



UML Compliance News

Issue 1 • November 2006

Is Your Project Human Subjects Research?

“It is better to know some of the questions than all of the answers.”

James Thurber

UML Contacts:

Director of Institutional Compliance, Ms. Elaine Major, ext. 3452

IRB Administrator, Dr. Stephen Moses, ext. 4134

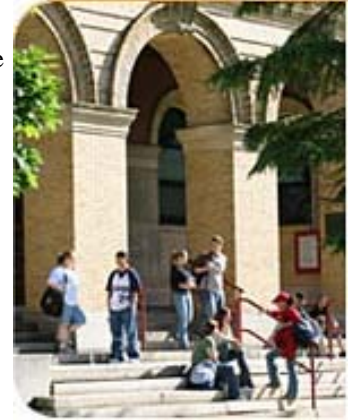
IRB Chair, Dr. David Wegman, ext. 4460

IACUC Administrator, TBA, ext. 3452

This newsletter is to provide guidance to UML investigators who may be uncertain if a research study meets the definitions of human subject research as stated in the federal regulations (45 CFR 46.102). Sometimes, it is difficult to determine if a proposed project does need IRB review. The purpose of this newsletter is to help you to identify what actions you should take to ensure you are in compliance with UML policies and procedures and the federal regulations that oversee research activities at UML.

Institutional Review Boards (IRBs) have been established to protect the rights and welfare of human research subjects and evaluate the ethics of research involving human subjects. The Institutional Official (Dr. John Wooding, the Provost) has signed a Federalwide Assurance that is a commitment that the Institution will comply with the federal regulations related to human research subjects. All projects that involve human subjects, whether biomedical or socio-behavioral, require IRB review. If you are unsure whether your project constitutes human subject research, please call the Institutional Compliance Office for assistance in making the determination.

The cost of non-compliance to these regulations can be steep. The Institution can risk the loss of federal funding if just one researcher is conducting research without the proper review and approval. Some faculty at other institutions have faced prosecution and jeopardized their professional reputations, and even been jailed for severe non-compliance or scientific misconduct. The Institutional Compliance Office has been established to help prevent these problems and to ensure that researchers have assistance in interpreting and meeting federal regulatory requirements for required research oversight committees. It is best to always err on the side of caution! If you are uncertain about whether a study is human subjects research or not, please feel free to contact the Office of Institutional Compliance for assistance in interpreting the regulations.



Inside this issue:

What is Research (cont.)	2
What 'Exempt' Status Determination Really Means	2
How is "Human Subject" Defined	2
Identifying Human Research Studies	3
What is NOT Human Subjects Research	3
Studies that ARE Human Subjects Research	4
Additional Resources	4

What is research?

Research is defined as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)). Further clarification as to whether it is human subject research is obtained by

evaluating how the data are obtained (if gathering data requires any intervention or interaction with humans) and if the data contains identifiable private information. The intent to publish the information gathered can also help define research. If the project is de-

scribed as “research” or the PI would receive any form of academic recognition for the project, then the project is considered research and must receive IRB review, if human subjects are involved.

(Cont. on page 2)



What Is Research (cont from page 1).....

Operational activities such as defined practice activities in public health, medicine, psychology, and social work and studies for evaluating internal management and operations are usually not defined as research. Generally, journalism or political polls are not considered research. Examples of projects that are not considered research include: classroom

assignments, oral histories, routine outbreak investigations and disease monitoring. However, there may be some circumstances in which these activities are considered research when there is a clear intent to contribute to generalizable knowledge.

What 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.

“Just definitions either prevent or put an end to a dispute.”

Nathaniel Emmons

How is “Human Subject” Defined?

A **human subject** as defined by the Federal Regulations is “a living individual about whom an investigator conducting research obtains (1) data through intervention or interactions with the individual, or (2) identifiable private information.” (45 CFR 46.102 (f) (1), (2))

Living individual—specimen (s) / data /information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased are not human subjects.

Intervention includes physical procedures, manipulations of the subject, or manipulations of the subject’s environment for research purposes. **Interaction** includes communication between the investigator and the subject, including face-to-face meetings, mail, or phone interaction as well as other types of communication.

