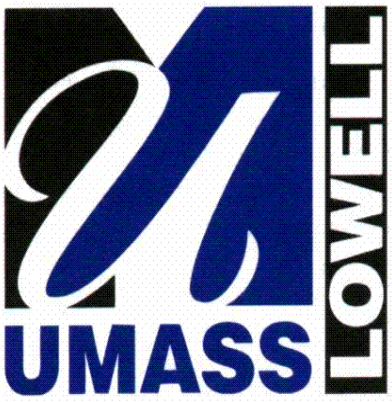

INSTITUTIONAL REVIEW BOARD

Policies and Procedures Manual

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Revision 5.0

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A note on terminology:

Institutional Review Boards have long used the term "subjects" to describe participants in research. Recent attempts to acknowledge the rights of individuals participating in research have veered away from the use of subjects in favor of "participants" though federal research regulations continue to employ the phrase, "human subjects."

We have attempted to replace our use of "subjects" with "participants" in recognition of the principles that guide our work as outlined in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research* by the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research (1979; see page). We continue to use the phrase, "human subjects," when consistency with federal regulations seems warranted. We hope that investigators see these terms as interchangeable and remember that respect for human persons must always characterize research involving them.

1.0. PURPOSE, REGULATORY OVERVIEW, AND INSTITUTIONAL POLICY

1.1 INTRODUCTION AND PURPOSE

The purpose of this document is to outline the responsibilities of the University of Massachusetts Lowell (UML) Institutional Review Board (IRB) and document the policies and procedures for the faculty, staff and students conducting research at UML that involves human participants. The mission of the IRB is to protect the rights and welfare of human research participants. The policies outlined herein are in accordance with the Federal Policy on the Protection of Human Subjects (DHHS Policy 45 CFR Part 46 and FDA Policy 21 CFR Parts 50 and 56). UML is responsible for the protection of human participants for any research activities conducted by, or under the supervision of, its faculty, staff or students regardless of funding source and the location of the project. The University and the Principal Investigators (PI) are responsible for insuring that high ethical standards are maintained for all research involving human participants.

Only human research is subject to Institutional Review Board review. It is defined as: **A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge** (45 CFR part 46 s. 102d), and includes:

- Classroom activities that are solely for instructional purposes do not require review by the IRB.
- If the instructor of the class or a student wishes to present or publish information gathered from human participants in a context beyond the class for which it was gathered, the activity is considered to be research and must be reviewed by the Institutional Review Board.
- Any researcher, who is in doubt about this policy, is encouraged to contact the IRB Administrator with questions or submit their proposal to the IRB.

Sometimes, the application and review process is complicated by the fact that an activity may not meet the federal definitions of "research" or "human subject". To help determine whether a project does include activities that involve human subjects, it is important to focus on **what is being obtained** by the investigator(s). *If you are not obtaining either data about living individuals through intervention or interaction, or identifiable private information, then the research activity does not involve "human subjects."* In any case, contact the IRB if you are at all uncertain about whether you need to submit an application.

IRB policies and procedures are reviewed and updated on an annual basis or more frequently as necessary. Any changes to applicable federal regulations will be implemented immediately, announced by memorandum, and will supersede these procedures. Researchers are held responsible to follow the UML Policies and Procedures

and use the most up to date forms for submissions
from http://www.uml.edu/Research/OIC/.

1.2. LAWS, REGULATIONS, AND GUIDING PRINICIPLES

Regulations for research activities that involve human participants are derived from the authority of the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) and UML will follow both sets of regulations. The DHHS regulations (45 CFR 46) apply to research involving human participants supported in whole or in part by DHHS and FDA regulations (21 CFR 50 and 56) apply to all research involving products regulated by the FDA regardless of funding source.

DHHS regulations are available at http://www.hhs.gov/ and FDA information and regulations are at www.fda.gov/.

UMass Lowell will also follow statutes, regulations, and case law for the Commonwealth of Massachusetts. The range of issues that may be determined under state law includes the age of consent, capacity to consent/legally authorized representative, children's consent, informed consent, genetic research, confidentiality of medical records, HIV/STD reporting requirements, laws about referral fees and recruitment methods, laws governing clinical research, laws governing IRBs, laws about investigational drugs, laws about vulnerable patients, and laws about medical practice and delegation of authority to perform procedures.

Guiding principles are outlined in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research* by the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research (1979). These principles are essential requirements for the ethical conduct of human participant research, and include:

- **Respect for persons:** Incorporates the ethical convictions that individuals are treated as autonomous agents and persons with diminished autonomy are given protection. The conditions that follow from this principle that are requirements for IRB approval include voluntary consent to participate in research, informed consent to participate in research, protection of privacy and confidentiality, and the right to withdraw from research participation without penalty.

- **Beneficence** (do no harm). Implies an obligation to protect human participants from harm by assessing the risks and benefits of the research, designing studies so risk is minimized and potential benefits are maximized.

- **Justice**. Requires that the potential risks of research should be born equally by the members of society that are likely to benefit from it. To apply this principle, the IRB must evaluate the characteristics of the study population and ensure that (1) the research project does not systematically select specific classes or types of individuals simply because of their ease of availability or their compromised position as opposed to reasons directly related to the problem being studied and (2)

the research project does not systematically exclude a specific class or type of person who is likely to benefit from research participation or in whom the results of a specific kind of research are likely to be applied.

1.3 INSTITUTIONAL POLICY AND IRB AUTHORITY

UML acknowledges and accepts the responsibility for protecting the rights and welfare of human participants recruited to participate in research activities. Requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) will be met for all applicable research without regard to the source of funding.

UMass Lowell has established an IRB to review all human subject research. Although federal guidelines require the IRB review federally funded projects, it permits the institution to determine the scope of IRB review for research involving human participants that is not federally funded. UMass Lowell requires that *all funded and non-funded human subject research be reviewed by the IRB prior to the initiation of the research.*

The involvement of human participants in research will not be permitted until the IRB has reviewed and made a decision on the research protocol. The IRB meets regularly to review research protocols. It is important to the Institution that the IRB have a high level of respect from the research community in order to better fulfill its charge and develop trust between all parties concerned.

The Vice Provost for Research is the Institutional Official (IO) and is appointed by the Chancellor to have responsibility for oversight of human subject research. The IO recognizes that the IRB can only carry out its regulatory, educational, and ethical functions when there are sufficient resources and high-level support staff to communicate effectively with the research community and to ensure adequate protections of participants through oversight, including review and monitoring of approved research. Research that has been reviewed and approved by the IRB may be subject to disapproval, suspension, or termination by the IO or Chancellor of the University but those officials may not approve research that has been disapproved by the IRB. For matters related to the execution of its duties and responsibilities, the IRB has direct access to the IO.

Funded research at UML is conducted in accordance with the approved Federalwide Assurance (FWA) on file with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) in which the UML IRB #1 is designated as the IRB of record. The FWA is an assurance that UML will comply with the federal regulations for the protection of human participants in research. It is a commitment, signed by the IO, that the institution will have written IRB procedures, provide review of nonexempt research covered by the FWA, obtain and document informed consent unless otherwise waived in accordance with the regulations, ensure that all collaborating institutions operate under an approved FWA, have formal written agreements of compliance from all nonaffiliated investigators, and the IRB will be provided with sufficient resources to fulfill these responsibilities. All sponsored human subject research must be reviewed by the IRB.

In summary, UML's institutional policy conveys the authority to the IRB to:

- Review *all research studies* involving human participants before their involvement may begin

- Require that faculty advisors take ultimate responsibility for any student directed research, including Ph.D. dissertations. Only full-time faculty (or persons appointed by the Vice Provost for Research) may serve as a Principal Investigator.

- Require revisions in research studies and consent documents as a condition of approval

- Approve new research studies and the continuation of previously approved studies

- Disapprove the initiation of new research studies, if necessary

- Monitor the activities of approved studies, including continuing review at least once per year and verify compliance with approved studies and informed consent procedures

- Develop mechanisms for prompt reporting to the IRB of unanticipated problems occurring in approved studies, or in other studies related in context to the approved studies

- Suspend or terminate a previously approved study, if necessary

- Restrict aspects of a research study for the purpose of participant protections, if necessary

- Review and monitor the use of test articles (investigational drugs, biologics, and devices) for the purpose of treating serious or life-threatening illnesses

1.4 MANAGEMENT OF FDA REGULATED RESEARCH

The U.S. Food and Drug Administration (FDA) regulates clinical studies conducted on drugs, biologics, devices, diagnostics, and, in some cases, dietary supplements and food additives, hereinafter referred to as "FDA regulated test articles". All such research studies must be conducted in accordance with FDA requirements for protection of human participants and IRBs, regardless of funding (21 CFR Parts 50 and 56).

When FDA regulated test articles are used in research being conducted at UML or funded by another federal agency, more than one set of regulations may apply. For example, clinical trials involving FDA regulated test articles that are supported by the Department of Health and Human Services (DHHS) fall under the jurisdiction of both the FDA and the DHHS Office for Human Research Protections (OHRP). Such trials must comply with the FDA and the DHHS human participant regulations. Where regulations differ, the UML IRB will apply the stricter one. Use of an off-label marketed product in research intended to support a new indication for use, change in

labeling or advertising requires IRB review and approval, informed consent, and submission of an IND.

The UML IRB will comply with the requirements of 21 CFR Parts 312 and 600 for the review and approval of research studies involving FDA regulated drugs and biological products. Studies that involve FDA regulated drugs or biologics that are submitted without a valid investigational new drug (IND) number are reviewed with respect to determining the need for an IND. If the IRB determines that the study is exempt from an IND and approves the study, the study may begin without submission of an IND application to FDA. If the IRB determines that an IND is needed, the PI/sponsor must submit an IND application to the FDA and provide documentation of the outcome of the FDA determination to the IRB before the IRB approves the study.

The IRB may consider a study using a drug product that is lawfully marketed in the United States to be exempt from the requirements for obtaining an IND if all the following apply:

- The research study is not intended to support a new indication for use nor any other significant change in the labeling of the drug
- The research study is not intended to support a significant change in the advertisement of the product
- The research study does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product
- The research is conducted in compliance with the requirements for institutional review and informed consent; and
- The research study is conducted in compliance with the FDA regulations with regard to promotion and charging for investigational drugs.

2.0 DEFINITIONS

Amendment: An alteration to an approved research application. Revisions to an approved study must be reviewed and approved by the IRB and include but are not limited to protocol modifications, methodology revisions, addenda, updates, administrative changes, additions or deletions of personnel, funding or title changes, adding additional survey tools or recruitment groups or sites, etc.

Anonymous: Information is collected in a way that makes it impossible to determine who was involved in the research project. Data are anonymous if no one, not even the researcher, can connect the data to the individual who provided it. For data to be anonymous, no identifying information may be collected from the individual.

Belmont Report: Sets forth fundamental principles that form the foundation for rules governing all government funded research on human participants. The basic principles are respect for persons, beneficence, and justice.

Beneficence: An obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks.

Department of Health and Human Services (DHHS): A cabinet department of the United States government with the goal of protecting the health of all Americans and providing essential human services.

Deception: Misleading participants about the purpose or procedures of the research by omission or commission. The use of deception, although frequently required for certain types of studies, raises a risk for participants and requires the PI use certain protections to minimize potential harm.

Exempt Status: Determination made by the designated IRB authority for categories of research that require minimal review and oversight, are of minimal if any risk, collects no identifying information from participants, and meet one or more of the six exempt categories. Projects that qualify for this type of review often fall under research conducted in commonly accepted educational settings or using common educational tests or practices.

Expedited Review: A decision made by the designated IRB authority for review of designated categories of research that present no more than minimal risk to human participants. Standard requirements for informed consent still apply.

Evaluation: Refers broadly to 'the systematic use of scientific methods to measure efficacy, implementation, utility, etc. of a program in its entirety or its components. Typical evaluations do not require IRB approval and the purpose should be to assess the success of an established program in achieving its objectives for a specific population and the information gained from the evaluation will be used to provide direct feedback to improve, change, or report on the program. Evaluations

are considered research when the purpose is 'to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective.'

Food and Drug Administration (FDA): An agency within DHHS that oversees research involving a drug, a biologic, or a medical device. Regulations related to IRBs fall under 45 CFR 46 and 21 CFR 50 and 56. FDA compliance includes routine IRB audits at regular intervals for institutions with FDA-regulated research.

Human Stem Cell Research: Stem cells found in a specific part of the embryo/fetus that develop into mature gametes and the use of human stem cell lines in research requires IRB (as well as IBC) review and approval. Some cell lines (NIH approved ones) may be reviewed under an exempt status determination.

Human Subject (Participant): A living individual about whom an investigator (professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.

Informed Consent: A required statement provided to the human participant that clearly states the study involves research, explains the purpose of the research, describes the expected duration of the individual's participation and the procedures to be followed, and identifies any potential risk to the study participant and experimental procedures included in the research. The consent process should also include information about privacy and confidentiality of the information collected.

Institutional Official (IO): An individual who signs, and has the authority to sign, the Institution's assurance and make a commitment on behalf of the institution that the appropriate regulatory requirements will be met.

Institutional Review Board (IRB): A board with diverse areas of expertise that is responsible for protecting the rights and safeguarding the welfare of human participants of research. They evaluate proposed research activities for the institution that involve human participants following federal regulations and guidelines.

Interaction: Communication or interpersonal contact between investigator and participant.

Intervention: Includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes.

Minimal Risk: Means "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (from 45 CFR 46.102(i)). When making a decision about risk, the following factors should be considered 1) the magnitude

and likelihood of risk, 2) risks of ordinary, non-invasive diagnostic tests are acceptable, 3) minimal risk may be age- or context-dependent, and 4) risks need not be physical to be more than minimal.

Noncompliance: Research not conducted in accordance with institutional policy or federal regulatory requirements for human participant protection.

Office for Human Research Protections (OHRP): An administrative unit within the DHHS with the mission to monitor and promote compliance with regulations promulgated by DHHS that relate to ethical standards of research involving human subjects (45 CFR 46). Assurances are established under DHHS that specify when and how the institution will comply with DHHS research regulations. OHRP has oversight and educational responsibilities wherever DHHS funds are used to conduct research involving human participants. This was formerly referred to as the Office for Protection from Research Risks.

Office of Human Subjects Research (OHSR): An office within the Office of the Deputy Director for Intramural Research, National Institutes of Health that was established to help investigators in the NIH Intramural Research Program understand and comply with ethical guidelines and regulatory requirements regarding research involving human participants. OHSR activities are limited to the Intramural Research Program and NIH.

Principal Investigator (PI) or Co-PI: To be eligible to serve as a principal investigator or Co-PI at UML for sponsored research, an individual must hold one of the following titles: professor, associate professor, assistant professor, research professor, or serve in a designated full-time, benefited professional position. To serve as a PI at UML for un-sponsored research or to supervise student research, an individual must hold one of the following titles: professor, associate professor, assistant professor, research professor, or be under a contractual relationship with UML that involves supervising students in the course of their responsibilities. All official IRB correspondence is addressed to the PI. Other personnel, as designated by the PI, may also be included on the correspondence. Individuals holding other than these titles or not affiliated with UML must obtain approval of the Provost to submit research applications to the IRB or for funding to an extramural sponsor. *The PI maintains full responsibility for all aspects of the research, including the IRB application.*

Students, including graduate students, are not allowed to serve as a PI. While graduate students may be fully engaged in the research activities, it remains the responsibility of the faculty advisor to ensure research is conducted ethically and that all IRB requirements are met for all research conducted on behalf of UMass Lowell.

