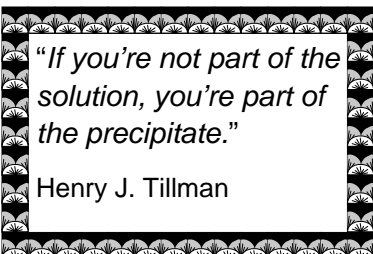




# UML Compliance News

Issue 3, September 2007



*"If you're not part of the solution, you're part of the precipitate."*

Henry J. Tillman

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## A&F Outreach Efforts

The Administration and Finance Office is testing some new approaches to deliver information to UML faculty and staff. An A&F Resource Fair will be held in Alumni Hall on September 18. Drop by between 9 and 11 am to meet the people who handle you're A&F needs, learn more about A&F functions and new processes, and gather information to help resolve any problems you may be having. The Resource Fair is set up to allow you to stop in as your schedule permits. Flyers will be posted around campus!

Also, starting on September 19, a series of weekly brown bag seminars will be offered to describe A&F functions in more detail. These presentations will be about one hour with time for questions and answers. Seminars will be offered alternate weeks on North Campus at Alumni Hall and South Campus at Dugan Hall, Admissions Conference Room. The seminar schedule by topic will be posted on UML Today and sent to the Deans and Department Chairs for posting.

## IRB Updates...

IRB operations continue to be streamlined to make the application and review processes easier for researchers. The complete version of the IRB Policies and Procedures, Rev 1 are available online for detailed information. Some of the updates include:

Research that involves minors may be reviewed under the exempt or expedited process as long as the risk is minimal and other requirements are met (see Risk page 4).

The consent form has a friendlier look and is now titled "Agreement to Participate". It can be modified to suit your needs. Parts of the consent process may be waived if you have a minimal risk project and the type of research justifies the request. Just check the appropriate box on the application form.

Database records are being reviewed and expired projects closed out if a final report or annual renewal has not been submitted by the anniversary of the approval date.

(Amendments do not affect the approval date.) PIs are responsible for filing final reports or annual renewals. Our goal is to send out notices 30 days before an approval expires. Research that involves human subjects may not continue after approvals expire. Please indicate your IRB protocol number for any correspondence with the IRB. It facilitates the processing of your paperwork!

## Online Training Information

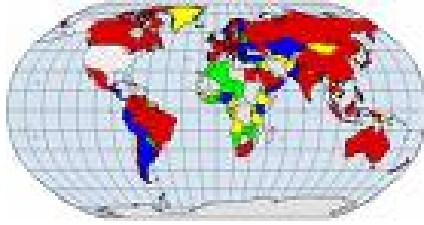
Training is required for all researchers, students, staff and committee members who are involved in animal or human subject research. Human subject and animal research training is available online at: [www.citiprogram.org](http://www.citiprogram.org). For human subject research training additional options include <http://ohsr.od.nih.gov/IRBCBT/intro.html>, or <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>.

Animal researchers are also required to attend the IACUC Health and Safety Train-

ing once per year and encouraged to complete a Health History Questionnaire. The form is online and used for baseline evaluations through Health Resources. This service is provided by the EHS Department.

New this year, online training for the Responsible Conduct in Research has been added at [www.citiprogram.org](http://www.citiprogram.org). All CITI training can be linked to UML and results are sent automatically upon successful completion of the course. Contact the Compliance Office for any training questions.

## What are Export Controls?????



U.S. export laws and regulations exist to protect the national security and foreign policy interests of the U.S. Regulations are enforced by the

Department of State (through International Traffic in Arms Regulations-ITAR), Dept. of Treasury (through the Office of Foreign Assets Control-OFAC) and the Department of Commerce (through Export Administration Regulations-EAR). In general, export controls govern the shipment, transmission, or transfer of certain sensitive items, information, or software to foreign persons or entities. In some cases, a license is required from the US Government. An export includes any item that is sent from the United States to a foreign destination or to a foreign national. "Items" include commodities, software or technology, such as clothing, building materials, circuit boards, automotive parts, blue prints, design plans, retail software packages and technical information.

