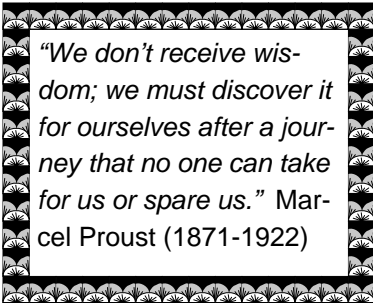




UML Compliance News

Issue 4, Spring 2008



"We don't receive wisdom; we must discover it for ourselves after a journey that no one can take for us or spare us." Marcel Proust (1871-1922)

Contacts:
 Director of Institutional Compliance, Elaine Major, x3452

IACUC Chair, Elaine Major

IACUC Administrator & IRB Assistance,
 Amy Finneral, x4698

IBC Chair, Dr. Susan Woskie

IRB Chair, Dr. David Wegman

IRB Administrator,
 Dr. Stephen Moses, x4134

Who Owns Data?

Data ownership can sometimes cause problems between funding agencies and researchers or between researchers so understanding policies and expectations will help to avoid such issues. NIH defines "data" as: "recorded information, regardless of the form or medium on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data." The NIH definition frames the definition on how the information is recorded. The Office of Management and Budget Circular A-110 defines data as "recorded factual material commonly accepted in the scientific community as necessary to validate research findings but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues." This definition depends on dissemination and validation. Most institutions traditionally recognized the investigator as owning the data that resulted from his/her research. However, with increasing sponsored programs, award requirements, and private sector contracts, some institutions and sponsors are asserting ownership over data resulting from research.

Staff News...

Mr. Alexis Cepeda, with Charles River Laboratories, will be joining us in mid-April to take over the management of the ORS Facility. He is replacing Ms. Sheryl Perry who previously managed the facility. Alex comes to UML from Beth Israel Deaconess Medical Center in Boston where he worked for CRL as an animal technologist. He can be reached at x2830 or Alexis_Cepeda@uml.edu. Welcome Alex!

Ms. Amy Finneral, the IACUC Administrator, is also helping with some IRB-related administration. Amy is responsible for tracking education training information, sending out reminders for training and continuing review/annual renewals, and managing final reports. Amy is helping us to keep our records up-to-date and accurate. You may be hearing from her!

Online Training Information

Training certification is required for all researchers, students, staff and committee members for research using animal or human subjects. Online training for both is at www.citiprogram.org. Additional options for human subject training include: <http://ohsr.od.nih.gov/IRBCBT/intro.php> and a new course at <http://phrp.nihtraining.com/users/login.php>.

Animal researchers must also attend the IACUC Health and Safety Training once per year.

The CITI site includes training about Responsible Conduct in Research with information on conflict of interest; misconduct in science; data acquisition, management, sharing, and ownership; publication and authorship practices; peer review; collaborative science; and mentor/trainee responsibilities. All CITI training results can be linked to UML and accessed by the compliance office upon successful completion of the course. Contact the Compliance Office at x3452 for any training questions.

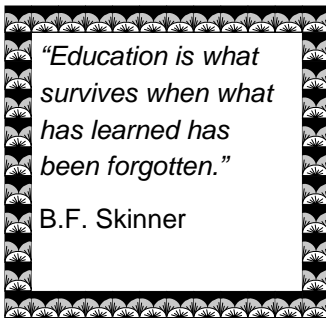
Inside this issue:

IRB Updates: Videotaping Informed Consent Internet Research	2
IBC News	3
Compliance Office Updates	3
Export News Deemed Exports	3
Conflict of Interest	4
Website Resources	4

IRB Updates

Videotaping Guidelines

Videotaping human subjects for research projects can be a useful tool to record events and gather more accurate data in addition to providing an effective tool for backing up initial data collection. However, care needs to be taken when using videotapes in research settings. With more and more videos available on the internet, it is very important that when videotaping is allowed in human subject research that measures are in place to protect subject privacy and confidentiality. The IRB typically requires a separate consent form that must be signed by the participant to approve the videotaping. The form should also indicate how long the tape will be stored, how it will be stored, and when it will be destroyed.



Informed Consent Guidelines

Efforts are under way to provide better guidance for exempt and expedited human subject research in the socio-behavioral fields. The underlying concern should always be focused on risk to the subject from participation. The informed consent process is really the cornerstone of all human subject research and its purpose is to fully identify and explain any risk/benefit to potential participants.

While the informed consent process should typically be conducted, did you know that many socio-behavioral types of research can justify a request for waiver of documentation of informed consent? Examples of where this is appropriate is for research in which no identifiers are being collected and the only record linking the subject to the research would be the consent form. The application form has a box that must be checked to request a waiver. The regulations allow for this but it must be requested by the PI **and** the IRB must specifically approve the waiver. ***Don't be afraid to check the box!*** A lot of survey research may meet the requirement for requesting a waiver of documentation of informed consent. More information is available online in the UML IRB Policies and Procedures (see page 42).