Quorum: A majority (> 50%) of the voting members of the IRB. Official committee actions require a quorum and a community member must be present. A vote to abstain is included as part of a voting quorum.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (intended for publication or public dissemination). Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective. Research generally does not include operational activities such as defined practice activities in public health, medicine, psychology, education and social work, polls used for journalism or politics, and studies used only for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits or marketing studies. However, some of these activities may be defined as research when there is clear intent to contribute to generalizable knowledge.

Research Protocol: A written description and scientific rationale for a proposed research activity. The protocol is submitted to the IRB and includes a discussion of the human participant protection issues that are relevant to the study. At a minimum, the discussion should address the risks to participants, all experimental procedures, anticipated benefits to participants, if any, anticipated number of participants, proposed consent document and consent process to be used, and appropriate additional safeguards if potentially vulnerable participants are to be enrolled.

Research Staff: Individuals, other than PIs, who interact with participants during research. Research staff must meet all training requirements for working with human participants. Interactions with participants do not include the activities of translators or transcribers who operate under the guidance of a PI; however, these individuals must indicate that they understand the importance of maintaining confidentiality as appropriate.

Sponsored Research: Research, training, and instructional projects involving funds, materials, or other compensation from outside sources, or sponsors under agreement with the institution. The IRB does not deviate from institutional policies at the request of a sponsor.

Students Involved in Research: Post-doctoral, graduate, or undergraduate students involved in a research project at UML. Students are not qualified to act as Principal Investigators (PIs) or Co-PIs. Every student research project must be done under the supervision of a faculty member who is qualified to act as the PI on the IRB application. The faculty advisor is responsible for the quality of the IRB application and for oversight of the research.

Transcribers and Translators. Transcription services are often used to transcribe recorded interviews. In some cases, translators may be used to help collect data. Training requirements for these individuals will depend on the level of engagement in the research and the PI should contact OIC for guidance. Typically, the transcription service personnel will not need to complete online training but must sign a confidentiality agreement for transcribing information to assure the IRB that the information they are processing is kept confidential and secure and that the final

disposition of all materials is clearly outlined as soon as their job is complete. The Confidentiality Agreement for Transcription Services form is available on the OIC website.

Vulnerable Populations: The regulatory framework identifies specific populations that might have certain characteristics that would interfere with their ability to protect themselves in research, particularly through the informed consent process. These populations may include the elderly, prisoners, children, cognitively impaired individuals, or people who are economically or educationally disadvantaged. When some or all of the participants are likely to be vulnerable, additional safeguards are necessary to protect the rights and welfare of these participants. The IRB and PI must consider whether the potential participant's ability to exercise free choice (autonomy) is limited in some way and extend protections to those not specifically named in the regulations.

3.0. INVESTIGATOR GUIDELINES

3.1 EDUCATION AND TRAINING REQUIREMENTS

Institutional policy requires that any faculty researcher (as well as UML student investigators), who submits an application to the IRB for approval of a research proposal, or who participates as a researcher on a project involving the utilization of human participants, must complete the minimum institutional requirements for education to demonstrate knowledge of human subject research, including ethics. A certificate of completion from the appropriate online training is required before any application is approved or research project may begin in order to demonstrate that the guidelines and ethical principles for human subject research are understood. IRB members are also required to complete the educational requirement. **Certification must be renewed every three years.**

To complete this requirement, UML offers two web-based options:

1. A comprehensive online training has been customized for UML through the Collaborative IRB Training Initiative (CITI) for human subject research. To logon to the University of Massachusetts Lowell CITI site, first go to www.citiprogram.org and click on the link "Register for CITI course". To select UMass Lowell as the affiliated institution, find it from the "All Others" drop down box. Proceed to create your own username and password and select the appropriate group for your needs (Biomedical Investigators, Social and Behavioral Research Investigators, or IRB Members). The advantage of this option is that the content is updated automatically annually, results are linked to UMass Lowell, and the campus administrator will be notified when you have completed the training requirement. The CITI UMass Lowell training also offers a Refresher Course. For researchers conducting federally funded work outside of the U.S., an international research course is also available. The CITI training will take several hours to complete and is recommended for faculty who routinely do human participants research and IRB members. If you register with UMass Lowell, a copy of your completed certification will be sent to the Office of Institutional Compliance.

2. The NIH offers an additional option that is less time consuming and may be more appropriate for student investigators. The NIH Office of Extramural Research provides training at http://phrp.nihtraining.com. The module is identified as "Protecting Human Research Participants". If your training is interrupted, login later and the program will remember where you left off. After completing the final lesson of the courses you will need to complete an online evaluation form and this will generate a certificate of completion. The NIH training certificate will not be sent to OIC, so you will need to retain a copy to submit with any IRB applications. To retrieve another copy of your certificate, you will need to remember your user name and password to log in and then follow the link to "reprint a copy of your certificate". Regardless of the training that you choose to complete, the IRB Office

requires a copy of your training certification before any research receives final approval.

All UML affiliated personnel must take either the CITI or NIH options outlined above. **For non-UML affiliated personne**l, alternate training may be approved by the Director of Institutional Compliance with appropriate justification. Contact the Director of Institutional Compliance or IRB Chair for more information. Teachers who are collaborating with a UML researcher and who serve principally as the means of collecting data from or the intermediary to their students, usually are not required to complete the educational training as they are not considered to be engaged in the research.

Specific in-person training is also provided by OIC for faculty teaching research methods courses, groups of graduate students, honors courses, department meeting, etc. Please contact OIC to schedule training anytime.

If translators are engaged in the research activity, they are required to complete online human subject research training to ensure they understand the ethical principles of conducting research with human participants. If not engaged in the research, translators do not need to complete training but would sign the Certification of Translation Form to be submitted by the PI. Transcription personnel do not need to complete training unless engaged in the research but must sign and submit a Confidentiality Agreement for Transcription Services to the IRB.

3.2 DESCRIPTIONS OF VARIOUS TYPES OF RESEARCH

Biomedical or Socio-Behavioral Research

There are some basic distinctions between biomedical and socio-behavioral types of research. Biomedical research can be either direct, involving interaction with the physical body of a human participant with the potential for physical injury or harm or indirect, involving human participants, human tissue, or medical, personal or genetic information relating to both identifiable and anonymous individuals in order to generate data about medical, genetic or biological processes, diseases or conditions in human participants.

Socio-behavioral research may include survey, ethnographic, or experimental research where risks to the participants may be minimal and generally related to social or emotional stress or the release of information gathered, rather than direct interaction with the physical body. While both types of researchers must complete the training requirements for human research participants, socio-behavioral research that involves surveys that are low risk and non-invasive may be designated as exempt status by the IRB.

When reviewing behavioral and social sciences research, the IRB ensures that investigators have made every attempt to minimize risk and possible harm to participants, whether social, psychological or physical. Potential risks to participating in behavioral and social science research could be, but are not limited to:

- Breach of confidentiality

- Invasion of privacy
- Embarrassment
- Risk to reputation, employability, or insurability.

Survey Research
The IRB may approve survey research under Exempt Status if risk is minimal and identifying information is not collected so the confidentiality of research participants is protected. In addition, all other applicable criteria for exempt status review must be fulfilled (e.g., the research must not involve specific vulnerable populations).

PIs may request a default waiver of written consent by presenting the research protocol to the IRB, which demonstrates that (a) the human participants will be informed of all applicable elements of consent prior to responding to this survey; and (b) all the criteria for exempt status review are fulfilled. The "default" aspect of the waiver of written consent is a new practice for the UML IRB. PIs presenting an Application for Exempt Status Approval and requesting a default waiver of consent must have documented training in the issues concerning human participant protection in survey research.

Surveys intended to be used through a website must still explain clearly all of the elements necessary for the consent process and allow participants to opt out at any time without penalty. Some suggested language for opting out could be like 'If you do not fit these requirements to participate or do not wish to participate in this survey, you may automatically opt out of future emails regarding this study: [add a link to 'Click here to unsubscribe'].
(See also section on Informed Consent.)

Secondary Data Analysis
Research using publicly available data (public use data files) is allowed if the data does not contain any identifiable information. This is not considered to be human subject research and, therefore, is not under the purview of the IRB. The use of data for *non-research* and internal evaluation purposes, such as for internal institutional research purposes, does not meet the test for human subject research and therefore also does not require IRB review.

Non-confidential public records also are included in the definition of "public use data files", regardless of whether the data in these non-confidential public records are identifiable. The analysis of secondary data is understood to have the following characteristics:

(1) No manipulation of human participants
(2) No new data collection; and
(3) No identification of research participants.

Research conducted on a data file that is not publicly available, even if it does not contain identifiable data, must be submitted for review to the IRB, typically for Exempt Status Determination. (If vulnerable populations are involved in the research, Expedited or Full IRB review may be required.) PIs planning to use these data files must demonstrate to the

IRB that the confidentiality of research participants is protected either by direct evidence that the data are free of identifiers or information to ensure the identity of human participants is protected. (Some examples of these types of data sets include records kept by the Department of Education, the Centers for Disease Control, and the US Census Bureau.)

IRB approval is also required for research that involves obtaining data from through an agreement with a public entity (e.g., Department of Education, Department of Mental Health) because it is not public domain, even if it is de-identified prior to being sent to the investigator. (Some examples include reports run by the UMass Lowell Office of Institutional Research.)

In summary, for research that involves

Using existing data for secondary data analysis DOES NOT require IRB review if:

- The data are in the public domain
- There are no individual identifiers associated with any of the data

Using existing data for secondary data analysis DOES require IRB review if:

- The data are NOT in the public domain

Evolving Research

Research that involves **only non-intervening observations** of **publicly occurring behavior** does not require an application for IRB review. The research must include no identifying information in the study records, pose no risk to human participants, and not be intended for publication, supporting the fact that any IRB review is unnecessary for this stage of data gathering.

The definition of publicly occurring behavior is also inclusive of the publicly accessible parts of the Internet. When conducting evolving research that may be based on initial non-intervening observations, such as some types of ethnographic research, oral history, or focus groups, PIs are still advised to complete the education training certification to assure that the research will be conducted in an ethically appropriate fashion, with full protection of the human participants. Once the intent to publish is established, the PI should submit an application for the appropriate level of IRB review.

PIs are responsible, however, for applying to the IRB as soon as the observations lead to an intent to publish or to involve human participants directly in the research. For pilot studies that are initiated with the intent to publish or where there is a possibility that publication may result from the pilot effort alone, an application must be submitted to the IRB to approve the research. Research projects that include evolving research may still require IRB review even if initial aspects of the project were conducted using observation only.

Research Requiring Conceptual Approval

In some instances, timing may be critical to begin a research project and a PI may submit

an IRB application that would provide enough information for the IRB to review and approve in *concept* the overall research and study design. For example, researchers who investigate acute responses to natural disasters cannot wait until disaster strikes to begin their conversations with the IRB. In cases such as this, as complete an application should be prepared in advance so that once the researcher needs to move quickly into the field, simple amendments may be filed following preliminary approval for the concept of the research proposal. Federally funded proposals may also fit this category as in some cases the funding will be used to support further development or planning of the human subject research portion of the funded research.

The application materials are submitted the same way as a regular application and must meet the same regulatory guidelines for the category in which it is submitted. Enough information must be included in the protocol to allow the IRB to understand the general nature of the research, risks involved, and methodologies that might be used to conduct the research. When the 'concept' is clarified, the PI must submit an amendment for IRB review and approval of the specific details that were not defined in the original application. (Details that could be outlined later include but are not limited to subject recruitment, study location, collaborators, student researchers, etc.). The term "concept approval" means approval of the overall research concept by the IRB with the understanding that the details submitted through the amendment process will not change the overall research design, risk, consent or any other part of the research that affects the review status (exempt, expedited, or full). The PI must explain that this is the process they are requesting in the study design section of the application form.

This may be applicable for situations where a PI is conducting research on events that could occur in the future and the PI must be mobilized and ready to begin in a moment's notice. It could also include research that is fairly well formulated or conducted routinely but some critical information may not be finalized, such as collaborators, questionnaires, student researches, etc. In these cases, the IRB may approve the application for the "concept" with the understanding that as the research design is finalized, *all documents and changes will be submitted through the amendment process for final IRB approval.*

Examples of research for which concept approval applications would be appropriate include:

- Research on people's reactions to natural disasters
- Research methods to be formed and developed under a planning phase included in grant support
- Research involving extensive sets of collaborators, each of whom may need modifications to the overall protocol to suit their settings, and each of the collaborators has not yet committed to the project

International Research

Research can be conducted outside of the United States and the CITI program has a module to inform investigators of additional considerations for conducting human subject research in other countries. It is important that the research incorporate and take into account local

customs and practices to respect the participants. The IRB may seek an independent outside review for such activities in order to understand the research activity from the local context. The researcher should allow adequate time for the IRB to find such assistance from the UMass Lowell community of researchers who has experience working in the foreign country and understands the local context, but may need to seek help from outside the campus community. All foreign research may not require this review but the IRB will notify the PI of this requirement if there are concerns about the proposed activity in the other country. The PI will be asked for permission to share the application materials with a third party for the local context review. The reviewer will only be evaluating the research activity in regards to the risks/perceptions within the local context.

3.3 USING UML DIRECTORY INFORMATION AND FERPA REGULATIONS

Researchers who intend to use UMass Lowell student directory or non-directory information for human subject research should first consult with the Office of Institutional Research (OIR) to determine whether OIR can generate and release the data of interest, assuming IRB approval would be secured. *Data used **only** for internal evaluations does not constitute human subject research.* Once OIR has indicated the data could be made available, the researcher should submit an IRB application for review. Reporting to the Vice Provost for Enrollments, the OIR's primary purpose is to compile, analyze and report the university's official data. OIR may not have the capacity to meet all requests for data to be used for individual research purposes within the particular timeframe requested by a researcher. Definitions of these terms are as follows:

Family Educational Rights and Privacy Act (FERPA). What does FERPA have to do with IRB review? Briefly, FERPA limits the types of disclosure institutions can provide with respect to student information with different classifications of data offered different levels of protection. Personally identifiable information requires consent of the individual or guardian in order for the information to be disclosed to third parties. Directory information, on the other hand, has no such restriction under the law once the University provides public notice of the type of information that may be disclosed (see above) and of students' rights to forbid such disclosure.

For more information see:

- UMass Lowell Undergraduate catalog
  http://www.uml.edu/catalog/undergraduate/policies/right_access-student_records.htm
- U.S. Department of Education, Family Privacy Compliance Office
  http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

FERPA Directory Information is defined by the University of Massachusetts Office of the President as:

- Student's name, major, participation in officially recognized activities and sports, date(s) of attendance.
- Weight and height of members of athletic teams.
- Degrees, certificates, and awards received.

- The most recent previous educational agency or institution attended by the student.
- Appointment as a Resident Assistant or Community Development Assistant.
- Work department, office address, and employment category for graduate students who are teaching credit courses.

This information is also subject to the student's preference, i.e., students may forbid disclosure of their data.