Export controls present unique challenges to universities and colleges because they require balancing concerns about national security and U.S. economic vitality with concepts of unrestricted academic freedom, publication and dissemination of research findings. Although the export control regulations cover virtually all fields of science and engineering, a license is not needed to transfer scientific, technical, or engi-

neering information to students and faculty if the information is in the public domain. A fundamental research exemption (FRE) applies for basic and applied research in science and engineering so long as the research is carried out openly and without restrictions on publication or access to or dissemination of the research results. The FRE does not apply to actual shipment outside the U.S. border of things (physical items) or services.

An item is also considered an export even if it is leaving the United States temporarily, if it is leaving the United State but is not for sale, (e.g. a gift) or if it is going to a wholly-owned U.S. subsidiary in a foreign country. Finally, release of technology or source code subject to the Export Administration Regulations (EAR) to a foreign national in the United States is "deemed" to be an export to the home country of the foreign national under the EAR.

A relatively small percentage of total U.S. exports and reexports require a license from the Bureau of Industry Security. License requirements are dependent upon an item's technical characteristics, the destination, the end-user, and the end-use. You, as the exporter, must determine whether your export requires a license. When making that determination consider:

- What are you exporting?
- Where are you exporting it to?
- Who will receive your item?
- What will your item be used for?

## Why researchers need to know about Export Controls!

Researchers are at the "front line" of export control because they

- ◆ Control the scope of the research project
- ◆ Make decisions about equipment or technology and to whom it may be transferred
- ◆ Penalties for non-compliance are high!

Considerations to meet export regulations:

If funding restrictions are involved, the Chancellor's Office must approve proposal submission or acceptance of funding as this may eliminate the Fundamental Research Exclusion.

Write a clear statement of work in proposals to

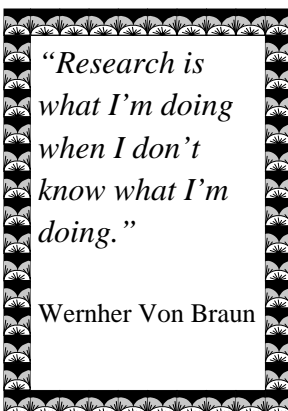
allow contract administrators to spot export control issues

Review the lists of controlled items and countries that have U.S. regulations limiting exports on items

Be aware of and avoid "deemed exports"

Laptops and GPS equipment may need to be registered for travel abroad

Be wary of discussions regarding controlled items that could be overheard by foreign nationals or foreign entities—this may be considered an export!



*"Research is what I'm doing when I don't know what I'm doing."*

Wernher Von Braun

## Institutional Biosafety Committee News

The IBC has been working effectively to review and approve registrations for use of biohazardous materials and rDNA. The committee recently completed a “Checklist for Biosafety Laboratory Evaluations”, based on guidelines from the 2007 Biosafety in Microbiological and Biomedical Laboratories, 5th edition. The checklist was evaluated by the IBC during a walk-through of two labs that have active IBC registrations and modified based on its utility. The checklist is intended to serve as a tool for PIs to use to evaluate their own laboratories and quickly identify areas that may need improvements or modifications. New information in the BMBL, 5th edition includes: Occupational medicine and immunization, Decontamination and sterilization, Laboratory biosecurity and risk assessment, Biosafety Level 3 (Ag) laboratories, Agent summary statements for some agricultural pathogens, and Biological toxins. The BMBL, 5th ed is available from the website at <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm> and the checklist is at <http://www.uml.edu/ora/institutionalcompliance/default.html>



## 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 also a good opportunity for us to hear from you in regards to problems or questions about regulations or compliance office procedures. Previous meetings have provided 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.