Internet Research and Ethics

The increased use of the internet is quickly increasing the amount and types of human subject research that may be conducted over the internet. While it is an exciting means to reach new and diverse subject groups, guidelines are not always clear as to how to proceed. (IRB review and approval is typically required for this type of research, too.) Some of the issues that need to be considered before conducting research over the internet include: How intrusive is the research? Is it conducted in a public or a private space? Are the subjects being studied in any vulnerable group or made vulnerable because of the research? Does the research itself or publication of results have the potential to harm subjects? How will you deter-

mine if the subjects are of legal age for consent (18 years or older in MA)? Is your site secure? Are you informing subjects how to log off appropriately and remove temporary files and cookies from computers on which they respond to maintain their privacy? Using direct quotes from MySpace websites, for example, can also identify subjects and this practice should be avoided. These questions and more are things that need to be thought out before conducting internet research. Both IRB members and researchers are learning to understand the usefulness and importance of this mechanism to conduct research.

Institutional Biosafety Committee News

Transporting Biological Materials?

Sometimes, researchers need to transport infectious or non-infectious materials between universities, between campus buildings and laboratories, or even overseas. It is important that proper procedures are followed in any case to ensure the safety of people transporting the materials, to maintain the integrity of the samples or materials, and to meet regulatory requirements if applicable. In addition to IBC review and approval, the Environmental Health and Safety Department requires prior review and approval of shipments to ensure compliance with various regulations from different agencies that may apply depending upon the material transported and where it is being transported. For over the road transport within the U.S., it is mandatory to comply with the Department of Transportation packaging and labeling requirements. Air transportation compliance is governed by the International Air Transport Association Dangerous Goods Regulations. For transport outside the U.S., researchers must comply with EPA's Toxic Substance Control Act, Center for Disease Control, U.S. Department of Agriculture, and the Ministry of Health for the importing country which may have regulations or require permits. Please check with EHS for the most up-to-date information for transport of materials at UML and within the U.S.



Compliance Office Updates

RCR Methods Course Any faculty or staff interested in helping or providing suggestions to develop a Responsible Conduct in Research methods course are encouraged to contact Elaine Major at x3452.

Forms to apply to the various research oversight committees are continuously being updated based on user feedback. Always go to www.uml.edu/ora/institutionalcompliance for the latest version of the form that you need. An example of a recent change is Informed Consent forms are unprotected in order to be modified to suit your project needs. Many forms can now be submitted electronically from your email account if the check box is selected!

Conflict of Interest disclosure form and guidelines have been updated and posted on the Institutional Compliance website (More on page 4!)

Misconduct in Science updates will be posted soon!

Customer Service Surveys will be sent to faculty by the Institutional Compliance Office to help us evaluate recent changes that have been made to research oversight committee processes. If you have submitted applications to the IACUC, IBC, or IRB, (especially over the past 5-10 years), we are interested in your feedback to continue to make process improvements and facilitate compliance. Of course, the surveys will be submitted for IRB review and approval first!

Export News: What are Deemed Exports?

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. An export includes any item that is sent (or communicated) 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. Please be aware that communication by email, telephone or discussion with foreign nationals is considered a "deemed export". Please call Elaine at x3452 for more information or visit the website, which has recently been updated with export control information (www.uml.edu/ora/institutionalcompliance)!

Conflict of Interest News

Conflict of interest (COI) issues have been in the news lately, typically due to relationships between clinical investigators and pharmaceutical companies. UML has recently updated its policies and the Disclosure Form and they have been moved to the Institutional Compliance website under the RCR program. COI is defined as: competing interest; an actual or potential conflict between the personal interests of a covered Individual and the interests of UML or the public or the reasonable appearance of such a conflict to the public. UML's goal is to minimize the extent to which the design and conduct of research is influenced by various relationships. Some questions that you might ask to help determine whether you have a COI include:

Am I serving two masters?

Who is my primary commitment to?

Am I "double-dipping"?

Am I in a financial relationship with a company and does the relationship exert any influence on my research?

Does the relationship compromise my independence when it comes to research and reporting results?

A great additional resource for COI information has been developed as a result of a Federation of American Societies for Experimental Biology meeting on COI policies and practices. Three guiding principles were used at the meeting to provide a framework to initiate discussion on national COI policy guidelines. The principles were objectivity, transparency, and accountability. One outcome of the meeting was development of a COI Toolkit. The Toolkit is online at: <http://opa.faseb.org/pages/Advocacy/coi/Toolkit.htm>. It also includes recommended practices to help achieve the COI guidelines. The list of tools covers topics such as Relationships in Biomedical Research, Academic-Industry Agreements, Patent Disclosure Language, Sample Wording for Disclosure of Financial Interests in Publications, and many more. Check it out for questions you may have about COI issues!

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>

"I am among those who think that science has great beauty. A scientist in his laboratory is not only a technician: he is also a child placed before natural phenomena which impress him like a fairy tail." Marie Curie (1867-1934)