UMass Lowell Non-directory information. Faculty may be surprised to find that information to which they have access in their daily teaching or advising function is not accessible to them for use as research without appropriate review and consent. This includes non-directory information, which is considered confidential and includes information maintained in the student's educational record (e.g., exams, papers, and grades). Without consent these data can be shared only with individuals with a legitimate educational interest in the information—e.g., other university personnel in academics, housing, or counseling who can better perform their university function by having that information.

For any other purpose, written consent must first be obtained from students whose data are being disclosed. Researchers may, however, apply to the IRB to use non-directory data in human subjects research and request a *waiver of the requirement for obtaining consent*, if that research can meet the standard of "legitimate educational interest." When researchers are requesting access to non-directory information for research without first obtaining consent from every student involved, the IRB will review the application to determine whether the research meets the test of "legitimate educational interest" and evaluate the proposed use of the information with respect to typical IRB concerns of ethics and protection of human research participants.

Examples of Activities using OIR Data

1) *Use of directory information.* A researcher is interested in the changes in BMI among athletes and requests heights and weights of UMass Lowell hockey players for the last 10 years. After contacting the OIR to determine the feasibility of obtaining these data, the researcher submits an application for exempt review to the IRB.

2) *Use of non-directory information with consent.* A researcher is interested in how student grades in a large lecture class correlate with student SAT scores. The researcher contacts OIR to determine the feasibility of obtaining these data. Since the students are all currently in the researcher's class, the researcher can obtain consent from these students. To eliminate potential bias in grade assignment, the researcher proposes to enlist the help of a colleague to obtain and hold onto consent until after the semester is over and grades are submitted. The researcher submits an application for expedited review to the IRB.

3) *Use of non-directory information without consent.* A researcher is interested in how student grades in a large lecture class correlate with student SAT scores, and how this relation has changed over time. The researcher contacts OIR to determine the feasibility of obtaining these data. Since the researcher is interested in 10 years worth of data, the

researcher is unable to obtain consent from the students whose grades and test scores are being studied, and therefore submits an application for expedited review to the IRB including a request to waive informed consent.

Process to Request Using OIR Data for Research
These procedures are to be used with data intended for *research purposes*; data used for internal evaluations does not constitute human subject research. **Use of any OIR information for research must be reviewed and approved by the IRB**, even if the researcher has access to that information as a faculty member for academic purposes. Because non-directory information is considered confidential, researchers should take special care in their IRB applications to specify the purpose of the research, the types of data requested, justification for the release of the data, who will have access to the data, and how privacy and confidentiality will be protected.

After consulting with OIR, researchers should determine whether their application is for exempt, expedited or full review, and submit an appropriate application to the IRB. If the application is for use of non-directory information without obtaining informed consent, the applicant should request a waiver of informed consent.

Directory information to be used in research may be released when:

- IRB review and approval is secured and
- The Director of OIR is in receipt of the IRB approval memo and
- The Director of OIR has agreed to release the information.

Non-directory information may be released following these same criteria. In addition, the Director of OIR may need to work in conjunction with other offices (e.g., Office of the Registrar) to extract and provide the information as requested.

The IRB cannot guarantee that OIR will release any information, even after IRB approval is secured. The PI should therefore communicate with OIR well in advance of submitting an IRB application to determine the likelihood of acquiring the data and the timetable for such once IRB approval has been secured.

If OIR agrees to the data request according to the timetable proposed by the researcher, it will be scheduled on a first come, first served basis by being placed in the OIR's standard project queue for processing. Researchers should allow adequate time for the request to be processed. The OIR report request form can be found at http://www.uml.edu/Academics/provost-office/IR/Report-Request-Form.aspx

Neither directory nor non-directory information is typically released to any parties outside of the University for research purposes.

3.4 RESEARCH USING STUDENT 'SUBJECT POOLS

Some UMass Lowell Departments use Subject Pools to recruit students for participation in human subject research. These pools are managed currently through the SONA system.

All research posted on any UMass Lowell Subject Pool must have approval by the IRB prior to its posting. Use of online participant recruitment tools, such as SONA, also requires that information posted on the system be provided to the IRB in the application for approval. So that students can make an informed decision about whether to participate, all postings must include more than the title of the study. A brief description of the study purpose and method as well as an indicator of any potential risk must be added. Inclusion and exclusion criteria must also be outlined. *Remember that individuals under age 18, even if they are college students, are considered minors and parental consent and assent documents may be required or in some cases, a full review IRB application may need to be submitted and approved before they may be included in any study.* Age guidelines must be clear on any recruitment tools, including SONA listings.

SONA listings must therefore include:

- Study title
- Very brief description of study purpose and method
- Brief indication of potential risk
- Inclusion criteria, including age 18 or older
- Exclusion criteria, including under age 18

The amount of participant time estimated to complete a study should be consistent across protocols by department for the types of credit, incentive, or compensation offered by the Department. Credit is earned for the participant's effort not any specific research activity. If a one hour research credit is being awarded, the amount of effort should be one hour--or close to it. If 10 points of extra credit is being awarded for participation in research, the effort to obtain the extra credit should be consistent from one project to another. This requirement addresses the issue of coercion by over-payment or over-rewarding student participants in such pools. For example, participants may be unduly influenced to participate in Study A if it requires only 15 minutes when Study B requires 45 minutes to obtain the same credit.

Departments may use the SONA system and student subject pools for either course credit or extra credit research experience, which may be obtained by participating in IRB-approved studies conducted in the department under the supervision of faculty. In addition, **because research participation must be voluntary, an alternate method of fulfilling that academic requirement or extra credit opportunity must also be made available to students**. Moreover, this alternate method *must be* an equivalent effort. If participating in a study for 30 minutes, for example, earns 2 points in extra credit, then the alternative cannot be writing a 5 page paper—it must be something that the student can do exerting no more effort than the research participation offered.

Federal regulations indicate that research participants may not be penalized for a decision to withdraw from research at any time. Therefore, **no department may penalize students for "no shows" when they have signed up for a study through the SONA system and then fail to attend the research session without cancelling the appointment in advance**. It is not allowed to give the student a failing grade for the no-show or increasing the

number of research participation credits to be required of the student.

The regulations, however, do allow for departments to set a maximum number of times that students can turn to the studies offered to fulfill their academic requirement. In other words, students may be informed that they have a maximum of four opportunities to participate in research to get the credit, and that, should they decide *not* to participate in a specific study, failure to cancel their appointment in a timely fashion (e.g., 24 hours in advance, midnight the night before the study, etc.) will count as one of those four opportunities. Any unfulfilled research credits will then have to be completed by an alternative research experience once those four opportunities have been used. These procedures, for each Department that uses the SONA System, should be clearly outlined and provided to students in writing in advance.

Brief studies may be combined. When projects are brief, investigators may elect to "double up" on some research sessions to keep the effort for any session consistent by the Department. This may especially be the case in student driven research projects. For example, if it really only takes 15 minutes to complete a survey for Study X, 20 minutes to complete the judgments required for Study Y, and 15 minutes to complete the memory tasks for study Z, they can be combined into one three-part experience that awards credit equivalent to one hour. Faculty may be required to submit one application that may include details on 2-3 completely unrelated studies.

When combining studies, the following suggestions may be helpful in completing the IRB application.

- Study titles on the IRB application (also the titles that must be used for recruitment) could be something like "Two brief studies: Memory and Personality" where what follows the colon is a broad description about the topic of each study.
- Start off the IRB application with a statement something like, "This IRB application covers two projects that are sufficiently brief that students enrolled in the Psychology Participant Pool can complete both in a one hour session to earn a one-hour research credit. They are otherwise unrelated."
- Proceed with the application, answering each question for Study A. and Study B. That will allow you to cut and paste from the applications that student researchers have developed under your supervision.
- You can do the same with the Informed Consent, starting with a statement that, "You are being asked to participate in two brief studies that are presented in the same time slot in order to provide you with a one-hour research credit." Proceed for each item, labeling the information as Study A or Study B where appropriate and using one description for items where no distinction is required.
- Department Chairs should file a description of the pool and how it is intended to work with the UMass Lowell Director of the Office of Institutional Compliance (OIC). This will allow the IRB reviewers to have a clear understanding of the effort required by Department for the specific type of credit awarded by that Department. **Department Chairs (or their designee) should consult with OIC before establishing student participant pools or making changes to them.**

The **Informed Consent form** must reflect the availability of alternatives to course credit. In a department where there is a research requirement in one course and in which others may offer extra credit for research participation (as in the Psychology Department), wording on the Informed Consent might be something like:

> "You will receive a one hour research participation course credit, which may be one way to fulfill a course requirement in General Psychology or one way to earn extra credit in another course depending on what course policy your instructor has set."

PLEASE NOTE:
SONA awards credit in whole units; however the department may choose how much time and effort each unit represents. Typically one research credit or unit is equivalent to an hour, but it can also be equivalent to 30 minutes. This needs to be clearly indicated to students participating in the pool.

The Psychology Department requires that all studies for which participants are recruited through the General Psychology Pool must have both IRB approval *and* at least one full-time faculty member *from the psychology department* listed as a PI. IRB approval is a requirement across the university. Other departments should determine which University PIs may recruit from their pool.

Subject pools may also be used to recruit participants for research where monetary incentives are offered. Departments should decide on the best policy for managing recruitment for paying studies, i.e., whether such recruiting will be on the same platform as recruiting for participation credits in courses.

3.5 STUDENT RESEARCH

Students undertaking research with the intent to publicize or publish findings beyond the classroom are considered researchers. *However, such research projects require a faculty advisor to take responsibility for the oversight and submission of the IRB application and all supporting materials, i.e., to serve as the Principal Investigator with respect to compliance. Students may not be listed as PIs or Co-PIs on any IRB applications.* If human participants are involved in the research and the results are to be shared outside the classroom, the research proposal requires IRB review even if for a classroom assignment. Both faculty advisors and student investigators are required to meet the mandatory educational requirements before conducting any research. The research *must* follow all other procedures outlined in this manual.

The faculty advisor is responsible to file final reports with the IRB at the conclusion of the research. The IRB is not responsible to oversee academic achievement in pursuit of degree requirements.

> *Academic Projects (Non-Research)*
> Classroom assignments designed to engage students in interaction with individuals or to collect data about individuals in order to teach research methods or to help

students understand concepts covered by the course may pose little or no risk to students or others. These types of activities are generally not intended to create new knowledge or to lead to scholarly publication; as a rule, they do not require IRB review.

However, any activities (classroom or otherwise) that include risk to students, to the individuals outside of class, or to vulnerable populations carry the potential for harm and the faculty member must take responsibility for such activities. Faculty members have an obligation to ensure that students understand their ethical obligations in carrying out their assignments. Instructors should provide guidance to students collecting information so as to minimize any unwitting or unintentional harms to human participants.

3.6 NOT HUMAN SUBJECT RESEARCH

The following research activities require no IRB oversight and are not subject to the requirements of the Federalwide assurance. These include the collection and study of

- Samples from deceased individuals
- Samples collected for diagnostic purposes only
- Samples or data that are available from commercial or public repositories or registries
- Established cell lines that are publicly available to qualified scientific investigators
- Self-sustaining, cell-free derivative preparations including viral isolates, cloned DNA, or RNA (although research with these types of materials may not require IRB review and approval, it is subject to other requirements, such as rules governing technology transfer or research involving use of biohazardous materials (refer to information for the Institutional Biosafety Committee under http://www.uml.edu/Research/OIC/).
- Oral histories (if the only purpose is to document the experiences of individuals or a specific historical event with no intent to draw conclusions, generalize findings, inform policy, or create an archive to provide others with a resource to do research.)

3.7 PROGRAM EVALUATIONS

Program Evaluation is the inquiry into past, present, and potential human service programs to understand or clarify their need, working process or impact. Program evaluations implement a variety of methodologies to accomplish diverse objectives. There are three major categories of program evaluation: **Needs assessments** (formative evaluations) establish whether or not a program is feasible or necessary; **process evaluations** determine whether or not a program's implementation is congruous with its conception; **impact evaluations** (summative or outcome evaluations) ascertain whether or not a program meets its goals.

Some program evaluations may constitute human subjects research and others do not[3]. If a program evaluation is going to be used for generalizable knowledge, then it is considered

research that involves human participants and requires IRB approval. Therefore, program evaluations that result in the information being published in scholarly journals likely require approval. The assumption being that publishing the findings generalizes the data. Evaluations connected to groups' or individuals' outcomes and affecting the development or implementation of other programs similar in nature, are generalizable human subject research and require human subjects review.

Generally, program evaluations do not require IRB review as information gathered is collected and analyzed for internal business or program use only. These evaluations' goals range from simple descriptive statistics to qualitative information, and examples include program enrollment data, constituent demographics, and outcome analyses. Therefore, irrespective of human participant involvement, these program evaluations remain internal and thus do not contribute to generalizable knowledge.

3.8 RESEARCH WITH MULITPLE COMMITTEE REVIEWS

For research activities that may require multiple committee reviews, the application form provides check boxes for the PI to indicate the other types of review required. The OIC Director is a member of the other committees and will coordinate the approvals to ensure no activity begins until all committee requirements are met. Office of Research Administration is also informed as to the status of committee approvals so no award is set up until OIC informs them that all committee reviews are completed and the PI may begin the research.

4.0. APPLICATION TYPES AND REVIEW PROCESSES

Three categories of IRB applications are accepted for review by the IRB:

1. **Exempt**
2. **Expedited**
3. **Full Review**

The PI should self-determine the regulatory category(s) that best fits the research proposed (for exempt and expedited applications) and check the box(es) on the applications as appropriate. For questions about the appropriate category, please contact the Director of OIC or the IRB Administrator for assistance.

For applications submitted in the wrong category, the IRB Administrator, OIC Director, and IRB Chair work together to evaluate and recommend the appropriate category. If the OIC Director's opinion is not in agreement with that of the IRB Administrator, then the information is forwarded to the IRB Chair for a final decision as to the correct status of the application. The IRB Vice-Chair can review appeals when the Chair is recused due to a conflict of interest or for any other reason.

4.1 PRE-REVIEW PROCESS FOR IRB APPLICATIONS

The IRB Administrator screens all applications to evaluate whether more details are required before sending the protocol for further review. The IRB Administrator will work with the PI to improve the application before it is sent out in order to respect the IRB committee members time and use it most effectively.

The purpose of this is to insure that the committee members' substantial commitment of time and effort to the IRB is devoted to review of complete applications. The IRB Administrator will conduct the initial pre-review to identify issues that need to be addressed. The PI is encouraged to work with the IRB staff to get the application prepared for full committee review. The application can be forwarded to the next appropriate review process as soon as revisions addressing the pre-review concerns are completed.

Researchers who clearly explain all procedures in the protocol applications increase the likelihood of quicker turn-around time for approval. In many cases, applications are submitted that are vague in key areas that reviewers need to evaluate in order to ascertain any risk to the participants.

> **Example**. It is not enough to assure the IRB that, for example, interview information will be kept confidential; tell the IRB reviewers *how* you are going to ensure that. The PI might state that names and all other identifying information will be deleted from transcripts, that reports of data will be in the aggregate and that, when quotations are used for illustration, all potentially identifying information will be deleted or pseudonyms will be used.