Identifiable private information includes information about behavior that occurs in a context in which an

individual can reasonably expect that no observation is taking place (such as a public restroom) and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record).

“Identifiable” means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual (e.g. Social Security No.).

Observational studies of public behavior (including television and internet chat rooms) do **not** involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Studies based on data collected for non-research purposes may **not** constitute human subjects research if indi-

viduals are not identifiable (e.g., school attendance data, crime statistics, or election returns).

Studies based on data that are individually identifiable **but** are also publicly available may **not** constitute human subjects research. “Publicly available” is intended to refer to record sets that are truly readily available to the broad public such as census data, federal health, labor, or educational statistics. An investigator should **not** assume information qualifies as “publicly available” merely because it has been posted on an electronic website and can be accessed without authorization. Contact the Compliance Office if you are ever unsure about your research project.

Identifying Human Research Studies

Certain projects may have the characteristics of human subjects research but may not meet the regulatory definition. Any study that meets the definition requires IRB review. There are three categories:

- Studies that **are** human study research
- Studies that **may be** considered human subject research
- Studies that **do not** qualify as human subjects research

If you are unsure, contact the Office of Institutional Compliance for guidance. **Federal regulations do not allow PIs to make this determination.**



What is NOT Human Subjects Research

Studies that fit any of the categories below do not need IRB review.

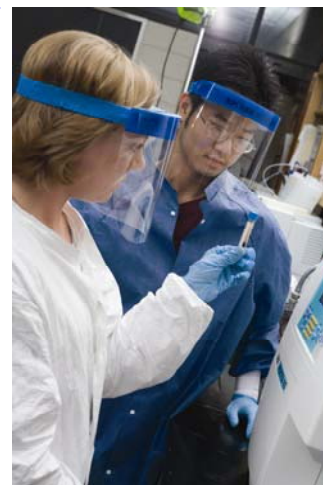
- 1) Data collection** for department, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys.
- 2) Service surveys** issued or completed by University personnel for the intent of improving services and programs or to develop new services or programs as long as subject privacy is protected, confidentiality is maintained, and participation is voluntary.
- 3) Information-gathering interviews** where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Example: questioning librarians about inter-library loan policies or increasing journal costs.
- 4) Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment but are **not** intended for use outside of the classroom. Example: instruction on research methods and techniques.
- 5) Biography or oral history** research involving a living individual that is not generalizable beyond that individual.
- 6) Independent contract for procedures** carried out for an external agency. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software developments.
- 7) Research involving cadavers**, autopsy material or bio-specimens from now-deceased individuals. Examples of research in this category that may require IRB review includes genetic studies providing private or medical information about live relatives.
- 8) Innovative therapies** designed solely to enhance the well-being of an individual patient or client with the purpose of providing diagnosis, preventative treatment, or therapy except when they involve “research” as defined above.
- 9) Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge **and** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.
- 10) Case histories** which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.
- 11) Publicly available data** do **not** require IRB review. Examples: census data, labor statistics.
- 12) Coded private information or biological specimens** that were **not** collected for the currently proposed projects do not need IRB review as long as the PI cannot link the coded data/specimens back to individual subjects.

If you have any questions as to whether your project is or is not human subjects research, contact the Institutional Compliance Office at ext. 4134 or 3452 for clarification. It is always better to get verification that you are in compliance with UML Policies and Procedures before a research project begins!

Studies that ARE Human Subjects Research

Studies that are considered human subjects research include the following:

- 1) Studies that utilize test subjects for new devices, products, drugs, or materials.
- 2) Studies that collect data through intervention or interaction with individuals. Examples: drug trials, internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.
- 3) Studies using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- 4) 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. However, such research may meet the exempt status determination if the materials/data are coded and the PI does not have access to the coding systems.
- 5) Studies that produce generalizable knowledge about categories or classes subjects from individually identifiable information.
- 6) Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living or working space or test chamber.



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>

For training certification www.citiprogram.org
Register and link your results to University of Massachusetts Lowell

Federal Policy for the Protection of Human Subjects (Common Rule) <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

Guidance on research involving coded private in-

formation or biological specimens <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>