### New Program Areas

The *Responsible Conduct in Research* program is sponsored by the Office of Research Integrity and is designed to support PHS regulations. Responsible conduct of research is simply good citizenship practices applied to professional life. It is an ongoing process of reconciling regulations, guidelines, standards, and ethics to promote integrity in the proposing, planning, conducting, reporting, and reviewing of research. It involves reporting and working honestly, accurately, efficiently, and objectively. The Office of Research Integrity directs Public Health Service funded research and has published the “Introduction to the Responsible Conduct of Research” as a resource guide that may be accessed from their website at <http://ori.dhhs.gov/education/>. Responsible conduct of research covers nine core areas that are considered significant to ensure integrity in research. The nine core areas include data acquisition, management, sharing and ownership; men-

tor/trainee responsibilities; publication practices and responsible authorship; peer review; collaborative science; human subject research; research involving animals; research misconduct; and conflict of interest and commitment. Instruction is available online through [www.citiprogram.org](http://www.citiprogram.org) and results can be linked to UML. UML’s Office of Institutional Compliance promotes and supports the responsible conduct of research program. In addition to online training, additional activities are being developed to support the RCR concepts and include developing and offering an RCR methods course for students, institutional-wide lectures, and RCR updates in campus publications.

**Note:** Any faculty or staff interested in helping or providing suggestions to develop an RCR methods course, please contact Elaine at ext. 3452 or email [Elaine\\_Major@uml.edu](mailto:Elaine_Major@uml.edu).

**Export Controls** policies and procedures and online forms for any exported-related needs are being developed. These will be posted on the UML Institutional Compliance website as soon as they are finalized and approved. If you have an export question in the meantime, please contact Elaine at ext. 3452.

Forms are continuously being updated throughout the year based on user feedback. Always go to [www.uml.edu/ora/institutionalcompliance](http://www.uml.edu/ora/institutionalcompliance) for the latest version of the form that you need.

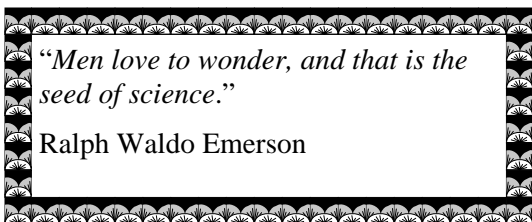
### Welcome New IACUC Administrator!

Amy Finneral joined the Institutional Compliance Office in July 2007. She graduated from Mt. Ida College with a B.S. in Veterinary Technology. Amy most recently worked as the Breeding Colony Manager for the Schepen’s Eye Research Institute. She also has experience as a surgical technician for Genzyme. She works part-time as the IACUC Administrator and will also be assisting with updating IRB records. Amy looks forward to meeting and working with you and can be contacted at ext. 4698 or by email at Amy\_Finneral@uml.edu

### It’s All About Risk.....



For IRB applications, try to think outside the box and identify any reasonably foreseeable sources of risk based on procedures, topics, population characteristics, etc. Next, identify the foreseeable types of risk: physical, psychological, social, economic, legal, or dignitary. Then ask yourself: Is the foreseeable harm **GREATER THAN MINIMAL RISK?** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than a) those encountered in daily life or b) during the performance of routine physical or psychological examinations or tests. Risk is often the determining factor for the type of IRB review that is necessary for any particular research project involving human subjects. Even projects involving vulnerable populations (with the exception of prisoners) can be reviewed through the exempt or expedited process as long as they meet the regulatory requirements.



### Website Resources

**Training:**  
**Human Subject and Animal Researcher Certification**  
[www.citiprogram.org/](http://www.citiprogram.org/)

**Human Subject Training Alternatives:**  
<http://ohsr.od.nih.gov/IRBCBT/intro.html>  
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

**UML Compliance Policies and Procedures & Forms, Office of Institutional Compliance:**  
[www.uml.edu/ora/institutionalcompliance](http://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>

**Responsible Conduct in Research, Office of Research Integrity:** <http://ori.dhhs.gov/education/>

### Fall Semester 2007 Research Oversight Committee Meeting Dates:

	IACUC	IBC	IRB
Sept	20	11	18
Oct	25	9	16
Nov	20	13	20
Dec	20	11	18
Jan '08	17	8	15

For location and time information, please contact Elaine Major at ext. 3452 or email Elaine\_Major@uml.edu