4.2 EXEMPT STATUS DETERMINATION APPLICATIONS

Research that meets the regulatory criteria to be classified as 'exempt' indicates that there is no more than minimal associated risk to the participants and no identifiers are collected. *Note: This classification DOES NOT mean that the research is exempt from IRB review and approval!* The IRB Administrator, OIC Director, or the IRB Chair and his/her designee are authorized to determine research that meets exempt status requirements and the interpretation of the regulations and exemptions. Examples of exempt status research includes use of existing data, evaluation of de-identified medical records, and research on de-identified pathologic specimens as this type of research usually has little, if any, associated risk, particularly if there are no subject identifiers attached to the information.

Projects involving children may meet exempt status requirements if the activities involving children involve educational tests or observations of public behavior **where the investigators do not participate in the activity** being observed.

The categories of research involving children that **cannot** be exempt are as follows:

- Research involving survey or interview of children.
- Research involving the observation of public behavior of children when the researchers participate in the activities being observed.
- Research involving prisoners (in this case, incarcerated minors).

Regulatory Categories for Exempt Determinations 45 CFR 46.101(b) (1)-(6)

For research activities to be approved under exempt status, risk must be minimal or less, information must be recorded in such a way that no participant can be identified either directly or through identifiers linked to the individual, and the only involvement of human participants must be in one of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless**: Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the previous statement, if: the human participants are elected or appointed public officials, or candidates for public office; or federal statute(s) require(s)

without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt Application Form Submissions

Submit an Application for Exempt Status Approval to IRB@uml.edu (send electronically as Word documents). Original signatures must be included on the PI Signature and Assurance page and may be scanned in and sent as a pdf attachment, faxed, or mailed.

Provide enough information to allow the reviewer to make a determination and include the following information in the form:

- Abstract describing the objective(s) of the project
- Methods used for the research
- Description of the subject population and recruitment plans
- Actions to protect privacy and/or confidentiality of the participants
- Certificate of completion to document that the training requirements have been met
- Original, signed PI Signature and Assurance page can be faxed to x6012, scanned and emailed as a PDF, or sent by intercampus mail to IRB, 2nd floor Wannalancit.

Projects reviewed and approved under exempt status do not require subsequent submission of other forms for IRB review *unless* a change to the research results in a change to the Exempt Status Determination. Any exempt status project will be closed out one year from the approval date by the IRB Administrator. However, if new student researchers are added to the protocol and research activity, please notify the IRB of the student name(s) and provide a copy of the human subject training certification(s).

For changes to research approved under Exempt Status, PIs are held responsible to consult with the IRB Administrator if the change may result in a change to the Exempt Status Determination. If changes to an approved exempt project will not result in a change in the review determination, additional forms do not need to be filed with the IRB.

Timeline for Review

Exempt applications are reviewed immediately upon submission to the IRB Administrator or OIC Director. Every effort is made to complete exempt reviews as soon as possible. The review time may vary depending on the quality and clarity of the application, and whether there are concerns that will need to be addressed by the PI. This type of applications does not need to wait for a meeting date for review.

4.3EXPEDITED APPLICATIONS

Expedited review and approval of research proposals can be undertaken if:

- Risk to participants is minimized,
- Risk to participants is reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result,
- Selection of participants is equitable,
- Informed consent is sought from each prospective subject or their legally authorized representative, in accordance with, and to the extent required by Sec. 46.116,
- Informed consent is appropriately documented,
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, and
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Research that meets the requirements for expedited review must involve no more than minimal risk to participants and the only involvement of human participants will be in one or more of the categories listed below. Research applications that qualify for expedited review are determined for eligibility by the appointed reviewers, and in consultation with the IRB Chair as necessary. Expedited applications are sent to reviewers only with the understanding that the reviewers should only approve research when there is no concern that an approval decision will meaningfully compromise the protection of research participants. The expedited review procedure may also be used to review and approve minor changes in previously approved research during the period for which approval is authorized. The members assigned to conduct the review document and report their concerns or approval back to the IRB Administrator to be communicated to the PI. The full IRB is informed of research approved by expedited review at monthly meetings and it is documented in the meeting agenda and minutes.

While *expedited review does allow for reviewers to disapprove the research, the application is usually sent for full committee for review* if the reviewers feel the research has more risk, participants may be vulnerable, or research methods warrant full committee review. A research activity may be disapproved only after review in accordance with the procedures outlined for full review. Expedited review cannot be used for research that includes risks beyond those encountered in normal daily affairs. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these participants. Research with these groups typically receives full IRB review.

Categories for Expedited Review

Expedited review and approval may be authorized for research that involves no more than minimal risk to the participants and in which the only involvement of human participants will be in one or more of the following general categories (regardless of the age of participants, except as noted):

- Clinical studies of drugs and medical devices only under certain conditions.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture with certain stipulations.
- Prospective collection of biological specimens for research purposes by noninvasive means (for example, hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if extraction is warranted, excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor).
- Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Continuing review of research previously approved by the convened IRB.
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption

For specific criteria on each of the above categories, refer to the regulations at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants, their financial standing, employability, insurability, or reputation, or be

stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human participants.

The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

Expedited Application Form Submission

Submit the Expedited Application form and related form to IRB@uml.edu (electronically as Word documents). The PI Signature and Assurance page must include an original signature and may be scanned in and sent as a pdf attachment, faxed, or mailed. Incomplete applications will not be sent for review and the PI will be notified that additional information is needed to proceed.

The following supporting documents as appropriate should also be submitted with the application form:

- Completed Project Application Review Form, with 'expedited' box checked and the appropriate category designated
- Informed Consent (or Agreement to Participate) Form, if necessary
- Certification of Translation, if necessary
- Recruitment advertising materials; such as, flyers, newspaper advertisements, etc.
- Questionnaire, if applicable, of the actual questions that will be used
- Statement from cooperating agencies or institutions on their letterheads
- Complete research proposal or project description, including Abstract and Methods sections
- Electronic copy of the entire grant application, if submitted for funding
- Transcription Confidentiality Form (if applicable)
- Photo/Video Release Form (if applicable)
- Copy(s) of the certification of completion(s) of education/training
- Original, signed PI Signature and Assurance page can be faxed to x46012, scanned and emailed as a PDF, or sent by intercampus mail to IRB, 2nd floor Wannalancit.

Timeline for Review of Expedited Applications

Expedited applications are reviewed upon submission to the IRB Administrator and assigned to two IRB reviewers who serve on a rotating basis throughout the year. Every effort is made to complete expedited reviews as soon as possible. The review time may vary depending on reviewers' schedules, the quality and clarity of the application, and whether there are concerns that will need to be addressed by the PI. These types of applications do not need to wait for a meeting date to be sent for review if all materials are submitted to support the application.

4.4 FULL REVIEW APPLICATIONS

A full committee review by the IRB is required if the research involves more than minimal risk and special precautions may need to be taken to protect the rights and welfare of the participants. Procedures are designed so that all IRB members receive materials for project review at least one week prior to the meeting or such time as sufficient to allow for review of the materials before a convened IRB meeting. Meetings are scheduled monthly throughout the year and are not always convened if there are no full reviews. Contact the IRB as soon as you think you might have an application that requires full review to get it scheduled. PIs are encouraged to be available for the meeting during which their protocol is being reviewed to answer questions and facilitate the process.

Full Review Application Form Submissions

Submit the application with 'Full Review' box checked and the following supporting documents as appropriate to IRB@uml.edu:

- Completed Project Application Review Form, with the box checked to indicate "full review"
- Informed Consent (or Agreement to Participate) Form(s), if necessary
- Recruitment advertising materials; such as, flyers, newspaper advertisements, etc.
- Questionnaire, if applicable, of the actual questions that will be used
- Statement from cooperating agencies or institutions on their letterheads
- Complete research proposal or project description, including Abstract and Methods sections
- Entire grant application, if submitted for funding
- Copy(s) of the certification of completion(s) of education/training
- Original, signed PI Signature and Assurance page can be faxed to x6012, scanned and emailed as a PDF, or sent by intercampus mail to IRB, 2nd floor Wannalancit.

Timeline for Full Board Review

Applications for **full review** should be submitted at least two weeks in advance of a scheduled IRB meeting. Protocol changes or amendments, depending on the nature of the amendment, may be submitted to the IRB for expedited review and approval, unless it involves greater than minimal risk. See the Review Process section for full descriptions of the categories that qualify for exempt and expedited review and an example timeline for project submission, review, and approval.

Once an application for full review is ready to be placed on a meeting agenda, the IRB Administrator notifies the PI of the meeting location, place, and time and invites him/her to attend the meeting to respond to any questions that might arise. Meetings are posted on the website by semester. ***For full review, allow a minimum of four weeks from the time the application is submitted to receipt of final approval***. The IRB Administrator will return communication to the PI regarding the outcome of the meeting within 3 working days of

the meeting if at all possible. OIC is not responsible for delays in approval caused by the PI.

4.5 UNDERSTANDING IRB APPROVAL CRITERIA

The following points provide an overview of the specific criteria that researchers should address to meet requirements to receive IRB approval for protocols:

- The research objectives and methods must be clear and outline **all** activities that will include human participants.

- The recruitment process and methods must be clearly outlined and described.

- Letters of support should be included for all research activities taking place at locations other than at UMass Lowell.

- Risk to the participant(s) must be clearly identified and communicated from any and all foreseeable sources.

    - ✓ Consideration should be given to risk from all procedures, topics, and populations as well as from any physical, psychological, social, economic and legal aspects.

    - ✓ Risk may also differ for different participant groups or in different conditions of the research. These should be considered by the PI and addressed in the application.

    - ✓ After the types of risk are identified, then ask: 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 those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- Risk should be minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.

- Risks to participants should be reasonable in relation to anticipated benefits, if any, to participants and the importance to society of the knowledge that may reasonably be expected to result.

- Selection of participants should be equitable. The IRB will consider the purposes of the research, the setting in which the research will be conducted, and the population from which participants will be recruited.

- Informed consent will be sought as it applies to each research project and from each prospective participant or his or her legally authorized representative in accordance with current federal rules on the protection of human participants.

- The informed consent document should be written in language appropriate for, and understandable by, the potential participants of the research. This is one of the most common reasons for requesting modifications prior to approving a protocol. When in doubt, simplify. See the Appendix for links to useful suggestions and models.

- The research plan must make adequate provision for regular monitoring of the data collected to ensure the safety of the participants. As needed this may be accomplished by a sub-committee of the IRB or an independent observer. Description of any data safety monitoring measures should be included by the PI in the section of the application on risk management.

- Adequate provisions to protect the privacy of participants and to maintain the confidentiality of the data as appropriate.

- Appropriate safeguards must be included in the study to protect the rights and welfare of participants who are vulnerable to coercion or undue influence. These safeguards must be

- Training certification information for each PI and student involved in the research must be completed and submitted to the IRB before approval will be granted.

Dissertation Committee Requirements are NOT the Same as IRB Requirements
Faculty and students should not confuse the different requirements for presenting a dissertation proposal to the student's appointed committee with the IRB requirements for protocol applications and protocol oversight. The IRB protocol application and human subject research oversight are distinct processes that will also be required for most UMass Lowell Ph.D. dissertations. While some aspects of the Dissertation process may be obvious to the Committee Members, it is not obvious to the IRB and the IRB must have completed protocols to outline each step of the process where human subject participants are to be engaged. IRB documents are also only available to the PI and student listed on the protocol application. Consent documents are not shared with Dissertation Committee members but are expected to be available at any time for IRB review and audit.

4.6 NOTIFICATION AND APPEAL OF IRB DECISIONS

The IRB Administrator will notify the PI of the results of the IRB decision in writing (by email on letterhead) within 3 working days of the decision for exempt or expedited review applications or of the Board meeting for full reviews. Approval memos include language specific to the type of review received. PIs are expected to read the approval memos thoroughly and understand that they have final responsibility for compliance with IRB requirements for human subject research. IRB decisions may be appealed to the IRB Chair within 30 days of the final determination. All types of protocol decisions may use the appeal process. The Chair will review the appeal and his/her determination is final. The IO may not overturn any IRB decision.

5.0. MISCELLANEOUS INFORMATION FOR APPLICATIONS

5.1 HOW TO SUBMIT AN APPLICATION

Application forms are available from http://www.uml.edu/Research/OIC/ under the 'Human Subjects: IRB' navigation bar. Always check the website for the most current version of the form you need. Please indicate in the e-mail submission, the forms submitted and attach the files appropriately named so the IRB Administrator can easily identify them.

5.2 TYPES OF ACTIVITIES THAT REQUIRE IRB REVIEW

Many types of activities require IRB review and it is important to understand what is required to be reviewed, as many journals will not publish results when data are obtained from human participants without IRB review and approval. Any and all activities that involve human participants (even observations) and that include the dissemination of results are considered human subject research and as such require IRB review and approval ***before the activity begins***. Some examples of such activities include research about teaching methods or activities, observations, research using human-derived materials (blood, saliva, etc.), surveys (even anonymous online), program evaluations for dissemination outside of the organization evaluated, and stem cell research. For researchers to use stem cells, the research will require review and approval by both the IRB and the Institutional Biosafety Committee.

Forms required for submission with applications will depend on the type of review but typically should include:

- Project Application Review Form
- PI Assurance and Signature Page
- Informed Consent or Agreement to Participate Form
- Translation Certification (if necessary)
- Proposal (if funded research project)
- Training certifications for all personnel engaged in the research

5.3 RECRUITMENT AT UML BY OUTSIDE ORGANIZATIONS

Research activities approved by IRBs from other institutions are generally **not** supported at UMass Lowell when UMass Lowell faculty, staff, or students are not engaged in conducting the research activity. A collaborative institution agreement will need to be in place for any collaborative research activity and designates the IRB of record. In addition, faculty, staff, and student contact information will not be released to any outside organizations for research purposes.

5.4 USE OF DUAL ENERGY X-RAY (DXA OR DEXA), RADIATION DEVICES OR MATERIALSs

For use of any of these materials in human subject research, the faculty PI must also notify the Radiation Safety Committee and describe the type of radiation to be used, exposure

levels, and controls to protect both human research participants as well as the personnel administering the radiation. The Radiation Safety Committee will provide written approval for the specific procedures and materials to be used at UMass Lowell. This letter must be received and on file with the IRB Administrator before final approval of a protocol that includes the use of any of these materials.

5.5 DATA RECORDING, RETENTION, AND STORAGE

Research data are defined as "recorded information" regardless of form or the media on which it may be recorded. The PI is responsible for recording, retaining, and storage of data and these components should be outlined in the IRB application. The term includes identifiable private information or specimens, personal health information, genetic information, etc. Data collected for IRB approved human subject research that include identifiable information must be under the control of the UML PI or personnel to protect the confidentiality of the participant in accordance with the information provided in the informed consent document. Storage must also take into consideration whether the data have participant identifiers and storage considerations must be appropriate for the type of information that is recorded. Data that include personal health information (PHI) should be stored on UML protected equipment or a UML secured server and *not on notebook or laptop computers*. Publicly available data is exempt from IRB oversight.

