Thurs. Oct 23: 11:30 to 1pm, Alumni Hall
- ◆ **Export Controls- Administrative Staff Briefing,** Oct 28, 9-11am Wannalancit, 2nd floor conference room

IRB Updates

New IRB Forms

Always check uml.edu/ora/institutionalcompliance for both new and updated forms. New ones include:

- ◆ Video/Photo Publication Release
- ◆ Sample Informed Consent Documents (3 examples)
- ◆ IRB Administrative Oversight Report
- ◆ IRB Self-Report Noncompliance by PI

Overview of Improvements

The Compliance Office continually works to improve the process to facilitate research compliance. Some of the most recent changes, reflected in the IRB Policies and Procedures, rev. 2 include:

- ◆ A **pre-review** step has been added for applications that come in that need additional information in order to insure that reviewers only devote time to review of complete applications.
- ◆ **IRB Clinics** are going to be offered Fall 2008 to see if this informal opportunity helps faculty and students in the process of developing applications.
- ◆ **Requests for Blanket Approval** are sometimes an appropriate way to submit an application. This allows for the IRB to review and approve a research concept with the understanding that specific information will be provided later through the amendment process. The purpose of this approach is to avoid missing opportunities to conduct research due to IRB review and approval timelines.
- ◆ **Data Storage** practices are now outlined more clearly in the newly revised Policies and Procedures. Note the difference between ‘data collection’ and long-term ‘data storage’ and that how and where this is done should be identified in the application with care taken to protect confidentiality.
- ◆ **Translated documents** should be submitted AFTER the English versions are approved to avoid wasting anyone’s efforts until the English version is finalized.
- ◆ **Education certificates** are kept on file with Amy Finneral. For questions, contact Amy at x4698.

IRB Applications by Department

College of Arts & Sciences	
Biology	1
Computer Science	15
Mathematics	2
Physics	2
Criminal Justice & Criminology	5
English	2
Music	6
Psychology	50
Sociology	3
RESD	24
Graduate School of Education 61	
College of Engineering	
Chemical and Energy	1
Mechanical	6
School of Health & Environment	
Clinical Lab & Nutritional Sciences	13
Community Health & Sustainability	3
Nursing	26
Physical Therapy	34
Work Environment	54
College of Management	
Accounting	1
Management	6

PIs with open protocols: 90

PIs with 5+ open protocols: 11

CITI training completed since 11-1-06: 326

Informed Consent News

Teach Back Method— this is a new tool to use in some situations to verify comprehension. In short, it allows the researcher to say “Tell me in your own words what will happen if you decide to participate in this study.”

Sample Forms are now posted on the website to serve as models that demonstrate all of the elements of consent.

Title Line has been added to the form for projects that have several groups being consented. It helps the IRB Office better track the forms and should help PIs, too.

Change in PI signature process—PI signatures are now only required on final approved forms. This should help to streamline the submission process.

Institutional Biosafety Committee News



Remember—UML Institutional Biosafety Committee Policies require registration for all **Teaching and Research** activities that involve the use of biohazardous materials. Definitions of covered materials are provided as a reminder of the types of materials that need to be registered with the IBC before work with such materials is initiated.

Biosafety measures apply to the handling of biological materials or organisms with a known potential to cause disease in humans. The principles and practices employed in biosafety range in complexity and detail in direct relation to the relative risks associated with a given microorganism or its products. Biosafety includes a complete program of administrative controls, medical surveillance, vaccination, and containment strategies for promoting safe laboratory practices, procedures, and containment equipment to reduce the risk of disease to employees from potential occupational exposure to infectious agents or other biologically derived molecules.

A broad definition for a biological hazard is any bacterium, prion, rickettsia, virus, fungus, parasite or its products (i.e. toxins) that can self-replicate, invade a host and cause an infection, or can cause morbidity or mortality in humans or animals. The key component is “those agents that can infect humans or are suspected of infecting humans primarily”. UML defines biohazards as:

“All infectious agents or biologically derived infectious materials that present either a risk or a potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. An IBC Research Registration Form must be submitted to the IBC prior to initiation of any project involving use of these materials or agents. The following is a list of the potentially hazardous biological materials and agents.

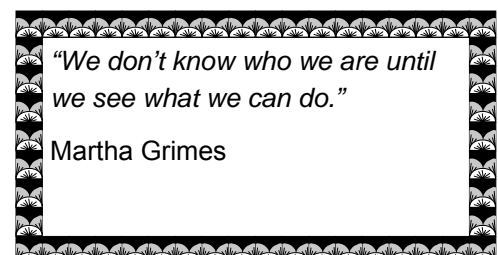
- Human, animal, and plant pathogens including viruses, oncogenic and defective viruses (viral vectors), Rickettsiae, Chlamydiae, bacteria (including those with drug resistance plasmids), fungi, parasites, undefined or other infectious agents, such as prions, and toxins (bacterial, fungal, plant)
- All human blood, blood components and products, tissues and body fluids
- Cultured cells (all human and non-human primates) and potentially infectious agents these cells may contain
- Infected animals and animal tissues
- Non-human primates and any tissues derived there from (can transmit Herpes B virus)
- Sheep and any tissues derived there from (can transmit *Coxiella burnetii*, the causative agent of Q-fever)
- Recombinant DNA

Compliance Office Updates

Do you know where to find us?

The Institutional Compliance Office is located at 215 Wanalancit at 600 Suffolk Street. Elaine Major, Compliance Director, and Amy Finneral, IACUC Administrator, are located here and the fax number is x6012.

The IRB Administrator, Dr. Stephen Moses, is also part of the Compliance Office and he is located at 203 Dugan Hall and the fax number is x3018.



Compliance Office Briefs

IACUC Protocols

25 Open and approved

Animal Research by Department	No. PIs	No. Protocols
Biology	4	13
Clinical Lab & Nutritional Sci	2	6
Mechanical Engineering	1	1
Physical Therapy	1	4

IRB Applications

195 Open Studies as of 9-25-08

2008— 90 to date

28% Exempt, 63% Expedited, 9% Full

2007— 156 Total

34% Exempt, 52% Expedited, 14% Full Review

2006— 139 Total

37% Exempt, 37% Expedited, 26% Full

IBC Registrations

17 registered to date

Website Resources

Training:

Human Subject, Animal and RCR Certification

www.citiprogram.org/

Human Subject Certification Alternatives from NIH:

<http://ohsr.od.nih.gov/IRBCBT/intro.php>

<http://phrp.nihtraining.com/users/login.php>

**UML Compliance Policies and Procedures & Forms,
Office of Institutional Compliance:**

www.uml.edu/ora/institutionalcompliance

USDA Office for Human Research Protections:

<http://www.hhs.gov/ohrp/>

Export Control information:

<http://www.bis.doc.gov/licensing/exportingbasics.htm>

Conflict of Interest Toolkit:

<http://opa.faseb.org/pages/Advocacy/coi/Toolkit.htm>

Comments?

If you have any questions or problems related to compliance issues, ideas for improvements, or questions about policies, please contact Elaine at x3452.