Data must be kept for as long as necessary to protect any intellectual property resulting from the work, to resolve any charges related to scientific misconduct or conflict of interest. Researchers must follow ethical guidelines to protect data and records at the conclusion of the research according to standard practice for the discipline. Data retention should be consistent with the information provided in the informed consent document. Once data have been de-identified, research using it is exempt from IRB review. Remember: **only the IRB can determine when a study is exempt after it has evaluated an application for Exempt Status Determination completed by the PI.**

For any photograph, video- or audiotape recordings, the Informed Consent Form should include a statement that indicates the participant agrees to consent to such recordings and allows the researchers to use the recording for research purposes. Photographs, videotapes, or recordings of a research participant that are obtained may only be done with the *expressed permission of all individuals who will be included in the image where there is an expectation of privacy (including classrooms and most work environments),* even if the other individuals are not participating in the research.

For retention of videotape, photographs, or audiotape recordings to be used for publication, the PI must have a separate Video/Photo Publication release form that accompanies the Informed Consent Form and that indicates the subject has agreed to their voice, photograph, and/or videotape likeness to be used for publication with an explanation of how it may be used. A Video/Photo Publication Release form is available from the website.

5.6 DATA: ANONYMOUS, CONFIDENTIAL, OR DE-IDENTIFIED

The IRB often finds that the terms *anonymous, confidential, and de-identified* are not used

correctly. These terms are described below as they relate to an individual's participation in the research and the way that their data are collected and maintained for analysis.

Anonymous indicates it is impossible to determine whether any individual was involved in the research project. Data are *anonymous* if no one, **not even the researcher**, can connect the data to the individual who provided it. No identifying information is collected from the individual. For example, participation in an online survey that cannot be linked in any way to the individual would be considered *anonymous*. Researchers should be aware however, that collection of information regarding other unique individual characteristics (indirect identifiers) could make it possible to identify an individual from a pool of participants. For example, a study participant who is a member of a minority ethnic group might be identifiable from even a large data pool.

Confidential indicates that the research team knows that any particular individual has participated in the research but is obligated not to disclose that information to others outside the team. When data are *confidential*, there continues to be a link between the data and the individual who provided it. The research team is obligated to protect the data from disclosure outside the research according to the terms of the research protocol and the informed consent document. In order to protect against accidental disclosure, the subject's name or other identifiers should be stored separately from their research data and replaced with a unique code to create a new identity for the subject. Note that coded data are not *anonymous*.

When confidential data are being transcribed or otherwise processed by a commercial service or provider, the individuals who are transcribing must sign a document indicating that they will maintain confidentiality, keep data secure, and delete copies of the data when their work is finished. The document should be submitted with the IRB application; the PI maintains the signed document in his or her records.

De-identified data are those data that have NO direct identifiers or codes linking it to an individual subject. For data to be deemed '*de-identified'*, all direct or indirect identifiers or codes linking the data to the individual subject's identity are destroyed. IRB research protocols that have been approved that involve the collection of identifiers must be reviewed and approved annually as long as any identifiers are attached to the data. When the data is de-identified, the protocol may be closed and the de-identified data may continue to be used by the researcher.

5.7 INSURANCE COVERAGE RELATED TO COMPENSATION FOR INJURY OR COMPLICATIONS RELATED TO HUMAN SUBJECT RESEARCH

Some protocols may include activities, usually other than surveys or interviews, in which there may be some risk from participating in human subject research that could result in harm or injury. Protocols of this nature should include a statement in the consent document similar to the following:

"The University of Massachusetts does not have a program for compensating subjects for injury or complications related to human subject research."

5.8 RECRUITMENT OF PARTICIPANTS AND INCENTIVES

Advertising to recruit study participants should be conducted to ensure that participation is voluntary. The IRB reviews all recruitment documents and the methods and materials that PIs propose to use to recruit participants. The recruitment information is submitted with the application to the IRB for review, regardless of the type of review. Direct advertising includes methods such as newspaper, radio, television, bulletin boards, posters and flyers intended for prospective participants.

Recruitment methods and materials are reviewed by the IRB to assure that the recruitment process is not unduly coercive and does not promise a certainty of cure or outcome beyond what is outlined in the consent and the protocol. This is especially important for studies that may include participants who are likely to be vulnerable to undue influence. Procedures should be clearly outlined so that the IRB is assured that the information collected is handled appropriately and if sensitive information is gathered, the PI should outline the steps that will be taken to protect the participants' confidentiality. If a PI intends to recruit participants in a non-public way, justification must be present to the IRB and approval must be granted to do so.

It is not uncommon for participants to be paid for their participation in research. This is not considered a benefit but a recruitment incentive. The amount and schedule of all payments should be presented to the IRB at the time of the initial review. Both the amount of the payment and the proposed methods and timing of disbursement are reviewed to assure that neither are coercive or present undue influence. Any credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. All information concerning payment, including the amount and schedule of payment(s), should be outlined in the informed consent document. Some funded research activities may have a requirement for a specific type of incentive payment. Please note this in the application, if applicable.

5.9 RECRUITING PARTICIPANTS FROM 'SUBJECT POOLS'

Some UMass Lowell Departments use Subject Pools to recruit students for participation in human subject research. These pools are managed currently through the SONA system. **All research posted on any UMass Lowell Subject Pool must have approval by the IRB prior to its posting.** Use of online participant recruitment tools, such as SONA, also requires that information posted on the system be provided to the IRB in the application for approval. So that students can make an informed decision about whether to participate, all postings should include more than the title of the study. A brief description of the study purpose and method as well as an indicator of any potential risk should be added. Inclusion and exclusion criteria should also be outlined. *Remember that individuals under age 18, even if they are college students, are considered minors and parental consent and assent documents may be required or in some cases, a full review IRB application may need to be submitted and approved before they may be included in any study.* Age guidelines should be clear on any recruitment tools, including SONA listings.

SONA listings should therefore include:

- Study title
- Very brief description of study purpose and method
- Brief indication of potential risk
- Inclusion criteria, including age 18 or older
- Exclusion criteria, including under age 18

The Psychology Department requires that all studies for which participants are recruited through the General Psychology Pool must have both IRB approval *and* at least one full-time faculty member *from the psychology department* listed as a PI. IRB approval is a requirement across the university. Other departments should determine which University PIs may recruit from their pool.

Subject pools may also be used to recruit participants for research where monetary incentives are offered. Departments should decide on the best policy for managing recruitment for paying studies, i.e., whether such recruiting will be on the same platform as recruiting for participation credits in courses.

5.10 POTENTIALLY VULNERABLE GROUPS

Some groups of human participants may be considered particularly vulnerable in a research setting. Federal regulations for protecting human participants in research include specific protections for children, pregnant women, human fetuses, neonates, and prisoners. In reviewing research studies, the IRB ascertains that the inclusion of the vulnerable population is adequately justified and that safeguards are implemented to minimize risks unique to each population.

Each research study is evaluated for inclusion of possible vulnerable populations. If a population is identified for which specific IRB policies and procedures do not exist, e.g., economically disadvantaged, elderly, terminally ill, or employees, the IRB addresses the recruitment process and the consent process to determine if additional safeguards are required.

Approval for research studies involving vulnerable populations is considered if one of the following conditions is met: (1) the research does not involve more than minimal risk to the participant; (2) the research is likely to benefit the participant directly, even though the risks are considered to be more than minimal; or (3) the research involves greater than minimal risk with no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the participant's disorder or condition.

For research projects that propose to use vulnerable groups, please refer to 45 CFR Subpart B, C, and D for more specific information.

5.11 RESEARCH USING PRISONER POPULATIONS

Research with prisoners or incarcerated persons (or persons who become incarcerated after research has been initiated) requires full IRB review of the protocol and a prisoner

advocate must be appointed to review any such protocol. Regulations provide additional protections for this group of potential participants (see 45 CFR46, subpart C). In addition, there are only a few types of research permissible with this population and risks to subjects must be minimized. Subpart C includes the following requirements to minimize risks to participants and ensure that the prisoner can give valid informed consent:

1) The research under review represents one of the categories of research permissible under 46.306 (a)(2).
2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.
4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitray intervention by prison authroirtes or prisoners. Unless the principal investigator provides to the Board justification in writing for following sowe other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
5) The information is presented in language which is understandable to the subject population.
6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
7) Where the Board finds there may be a need for follow-up examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

For research with prisoners, additional IRB reviews and approvals are required by the U.S. Department of Justice, Federal Bureau of Prisons and the federal agency funding any such research. Typically, the UML IRB would review and approve such protocols and then forward all documentation to the appropriate IRB(s) for review and approval before any research may be initiated. For research with this participant population, the IRB approval process is lengthy. Researchers allow adequate time for all of the various levels of IRB review and approvals that may be required. Contact the Director of the Office of Institutional Compliance for assistance with this type of research.

5.12 INCIDENT AND ADVERSE EVENT REPORTING

Any unanticipated problem involving "risk" that ultimately results in harm to the participant and is related to a research intervention encompasses a reportable adverse event. "Problems involving risk" could indicate that only the possibility of harm occurs rather than actual harm. However, loss of research records that contains identifiable private information would be a reportable event. Procedures for prompt reporting of unanticipated

events that involve risk to the participant or others must be in place. Typically, only events that are very serious and related to the research are reported to DHHS or FDA as adverse event reports. Any unanticipated incident that occurs during a research activity should be reported to OIC as soon as possible to assist the PI in determining whether the protocol should be revised to prevent any similar subsequent incidents.

Adverse event or incident reports should be submitted to the IRB Administrator, IRB Chair, and Director of Institutional Compliance. The report should provide the IRB with a reasonably detailed analysis of the event and allow the PI to assess the situation and determine whether the protocol requires modification to minimize risk, whether the consent form should be revised, or if participants should be contacted to re-consent to participate in the research study. Adverse events can be internal (those that occur at UML and are served by the UML IRB) or external (those that occur at external unaffiliated study sites). The event report should include:

- Description of the event in sufficient detail as to allow an informed review of the occurrence (description, causality, prognosis)
- Explanation as to why the event is unexpected and related (for internal adverse events a report is required if the event meets both criteria only)
- Explanation as to why the event is unexpected and related and serious (for external events a report is required if the event meets both criteria only)
- Description of changes to the protocol to minimize further risk, or the rationale if no changes are required
- Description of changes to the consent or the rationale if no changes are required
- Description of the plan to reconsent current participants or the rationale if no reconsent is required
- Risk/benefit analysis update: explain why the overall risk/benefit relationship of the research is still acceptable in light of the information concerning this adverse event report

Terminology related to adverse events includes:

- *Unanticipated*: the specificity or severity of the adverse event is not consistent with the current investigator's brochure or with other current risk information (based on 21 CFR 312.32 (a)).
- *Related or possibly related*: there is a reasonable possibility the adverse event may have been caused by the drug or intervention or it is possible that the adverse event may have been caused by the drug or intervention, but there is insufficient information to determine the likelihood of this possibility (based on 21 CFR 312.32(a)).
- *Serious*: (1) results in death or (2) is life threatening or (3) requires inpatient hospitalization or prolongation of existing hospitalization or (4) results in serious, persistent, or significant disability or incapacity or (5) results in a congenital anomaly or birth defect or (6) causes cancer or (7) is an overdose or (8) is any medical event which requires treatment to prevent one of the medical outcomes listed previously (based on 21 CFR 312.32(a)).

6.0 DATA SECURITY PLANS INVOLVING THE USE, STORAGE OR TRANSMISSION OF ELECTRONIC RESEARCH DATA CONSTITUTING SENSITIVE DATA

Pursuant to regulations of the Department of Health and Human Services (DHHS), including the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), the IRB is charged with ensuring that each human subjects protocol includes provisions for protecting the privacy of subjects and maintaining the confidentiality of study data. This is particularly important when the study involves data constituting Sensitive Data pursuant to the terms of the UMass Lowell Data Classification Policy (the "Data Classification Policy") and therefore subject to the most stringent data security requirements. This policy is effective as of November 1, 2014.

This Policy provides standards for IRB review and approval of data security plans involving the storage of electronic research data constituting sensitive data in human subjects research conducted at UMass Lowell, including UMass Lowell researchers and support staff. The intent of this Policy is to ensure that the protection of the privacy of research subjects and the confidentiality of identifiable research data is in accord with the requirements of HHS, NIH and FDA regulations and the Health Insurance Portability and Accountability Act (HIPAA).

6.1 DEFINITIONS FOR TYPES OF DATA

Pursuant to the Data Classification Policy, Sensitive Data is defined as follows:

> **Sensitive Data:** any information protected by federal, state and local laws and regulations or industry standards, such as HIPAA, the Health Information Technology for Economic and Clinical Health Act (HITECH), the U.S. Family Educational Rights and Privacy Act (FERPA), M.G.L. c. 93H, and the Payment Card Industry Data Security Standard (PCI-DSS).
>
> For purposes of this Policy, Sensitive Data include, but are not limited to:
>
> **Personally Identifiable Information (PII):** any information about an individual that (a) can be used to distinguish or trace an individual's identity, such as name, date and place of birth, mother's maiden name or biometric records (b) is linked or linkable to an individual, such as medical, educational, financial and employment information, which if lost, compromised or disclosed without authorization could result in harm to that individual and (c) is protected by federal, state or local laws and regulations or industry standards.
>
> Examples of PII include, but are not limited to, any information concerning a natural person that can be used to identify such natural person, such as name, number, personal mark or other identifier, in combination with any one or more of the following:

- Social security number
- Driver's license number or non-driver identification card number
- Account number, credit or debit card number, in combination with any required security code, access code or password that would permit access to an individual's financial account
- Email address with password (in certain narrow instances)

Protected Health Information (PHI): any information processed, transmitted or stored by a Covered Entity (as defined in HIPAA) that relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual or the past, present or future payment for health care and (a) identifies the individual or (b) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. The University's Office of the General Counsel and Office of HIPAA Compliance are responsible for determining whether particular information maintained or disclosed by the University constitutes PHI.

Examples of PHI include, but are not limited to, any health information about an individual, in combination with any one or more of the following:

- Name
- Geographic subdivision smaller than a state
- Any element of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date or date of death
- Telephone number
- Fax number
- Electronic mail address
- Social security number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate/License number
- Vehicle identifier and serial number, including license plate number
- Device identifier and serial number
- Web Universal Resource Locator (URL)
- Internet Protocol (IP) address number
- Biometric identifier, including finger and voice print
- Full face photographic image and any comparable image
- Any other unique identifying number, characteristic, code or combination that allows identification of an individual.

6.2 CODING SENSITIVE DATA

Any codes used to replace identifiable data must not be derived from any information

relating to the individual and neither the master codes, nor the method to derive the codes, may be disclosed. Additionally, although the use of codes is highly recommended as a means of reducing risk, if a Principal Investigator (PI) or his/her research team has the ability to link coded data to identifiable information, the coded data will be considered to be identifiable. If the PI and his/her research team have no access to identifiable information, the coded data may be considered de-identified.

All IRB protocols must have a data security plan that specifies whether Sensitive Data will be obtained or created and if so, how it will be stored and transferred. Any modification to the data security plan must be approved by the IRB. Protocol renewals must identify any changes in such data security plan and, at the time of renewal, the IRB will require that the plan be updated to meet new requirements. The data security plan must be acceptable to the IRB for a protocol or protocol renewal to be approved by the IRB.

No data shall be removed from the UMass Lowell campus via any media, such as CD, DVD, USB storage cards, external hard drives, or any computing systems, such as laptops and mobile devices to further reduce risk of unauthorized access, uses, or disclosure of sensitive or confidential data.

It is the responsibility of the PI of any research study involving Sensitive Data to comply with all applicable University policies and guidelines, including all Information Security Policies (as defined in the UMass Lowell Information Security Plan).

6.3 DATA STORAGE

The following methods of storing electronic research data containing Sensitive Data will be acceptable to the IRB:

1. Server Based Systems

The data is stored on a System (as defined in the Plan) in compliance with the UMass Lowell Registration and Protection of Systems Standard. The specific server name and IP address and, System Administrator is required at a minimum. Additionally, the server and associated storage must be located in a secure network segment, protected by the UMass Lowell firewalls, and encrypted using industry standard encryption software. Access to the server and or storage from off campus can be accomplished by the campus VPN product.

2. Endpoints

The data is stored on an Endpoint (as defined in the Charter) in compliance with the UMass Lowell Registration and Protection of Endpoints Policy (the "Endpoints Standard"). The inclusion of a statement to such effect in a protocol will constitute a certification by the PI that each Endpoint to be used in the study will be so protected. Data located on each endpoint must be encrypted using industry standard encryption software.

6.4 DATA TRANSMISSION

An acceptable data security plan must provide that all electronic transmissions of Sensitive Data over the internet (including by email), file transfers or other data transfer modalities, are made in compliance with the Systems Policy or the Endpoints Standard and the UMass Lowell Email Policy. At a minimum, the data transmission must be made using secure protocols (https, SSL) between the sender and the recipient.

6.5 DATA LOSS OR SECURITY BREACHES

Any loss of or breach of security relating to research data containing Sensitive Data must be reported (1) to the IRB as an Unanticipated Problem Involving Risks to Subjects or Others and (2) in compliance with the UMass Lowell Electronic Data Security Breach Reporting and Response Policy.

Examples of security breaches include: (1) lost or stolen desktops, laptops, USB drives, CD/DVD/Zip drives, etc. with stored data; (2) a compromised account that is used to look up data (e.g., unauthorized user has had access to the account); (3) a compromised work station or server that contains data; and (4) accidental disclosure or data to unauthorized recipients (e.g., sending data to an incorrect email address).

7.0 INFORMED CONSENT INFORMATION

The informed consent process is to be an active process of sharing information between the PI and the *prospective* participant. The process is the critical communication link between the prospective participant and the researcher, beginning with the initial approach of an investigator to the potential participant and continuing until the completion of the research study.

The consent process should

- Tell the prospective participant that there is a study in which he or she might wish to participate
- Give the prospective participant a consent form to read
- Ask the prospective participant whether he or she has any questions
- Ask the prospective participant to sign the form, if documentation is required
- Provide the participant with a copy of the informed consent form that includes the PI contact information

The Informed Consent document is not in and of itself "consent," but the record of what is communicated to participants or prospective participants in a research study. The consent form documents informed consent. It may also be referred to as an "Agreement to Participate" and PIs may feel free to develop the form to suite the participants as long as the required elements of consent are included.

Consent is obtained using a form that has been reviewed and approved by the IRB. Forms are available on line and may be edited to meet the needs of researchers. Final approved forms are signed by the IRB Administrator and then the PI (or approved research assistant), participant (or the participant's legally authorized representative), and the person obtaining consent at the time the participant provides consent. If more than one Informed Consent document is necessary for a single protocol, each consent form should indicate at the top the group for which it is intended.

In some situations, the documentation of consent requirement may be waived by the IRB but waivers must be requested by the researchers and specifically approved by the IRB. In addition, PIs must insure that each person signing the Informed Consent Form is provided with a copy of that form. **PIs are responsible for the safeguard of consent documents signed by human research participants for three years following the termination of the project.**

The written consent document should be written so it is grammatically correct and to communicate the required information as clearly as possible. *It should typically be written at a sixth- to eighth-grade reading level, free of jargon, and in a language the participant can understand.* It should be consistent with what the PI has described in the application and/or grant proposal and be obtained without undue inducement or element of force, fraud, deceit, duress, or other forms of constraint or coercion.

Legally effective informed consent shall:

- Be obtained from the participant or the participant's legally authorized representative
- Be in language understandable to the participant or the representative
- Be understandable to the participant if the participant does not read or write, or is blind or hearing impaired
- Be obtained under circumstances that offer the participant or the representative sufficient opportunity to consider whether they should or should not participate
- Not include language through which the participant or representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the PI, the sponsor, the institution, or its agents from liability for negligence

Regulations require that investigators obtain legally effective informed consent of the participant or the participant's legally authorized representative *unless:*

- The research is designated as exempt status;
- The IRB finds and documents that informed consent can be waived; or
- The IRB finds and documents that the research meets the requirements of a waiver in a limited class of research in emergency settings.

7.1 REQUIRED ELEMENTS OF CONSENT

Informed consent must include the following elements:

- Statement that the study involves research conducted on behalf of UMass Lowell
- Purpose of the research
- Explanation of the expected duration of the individual's participation
- Description of the procedures to be followed
- Identification of any procedures that are experimental
- Description of any reasonably foreseeable risks or discomfort to the participant
- Description of any benefits to the participant or to others that may reasonably be expected from the research
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained and that notes the possibility that the FDA may inspect the records if appropriate
- Explanation of whom to contact for answers to pertinent questions about the research and research participant's rights and whom to contact in the event of a research-related injury to the participant. (For student research, the Faculty Advisor's name, university address, and university telephone number is included)
- Statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and

that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled
- Name and information about the person obtaining consent.

As appropriate, one or more of the following elements shall also be provided to each participant:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is, or may become, pregnant)
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent
- Any additional costs to the participant that may result from participation in the research
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant
- A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant
- The approximate number of participants involved in the study
- The IRB may require that information, in addition to that required in Federal Regulations, be given to research participants when the information is judged to meaningfully add to the protection of the right and welfare of participants

7.2 SIGNED CONSENT DOCUMENTS AND RETENTION

After IRB approval, the approved consent forms are returned to the PI to use to initiate the study. Those listed on the form should sign the approved form as appropriate to use for recruitment of participants. PIs are responsible for obtaining the participant's informed consent to participate in the research and ensuring that no human participants will be involved in the research prior to obtaining their consent. The consent form may be read by the participant or the participant's representative, or by the investigator (or a researcher approved to be involved in the research) to the participant. Investigators are responsible for ensuring that the consent process is typically documented using the form approved by the IRB and then gathering the signature(s) of the participant or the participant's legally authorized representative, unless this requirement is specifically waived by the IRB. Each person signing a written consent form must be given a copy of that form, unless the possession of such documentation presents a risk to the participant and a waiver has been obtained and approved by the IRB.

The PI should keep copies of all signed consent forms and be able to provide them to the IRB upon request. The IRB will request signed copies of the consent forms for review during IRB audits. The signature of a participant or the participant's representative who may provide legally effective informed consent is required for signed informed consent. The signature of a witness is required when a participant or participant's representative is unable to read or when the IRB authorizes the use of a short written consent procedure for limited English speaking individuals. The witness observes the informed consent process

and signs a statement attesting that the consent process was done voluntarily on the part of the research participant, as well as being accurate.

If participants are patients, signed consents become a part of their medical records. For participants who are not patients, consent forms may be stored securely in the files by the PI and procedures must be outlined to ensure that the consent forms are kept in a secure location and can be retrieved expeditiously when necessary upon request by regulatory authorities or UML IRB administrative personnel.

7.3 USE OF TITLES

To avoid confusion for research participants who may assume the title of 'Dr.' means the individual is a medical doctor, the IRB recommends that the term "Dr." not be used in front of your name. Instead, the IRB recommends that the researcher's professional credentials are noted after the full name to indicate degrees, certifications, licenses, and so forth. For example, rather than "Dr. Mary Smith," please use "Mary Smith, Ph.D."

7.4 OUTLINING DETAILS ABOUT RISK

Participants should be informed of any and all potential risks in language that is clear and easy to understand. There is probably no research that is without any risk at all—either with respect to stress or disclosure. Even with surveys that do not seem to deal with emotionally charged issues, there is the risk that an individual will be upset by some of the questions. Similarly, under the most secure conditions, there is always the risk of an accidental release of information. Therefore, the IRB recommends including a statement in the consent document such as:

> "Although we believe the questions we are asking will not cause you distress, there is always some slight risk that some individual might find them upsetting or otherwise stressful. We also will take every precaution to protect the confidentiality of your responses, but there is always a slight risk of disclosure from participating in any research."

Researchers must not make promises they cannot keep. If data can be obtained by law enforcement by subpoena, for example, then the researcher cannot promise to keep the data anonymous or confidential, but can promise to make every effort to do so. When the risk of disclosure to the participant is great (e.g., prosecution for illegal activity), the researcher should be as frank as possible about the conditions under which he or she might be required to disclose data.

Researchers engaged in high risk research with respect to disclosure may want to consider a federal Certificate of Confidentiality. See http://grants.nih.gov/grants/policy/coc/faqs.htm

7.5 DECEPTION

When it is necessary to deceive a research participant about the nature of the research or procedures in order to obtain non-biased responses, it becomes impossible to obtain truly informed consent. For example, it may be important that participants believe they are playing a zero-sum game against another human participant so that their decision-making

and risk-taking strategies can be observed, while they are really playing against a computer programmed to respond randomly. In this case, the researcher cannot fully disclose the nature of the task until it is finished, and must, instead, apply for a waiver of informed consent (see below). In no case should the Informed Consent Form be used for deception or contain information that is untrue.

Researchers must provide all other information necessary to inform the decision of potential participants about whether or not they want to continue with the research. This information should be discussed as it would with informed consent in place, and it should be given to the participants in writing. **In no case may deception be used to recruit participants or influence the decision to participate.**

The IRB will review requests to deceive participants carefully, attending to the potential risks inherent in the deception, the scientific value of the deception, and the availability of non-deceptive alternatives. **Deception may not be used for research that may be expected to cause pain or significant emotional distress.**

In all cases involving deception, participants must be debriefed at the conclusion of their participation and informed about the deception and why it was necessary for the research. At that point, participants must also be allowed the opportunity to withdraw their data from the study since it was obtained under, ostensibly, false pretenses. This must be done without prejudice to incentives. Researchers may ask participants not to reveal the nature of the research after they leave.

7.6 RESEARCH STUDIES THAT INCLUDE THE USE OF DUAL ENERGY X-RAY (DXA OR DEXA), RADIATION OR RADIOACTIVE MATERIALS

Certain types of protocols involve the use of a radiology device or radioactive materials in a research-only setting. In these situations, the Radiation Safety Committee (RSC) must assess the level or dose of radiation exposure, evaluate risk, and approve the activity as well as the device and any materials used. The RSC application can be submitted simultaneously with the IRB application but the IRB protocol will not receive final approval until the RSC approval is granted for use of any radiological or radiative devices or materials.

Suggested Consent Form Language for Studies Using *DXA or DEXA* [Note: *Italicized* words and phrases may or may not apply to your study]

Research Purpose Description for Studies Using DXA (or DEXA):
The purpose of this research study is _____. We will measure your height, weight, *body composition (percentage body fat)* and bone mineral density (or BMD). We measure *body composition and BMD* with a Dual Energy X-ray Array (DXA or DEXA), a medical device that exposes you to a low dose of radiation.

DXA (or DEXA) Scan Procedure (20 minutes) Lanugage:
1) Remove all metal objects, including clothing containing metal

2) Remove at least your outer clothes and change into shorts and a t-shirt or wear a hospital gown
3) Measure height & weight
4) Lie on the DEXA padded table
5) A research technician will position your body on the table
6) Lie still for about 30 seconds during each of two scans (hip and spine) *and for about 6 minutes for the body composition scan*
7) Receive DEXA results (and an opportunity to sign a release form to fax results to your physician)

Potential Risks and Discomfort Language
The DXA (or DEXA) device exposes you (and any unborn fetus) to a low dose of X-ray radiation . X-ray exposure during DXA: The total amount of radiation you will be exposed to is relatively small (approximately 2 millirems, less than 1/20 of the radiation received during a single chest-x-ray) or less than what a person would receive while traveling by plane from Boston's Logan Airport to San Francisco International Airport. One scan poses no known health risks in non-pregnant women. Because exposure to radiation may cause harm to an unborn fetus, you should not participate in this study if there is any chance you are pregnant. By signing this consent form, you agree that you have been made aware of this risk. Some people experience anxiety during this test, just like any medical test.

FEMALES: Because the radiation could harm a fetus, we are required to give you a urine pregnancy test before doing a DEXA – if it has been less than a year since your last period. You will provide your urine sample in a cup in the restroom. The pregnancy test must be negative for you to participate in *any part of this study*.

Potential Benefits Language
One benefit is that you will find out your percent body fat and how it compares to most other people. You will *also* find out if your bone mineral density (a contributor to bone strength) is within normal limits. If your bone mineral density appears to be low, we can fax the DEXA results to your physician with your written permission.

7.7 CONSENT FOR RESEARCH USING AUDIO, VIDEO OR DIGITAL RECORDINGS

For research involving the use of audio, video or digital recordings, researchers must inform participants in the informed consent form where recordings will be stored, who will have access to them, and the year by which the tapes will be destroyed. A special form must be used if the recordings are to be released as part of the research.

Researchers have the option to archive recordings or use recordings in future research, classroom or conference presentations, etc. In order to plan to archive recordings, researchers must provide a justification to the IRB for archiving the recordings and provide the participant, in the informed consent form, the option of declining or allowing the

recordings to be archived or used for future research, educational or conference presentations with appropriate confidentiality protections. It is recommended that the researcher prepare a separate "release document" for the participant to sign that indicates their approval for the use of these types of recordings or images. The IRB may request a researcher to obtain a Certificate of Confidentiality from the NIH if the research is of a sensitive nature and protection is warranted.

7.8 WAIVERS OR ALTERATIONS TO THE CONSENT PROCESS

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent as stated, or waives the requirement to obtain informed consent as outlined in 45CFR 46.116 (d) provided the IRB finds and documents that the:

1. Research involves no more than minimal risk to the participants;
2. Waiver or alteration will not adversely affect the rights and welfare of the participant;
3. Research could not practicably be carried out without the waiver or alteration; and
4. Participants will be provided with additional pertinent information after participation, whenever appropriate.

Waiving the consent procedure may be used for protected groups if the research is considered minimal risk. PIs must request and justify the reason for the waiver.

7.9 WAIVER OF DOCUMENTATION OF INFORMED CONSENT

Under certain conditions, the IRB may waive the requirement to obtain a signed consent form for some or all participants if it finds that:

- The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; **or**

- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of research context.

In cases in which the signed documentation requirement is waived, the IRB may require the investigator to provide participants with a written consent statement regarding the research and obtain verbal consent. The Project Application Review Form should clearly explain the reasons to request a waiver of documentation of consent. DHHS provides for waiving or altering elements of informed consent under certain conditions (see 45 CFR 46 subparts 116, 117, 408). In some instances the IRB may also waive the requirement for documentation of informed consent if the research is more than minimal risk but the risk is associated with a breach of confidentiality AND the consent document is the only record

linking the participant to the research. If a waiver of documentation of informed consent is approved, edit the form as appropriate to remove the signature line for participants to avoid any confusion.

7.10 PASSIVE CONSENT

Passive consent, where the lack of an objection to research participation would be considered an agreement to participate, may be approved only if the investigator justifies this consent process and the IRB determines that the study meets the criteria to waive the requirement for signed informed consent. Minimal risk online surveys and classroom projects may utilize this type of consent process with IRB approval, especially when no identifiable information is collected or recorded. Surveys may be written with the elements of consent included in the instructions and *must state clearly* that the participant is free to stop at any time, skip any questions that they do not want to answer, or not return the survey to the investigator.

7.11 WAIVER OF CONSENT

In some cases, the PI may request that the consent process be waived entirely. The PI must request and provide justification for the request and then the IRB determines and documents that the request meets the regulatory requirements (the four criteria noted above). If the request is reviewed at a full IRB meeting, the meeting minutes must document the IRB's findings regarding the decision to grant a waiver. Similarly, if the study meets the criteria for review under expedited procedures, the reviewer documents the findings and decision to grant the waiver. Circumstances where consent may be waived entirely can include emergency medicine research interventions where the subjects are in life threatening situations and cannot give consent as a result of their medical condition or when there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

7.12 INCENTIVES

Where incentives are to be provided, the incentive should be clearly explained in the informed consent process and an explanation as to what will occur should a participant withdraw from participating in the study. Incentives should not be so great that they encourage participation in the research when otherwise a participant might decline. Some federal funding now requires that incentives be only cash payments (National Science Foundation, for example) so the incentive may be dictated by the funding organization.

7.13 CONSENT FOR VULNERABLE POPULATIONS

When informed consent discussions are conducted for individuals who may provide legally effective informed consent but are not able to read the consent form, or for individuals who are capable of legally effective informed consent but are physically unable to sign the written form to document their informed consent decision, a witness must be present during the entire informed consent process. This applies to individuals who are capable of providing legally effective informed consent and understand English.

Following the presentation of the information, reading of the consent form if applicable, and the informed consent discussion, prospective participants (or representatives) who are

capable of providing legally effective informed consent should sign and personally date the consent document (including making their mark), if able.

Individuals who are physically unable to sign the consent form may indicate their approval or disapproval by other means. The investigator conducting the informed consent process should then document on the consent form, the date and time, print the name of the individual providing consent and indicate by what means consent was communicated. An impartial witness must be present during the entire consent process to observe that the information in the consent form and other material presented about the research was explained accurately, and that the potential participant (or representative) understood and made the consent decision freely.

7.14 WITNESS TO CONSENT

A witness to the informed consent process is required when an informed consent discussion will be conducted with a prospective participant, or participant's representative, who is eligible and capable of providing legally effective informed consent, but the individual is:

- Unable to read the consent form; or
- Physically unable to sign the consent form; or
- Non-English speaking and a Short Form Consent and Oral Translation Process will be used.

To qualify as a witness for the consent process, an individual must be an *impartial third party who is not connected with the research* such as, a non-research team employee, a relative of a participant, or person similarly unconnected with the research. The witness must be present during the entire consent process, while the consent form and any other written material and information for the participant is read, explained, and discussed. The role of the witness is to observe that the information in the consent form and other material about the research is explained accurately, that the potential participant or participant's representative understands, and that the decision to participate is made freely.

After witnessing the informed consent process, the witness signs a witness statement attesting that the consent process has been done voluntarily on the part of the research participant, as well as being accurate. The witness statement may be incorporated in the IRB approved informed consent document, or a separate witness form may be signed and attached to the informed consent form, becoming a part of the consent documentation for the participant.

7.15 CHILDREN AS PARTICIPANTS IN RESEARCH (ASSENT AND CONSENT)

"Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (individuals under 18 in Massachusetts). In such cases, a parental consent document and an Assent document may need to be prepared for review. Separate forms may be required for different participant groups (e.g., parents, children, non-English speaking) as well as for release of particular kinds of information (photographs, audiotapes, videotapes). Assent, a child's affirmative agreement to

participate in research, should be used when participants are seven years of age or older. IRBs are granted wide discretion in determining whether a child is capable of providing assent and how to document assent. In some cases, the consent and assent information can be combined in one form to keep the parental consent tied with the name of the child and the child's assent documentation. Efforts should be made to conduct research using children capable of assent before enrolling those less able to provide assent.

Assent indicates a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. A sample assent form is provided on the website to be modified to suit your individual research objectives. Assent is typically required for participants age 7-17. Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

"Guardian" indicates an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. "Emancipated minor" means a legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law, but who are entitled to treatment as if they had by virtue of assuming adult responsibilities, such as self-support, marriage or procreation. "Mature minor" indicates someone who has not reached adulthood (as defined by State law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor.

PIs may request a waiver of documentation of informed consent for research that involves children but the IRB must review and approve it. The PI may still be required to complete the consent process and a form should be available to any participants that want to have one that documents the elements of consent.

7.16 CONFIDENTIALITY AND ANONYMITY OF INFORMATION

In the informed consent procedure, participants are often given assurances that the confidentiality of records identifying the participants will be maintained. Loss of confidentiality may occur however when a court orders that research files or information be submitted as evidence in a legal matter. The court decides who has access to the files and what information may be required to be released.

When FDA regulated products are being studied, the informed consent document should state that the FDA may review and copy the participant's medical records and, if necessary, obtain the identity of the participant. Research projects that involve focus groups may also breach confidentiality of participants and a statement should be made to the group at the beginning that the discussion(s) that take place must be kept confidential to preserve the identity of the participants.

Unless there are no identifiers on project materials and participant lists are not maintained, complete confidentiality of records identifying the participants may be assured only to the extent that disclosure is not compelled by court order. The IRB recommends the following language be included in the informed consent form related to privacy and confidentiality:

"Every effort will be made to protect your privacy and confidentiality, but there is always a slight risk of disclosure from participating in any research study."

Security of storage, limitation of access, and coding constitute the best measure to minimize risk of inadvertent disclosure to unauthorized parties. Measures to prevent this problem should be described in applications for studies in which the data collected are sensitive.

The IRB follows 45 CFR 46.111(a)(7) and 21 CFR 56.111(a)(7), the DHHS and FDA criteria for IRB approval for research, when determining the adequacy of the plan provided by researchers to protect the privacy of participants and maintain confidentiality of the data. (If a research study will involve protected health information, all privacy and confidentiality mandates outlined in the HIPAA regulations (45 CFR 160/164) are also followed.)

In accordance with 45 CFR 46.116, the IRB takes into account the description of the extent, if any, to which confidentiality of records identifying the participant will be maintained when reviewing the informed consent form. For research that falls under FDA jurisdiction, a statement that the FDA may inspect the research records is added to the consent form. **All investigators must outline in their application how they will store and secure their data to maintain confidentiality**. If possible, the research is conducted without any type of identifiers associated with the data. If data are gathered with personal identifiers, whenever possible, personal identifiers are removed from data and code numbers are used associated with master code lists. The master code list and signed informed consent forms are stored separately from the data.

In accordance with federal regulations, researchers must maintain their signed informed consent forms for a minimum of three years from the close of the study or if the study falls under HIPAA regulations, for a minimum of six years. Study sponsors may have additional requirements regarding retention of data and consent forms. UML record retention policy is for three years from the close of the study unless otherwise noted by the funding agency.

7.17 AUTHORIZATION FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

When human participant research includes the use and disclosure of Protected Health Information (PHI), an authorization for use of the information is required from the participants. The authorization may be (1) part of the research informed consent form, or (2) a stand-alone document.

The research informed consent form or the authorization document should include the following elements:

- Description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion
- Name or other specific identification of the person(s) or class of persons, authorized to make the requested use or disclosure

- Description of each purpose of the requested use or disclosure
- Expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research” or “none” is sufficient if authorization includes use or disclosure of PHI for creation of a research repository or database
- Signature of the participant and date. If the authorization is signed by a personal representative of the participant, a description of the representative’s authority to act for the participant

The following statements must be included in the authorization:

- The participant’s right to revoke the authorization in writing, and the exceptions to the right to revoke
- A description of how the individual may revoke the authorization
- The consequences to the participant if he or she refuses to sign the authorization
- When UML can condition enrollment on failure to obtain authorization
- The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by this the federal regulations

The information in the authorization form must be written in plain language and understandable to the participant.

7.18 “TEACH BACK” METHOD

This method may be used in the informed consent process as another tool to verify that participants fully comprehend the information provided in the consent process, and may be helpful in situations where the research is complex, the consent form may be long and complicated, or the participant group may include vulnerable participants. It is not a replacement for any other part of the informed consent process but allows an opportunity for researchers to get confirmation that the participants are informed and fully understand the key points of the research.

To implement this method, researchers might say to the participant, "Tell me in your own words what will happen if you decide to participate in this study." It may also be implemented in a variety of ways from verbal discussion up to and including written responses and multiple choice questions with the choice of method depending on study complexity, risk, and need for documentation of depth of understanding by participants. It can be especially useful for critical components of the consent process such as procedure and duration, risks and discomfort, and right to refusal or withdrawal.

Note: Teach-back is not a substitute for obtaining written informed consent but is a mechanism to confirm comprehension and enroll participants who fully understand the nature of the research in which they have agreed to participate.

8.0 IRB ADMINSTRATION AND OPERATION INFORMATION

8.1. COMMITTEE COMPOSITION

IRB members are appointed by the Institutional Official for a three-year renewable term on a rotating basis. Re-appointment is at the discretion of the IO.

The board must have at least five members. There are several factors that are considered when determining the size of the IRB. Federal regulations require that an IRB include at least one scientist, one nonscientist, one person not affiliated with the institution and that the board have sufficient expertise and diversity to evaluate ethical issues involved in protocols sent for review. An odd number of members makes it easier to obtain a quorum. The volume and complexity of studies submitted for IRB review is another factor in determining the size of the board. Alternate members may be used for a specific IRB roster position or serve in an at-large capacity. An alternative to adding new members to meet expertise requirements is to use consultants to advise the IRB on specific issues.

It is the policy of UML that faculty members must represent a variety of academic disciplines to provide diverse knowledge and expertise relevant to the many types of studies that may be reviewed and evaluated. The UML Director of Institutional Compliance is an *ex officio* voting member to assure that available knowledge in areas of institutional commitments and regulations, standards of professional conduct and practice, and applicable law is met.

8.2. ROLES AND RESPONSIBILITIES

IRB Chair

The IRB Chair is appointed by the Institutional Official for UML. The Chair shall be a senior-level faculty member of the academic community and have a basic understanding of ethical issues, state law, institutional policies, and federal human participant research protection issues and regulations. The Chair must be willing to commit the time required and possess administrative and organizational skills involved in conducting committee meetings. He or she is responsible for assuring the protection of human subject research participants and serving in a leadership role to encourage respect and compliance for the IRB process.

The duties of the chair may include reviewing protocols submitted for exempt or expedited review; assigning studies to IRB reviewers; adding to or altering the IRB meeting agenda; summarizing IRB review recommendations for dissemination to PIs; reviewing and signing letters generated from board actions; approving minor amendments and determining which amendments go to the convened IRB; responding to concerns or complaints from research participants, research staff, or investigators and determining when they should be referred to the convened IRB; assisting with ongoing development of IRB Policies and Procedures; reviewing and approving protocol exemption requests or appointing a designee to do so;

and suspending or terminating research protocols if necessary. The above duties may be assigned to the Vice-Chair in his or her absence or if a conflict of interest arises.

IRB Vice-Chair

The Vice-Chair is an active, respected member of the IRB who is well informed of the regulations relevant to the use of human participants in research and will step in as Chair at the end of the Chair's term, typically three years. The Vice-Chair has signatory authority in the absence of the IRB Chair.

IRB Administrator

The IRB Administrator is the individual assigned with the administrative responsibility for oversight of the human protection programs. The IRB Administrator's primary responsibilities are to coordinate, review, and manage all documents for the IRB to ensure that a) research protocols are reviewed appropriately and in a timely manner, b) records and files are maintained, c) information is communicated to the appropriate parties, and d) UML is in compliance with federal human research regulations and other applicable federal guidelines. The IRB Administrator schedules meetings, arranges meeting location(s), drafts agenda for approval, distributes materials for review, takes meeting minutes, documents meeting actions, communicates actions to PIs in a timely manner, and enters and tracks all related documentation in a database. He or she must maintain knowledge to serve as a regulatory resource on human resource protection and to ensure that proposals are in compliance with federal regulations and guidelines. The IRB Administrator is responsible for preparing regulatory documents for review and the Federalwide Assurance submitted to OHRP. The IRB Administrator reports to the Director of the Office of Institutional Compliance (OIC).

Principal Investigators

PIs are responsible for consulting with appropriate IRB staff to determine whether research requires IRB review and approval, regardless of whether it is funded research or not. If review is required, PIs must ensure that an application and protocol are submitted to the IRB. PIs must comply with IRB decisions, conditions, and requirements and obtain informed consent to insure that no human participant will be involved in the research without consent. PIs are responsible for retaining consent documents, providing progress reports on the research, submitting annual review reports on IRB forms and adverse event reports, reporting any amendments for changes in research, and submitting a final report at the conclusion of each project.

PIs are also responsible for being aware of any new research publications in the peer-reviewed scientific literature that may impact their ongoing human subject research. The PI must report to the IRB when new scientific literature is found that impacts their UML approved research and describe any such impacts that the new results may have. In some cases, the PI may need to make modifications to the research design or provide justification to continue the research design as approved. The IRB will consider the information submitted and make recommendations, if necessary.

PIs and their personnel involved in conducting human subject research must agree to maintain in strict confidence the names, characteristics, questionnaire scores, ratings, incidental comments, and other information on all participants and participants' data they encounter so as not to conflict with State and Federal laws and regulations. PIs and their personnel must understand that "confidentiality" means they may not discuss nor divulge in any manner a participant's name or any identifying information or characteristics, scores, ratings, comments, or information about a participant with anyone who is not an authorized member of the research team. Information should not be discussed in a place where in may be overheard.

Office of Institutional Compliance (OIC) Director

The OIC Director serves as an *ex officio* voting member of the board and as a resource for regulatory related questions and compliance issues. The Director also is *ex officio* a voting member of the Institutional Animal Care and Use Committee and Institutional Biosafety Committee to ensure projects that involve approval from more than one board or committee are coordinated, information provided is consistent and the requirements of each committee/board are fulfilled. The OIC Director provides administrative support to the IRB Chair as necessary and oversight to the IRB Administrator. The Director fills in for the IRB Administrator in their absence to process and approve protocols as outlined under the responsibilities for the IRB Administrator.

Board Members

Members are appointed by the Institutional Official from diverse academic disciplines and the community to provide sufficient experience and expertise to the board. The board must include both male and female members and at least one member whose primary expertise is in a non-scientific area. At least one member must be appointed who is not affiliated with the institution in any way. Members serve a three-year term (with one-third of the board eligible for renewal each year) and may be re-appointed. They are not compensated for their service. Members are required to meet the training requirements, perform the assigned duties for the board or notify the Chair of their inability to do so, be available to attend regularly scheduled meetings, acquire and maintain a working knowledge of federal human participant protection through the education and training requirements, and review protocols and come to meetings prepared to discuss them. Board members also review and approve IRB Policies and Procedures. Alternate members may be appointed to serve at-large or to take the place of a regular appointed member. If both the alternate and the regular member(s) attend the same meeting, only one may vote and the minutes must reflect who is in attendance as a voting member.

Students

Student investigators who are conducting human subject research as part of their degree work must be knowledgeable of human subject research, including ethics, and must meet the mandatory training requirements. Classroom or course projects that are developed for the sole purpose of education for individual students and involves data gathering from human participants as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice must either seek IRB approval for their project or abrogate their rights to publish data as research data. If students choose to share

these observations with others in ways that do not fit the definition of research (contributing to generalizable knowledge), their actions should be governed by the ethical standards of their discipline. Data gathered may only be shared with the course instructor or faculty advisor, or in the case of an internship/practicum, the collaborating party.

Student investigators, who intend to gather data as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice **AND** intend to use the data as research data for the purpose of publishing or sharing with a research community or the public at large, must obtain IRB approval **PRIOR** to conducting the activity from the UML IRB.

8.3. IRB ADMINISTRATIVE PROCEDURES

The Office of Institutional Compliance (OIC):

- Understands and keeps informed on federal research regulations regarding human participants research,
- Provides advice and information to help researchers based on the regulations,
- Applies knowledge to help meet compliance requirements,
- Maintains records associated with IRB applications and reviews, and
- Disseminates materials to IRB members to facilitate timely responses related to IRB applications.
- Screens applications for completeness before sending application materials out for review, prepares and disseminates meeting agendas and minutes, and corresponds with PIs in regards to applications.

Record Keeping

OIC, typically the IRB Administrator, is responsible for preparing and maintaining adequate documentation of all IRB activities. Minutes are taken at each meeting by the IRB Administrator or other appointed person and must include all of the information stipulated by HHS regulations in 45 CFR 46.115(a) (2). Minutes are drafted and sent out to the IRB members electronically within 10 working days of the meeting. Records managed and maintained by the IRB Administrator include all records for protocol reviews, correspondence related to research applications, Federalwide assurance documents, and miscellaneous related reports.

Record Retention

All IRB records relating to research activities are retained for 3 years after completion of the research as per HHS 45 CFR 46.115(b) and FDA 21 CFR 56.115(b) or 5 years after completion for federally funded research. All records are accessible for review (whether hard copy or electronic) by authorized representatives of the FDA, OHRP, and the institution upon request. IRB protocol files contain:

- The approved research protocol, approval and concerns memos, approved consent documents, annual renewal forms, amendments, reports of injuries to participants, and if federally funded, an electronic copy of the proposal.

- Meeting minutes include attendance, actions taken, the basis for requiring changes

in or disapproving research protocols, and a written summary of discussion of each protocol and record of votes on the actions. If actions are not unanimous, the vote will include the numbers voting for, against, and abstaining and the reason for any opposing vote. For example, if not unanimous, votes would be recorded as: Total present=12, Vote: For-8, Opposed-2, Abstained-2;

- Records of continuing review submissions and approvals
- Copies of all correspondence between the IRB and the PIs
- List of IRB members
- Written procedures for the IRB, including an assurance to DHHS that the institution complies with the federal policy for the protection of human subjects, as described in 46 CFR 103 (b)(4) and 46 CFR 103 (b)(5)
- Documentation of informed consent and consent procedures which alter some or all of the required elements of informed consent or waivers of the requirement to obtain informed consent.
- Records related to determinations regarding risk and any alterations to the approval period (review interval)
- Other records, including but not limited to grant applications or dissertation proposals, will be stored electronically to be available for review

Review Notification for Full Review Applications

Upon receipt of an application for full review, the IRB Administrator will notify the PI as to the date, time, and location of the meeting at which the proposal will be reviewed so the PI may be present to answer any questions that may arise during the review process. The PI will be excused when the IRB deliberates on the action and votes on the application.

Communication of Review Results

After the IRB has reviewed the protocol, the IRB Administrator or appointed person will notify the PI of the status of the application and send a detailed concerns memo that itemizes information that needs to be revised or clarified. OIC will make every effort to send the concerns memo to the PI within three working days after the meeting or review.

Training Documentation

Training and education record certifications are kept on file with the OIC. CITI training records are automatically sent to the IRB. For persons taking NIH training, each person is responsible to submit the certification to the IRB.

Protocol Management Software

ProIRB is used to facilitate the quality, accuracy, and tracking of the IRB review processes and workflow. The software is used to generate agendas, minutes, letters, annual and continuing review reminders, and specialized reports. ProIRB records are updated with

meeting actions as soon as possible after each meeting is concluded.

Protocol Application Numbering System
All incoming new protocols are assigned a distinct protocol number. All documentation sent out includes the numerical identifier. After an IRB Protocol number is assigned, this number should be used on all related forms and correspondence.

8.4 ASSIGNMENT OF PROTOCOL NUMBERS

The IRB Administrator assigns a protocol number based on the calendar year, a consecutive number assigned for each application, the first three initials of the PI's last name, and the type of review. All future communication regarding applications should reference this IRB protocol number.

8.5. BOARD PROCEDURES

The primary concern of the IRB is the protection of the rights and welfare of human participants in research. The efforts of the IRB are directed at (1) identification of the risk, (2) evaluation of the risk, (3) evaluation of procedures to minimize risk, and (4) evaluation of the informed consent document which explains the risks to the participants. Only the IRB has the authority to approve research that involves human participants.

Full Board Meetings
Meeting schedules are set to accommodate, as best as possible, the availability of all the members. Schedules are set by semester to accommodate teaching faculty and to allow for the maximum number of board members to be available and present. The frequency of meetings is typically monthly and the duration is approximately two hours. Meetings are scheduled based on need and can be scheduled for special circumstances by contacting the IRB Administrator. In exceptional cases, meetings by telephone conference call are authorized if a meeting is necessary and an in-person meeting cannot be scheduled.

Conflict of Interest
A conflict of interest is considered to be a committee member who has any of the following:

- an affiliation with any organization, company, venture or other body that involves a direct financial interest or benefit, directly or through relatives by blood or marriage, in the subject matter or materials of a protocol or registration for review by the committee;
- direct involvement in the research subject matter under review by the committee;
- is related, by blood or marriage, or a business partner of a person who is a researcher undertaking a protocol or registration considered by the committee;
- is a research competitor or has a personal conflict with the project or the investigators, so could be perceived as having a potential bias.

Conflict of Interest Policy
Any conflict of interest must be disclosed at the beginning of a meeting or before review of

any IRB applications to the Committee Chair or to the Director of Institutional Compliance to ensure:

- the responsible conduct and integrity of decisions made by the Committee;
- to protect the Committee membership and the University from unnecessary and avoidable litigation and;
- to ensure the committee membership complies with agreements entered into with third-party funding organizations for whom the committee approves facilities, protocols, activities or research projects.

The meeting agenda includes an item titled **"**identification of conflicts of interests". At that point in the agenda, the Chair of the meeting asks the members present to disclose any conflict of interest.

- Committee members are obliged to disclose, as soon as it comes to their attention, any conflict of interest or potential conflict of interest.
- If a committee member is unaware of any conflict of interest or potential conflict of interest at the time they sit in a meeting in which they later discover they are in a conflict situation, they should let the Chair of the Committee or the Director of Institutional Compliance know immediately once the conflict comes to, or is brought to, their attention.
- If a committee member is in any doubt about whether or not they are in a potential conflict situation, they must state this to the committee members at the commencement of the meeting.

Faculty members residing in the same Department are allowed to review protocols and registrations coming from the same Department as long as the Committee member does not have a personal or financial interest in the research being proposed. If a conflict is identified, the member shall recuse him or herself from participating in the discussion and vote on the research with which there is a conflict of interest. The conflicted member shall leave the room for the discussion and vote on the research, except to provide information at the committee's request prior to the discussion and vote. Recusals shall be documented in the minutes of the meeting as not present for the discussion and vote. Recusals shall not count towards the quorum requirement for the review.

Confidentiality Statement

IRB members are required to keep all information related to research applications confidential. This means that information reviewed by the members, which may be sensitive in nature, should not be discussed outside of the review process or discussed in a place where the discussion might be overheard. Each board member signs a confidentiality statement to agree to keep all information confidential and the forms are kept on file with the OIC Director.

Board Actions

The IRB may vote to 'approve', 'require modifications for approval', 'table', or

'disapprove' a research protocol. These actions require a vote of the majority of the members present at a meeting with a quorum present. A quorum is a simple majority of the active full membership but must include one non-scientist, community member. The Chair does NOT vote, except to break a tie. If the vote is not unanimous, the minority opinion(s) are recorded in the minutes. An IRB member may abstain from voting for any reason, without explanation. PIs are informed in writing of all IRB decisions. Decisions may include:

> *Approve:* Action taken if there are no changes required and no more than one dissenting vote. Along with the notification of approval, PIs are informed that any subsequent changes in projects must be reviewed and approved by the IRB before they are initiated and that unexpected or adverse events must be reported.
>
> *Requires Modification to Secure Approval:* Action taken if revisions are required before approval may be granted. Necessary revisions are agreed upon at the meeting and communicated to the PI. When the revisions are made by the PI, either the IRB Chair or the designated representative is authorized to provide approval for the study to begin. This action will be documented in the IRB records.
>
> *Tabled:* Action taken if substantial modification is required or if insufficient information is provided to evaluate the application adequately. The PI is informed in writing of the reason(s) for the action. To receive approval for a tabled protocol, it must again be submitted for a full IRB review at a subsequent meeting.
>
> *Disapproved:* Action taken if a majority considers that the decision would not be changed by modifications to the protocol.

The IRB is authorized to modify, suspend, or terminate approval of research that has been associated with unexpected serious harm to participants, or is not being conducted in accordance with 45 CFR 46 or the decisions, conditions, and requirements set forth by the IRB. **PIs must respond in writing to IRB stipulations and recommendations on new protocols and continuing reviews within 90 days or the application will be terminated.** Notification will be sent one month in advance of termination.

Further Review of Tabled Protocols

If an application is tabled, the PI will be informed in writing of the IRB decision and concerns. The PI response will be provided to the IRB by the IRB Administrator with the revised protocol, if necessary, and the previously submitted protocol. The revised application, with all the noted concerns addressed, will be placed on the agenda for review at the next meeting after receipt and the outcome will be provided to the PI in writing if he or she cannot attend. The pre-review process should reduce the need for this action. Approval will not be granted until all deficiencies are corrected to the satisfaction of the IRB.

Appeal of an IRB Action

By Federal regulations, institutional officials may not approve research that has not been

approved by the IRB. A PI may request the IRB to appeal or reconsider a decision regarding a human subject research activity. A final decision regarding the appeal will be made by a vote of the IRB. PIs do not however have the option to seek the reversal of an IRB decision by submitting the same protocol to another NIH IRB or the IO.

Projects Using Animals or Biohazardous Agents

Any research projects that involve the use of animals or biologically hazardous materials, in addition to the use of human participants, are also required to be reviewed by the appropriate oversight committee. Animal research must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) and research using biohazardous agents must be reviewed and approved by the Institutional Biosafety Committee (IBC) before any research project may begin. Go to http://www.uml.edu/Research/OIC/ for more information.

Periodic Review and Update of Policies and Procedures

IRB policies and procedures will be reviewed annually to assure compliance with changes in regulatory requirements. The Director of Institutional Compliance may also update policies and procedures as necessary to meet new regulatory changes.

8.6 APPLICATION REVIEW INFORMATION FOR IRB MEMBERS

Exempt and expedited approvals are reported to the IRB at the monthly scheduled meetings and IRB actions recorded in the meeting minutes. Copies of the applications reviewed through the expedited process or those determined to meet exempt status will be made available for an optional review at the request of any member.

Applications for full review are distributed to the IRB members (electronically) at least one week before regularly scheduled meetings and reviewed only at meetings in which a quorum is present. All research involving human participants that is conducted by those acting as an agent of UML, regardless of where the research is to be conducted or the designated category must be submitted to the IRB for review regardless of funding.

Review Assignments

IRB members are assigned responsibility for expedited reviews on a rotating basis for one month at a time throughout the year. Some more complex research applications may require certain types of expertise for adequate review. In these situations, applications will be assigned specifically to those IRB members with the appropriate biomedical or socio/behavioral expertise as needed. Assignment of a review schedule also allows for faculty members to schedule times when they will be available for this service and to improve the turn-around time for expedited reviews. Two different members are assigned primary responsibility by month to conduct full reviews on a rotating basis in order to lead the review discussion at meetings. A project is considered research if the purpose is to develop or contribute to generalizable knowledge. Projects considered research require IRB review, whether funded or not.

Timelines for Initial Review

Timeline for reviews will vary depending on the type of application submitted and the completeness of each. Exempt applications, if all materials are provided, can typically be approved within a few days. Expedited applications typically take longer but if the application is well written, clear, and all supporting documentation is provided at the time of the initial submission, it can be approved within one to two weeks. **Full review applications should be submitted at least two weeks before the next scheduled meeting** to ensure all materials are ready to be sent to the committee. Typical turn around for full review from submission to final approval is usually four to six weeks. If you know you will be submitting an application for full review, contact irb@uml.edu to verify it can be added to the meeting agenda.

See IRB website for a calendar of meetings: http://www.uml.edu/Research/OIC/human-subjects/contacts.aspx

International Research Activities

For research activities outside of the United States, the IRB may seek an independent outside review in order to understand the research activity from the local context. In addition to the normal board review process followed, such assistance will be sought out from the UMass Lowell community of researchers who has experience working in the foreign country and understands the local context, but may need to seek help from outside the campus community. The reviewer will only be evaluating the research activity in regards to the risks/perceptions within the local context.

Full Board Reviews

A majority of the members must be present, including a community and non-scientist member. If any IRB members have a conflict of interest, they may provide information as requested by the IRB and then must recuse themselves from the voting related to that specific protocol. If primary and secondary reviewers have been assigned, they will lead the in-depth review and open discussion for comments from other IRB members. *These lead reviewers are also responsible to review grant application materials submitted to ensure that all research described in the grant application is consistent with the application submitted to the IRB.* Suggestions for necessary changes will be agreed upon by the IRB and documented in the meeting minutes and considered in the vote to decide on the IRB action.

Consent Alterations

When the IRB approves a consent procedure that does not require or which alters, some or all of the elements of informed consent outlined above, the IRB determines and documents that the specific findings are met as required by the regulations. If the request is reviewed at a full IRB meeting, the meeting minutes document the IRB's findings regarding the decision to grant a waiver. Similarly, if the study meets the criteria for review under expedited procedures, the reviewer documents the findings and decision to grant the waiver.

Review of Applications using Student Subject Pools

Use of online participant recruitment tools, such as SONA, also requires that information posted on the system be provided to the IRB in the application for approval. So that students can make an informed decision about whether to participate, all postings must include more than the title of the study. A brief description of the study purpose and method as well as an indicator of any potential risk must be added. Inclusion and exclusion criteria must also be outlined.

The amount of participant time estimated to complete a study should be consistent across protocols by department for the types of credit, incentive, or compensation offered by the Department. Credit is earned for the participant's effort not any specific research activity. If a one hour research credit is being awarded, the amount of effort should be one hour--or close to it. If 10 points of extra credit is being awarded for participation in research, the effort to obtain the extra credit should be consistent from one project to another. This requirement addresses the issue of coercion by over-payment or over-rewarding student participants in such pools. For example, participants may be unduly influenced to participate in Study A if it requires only 15 minutes when Study B requires 45 minutes to obtain the same credit.

Brief studies may be combined. When projects are brief, investigators may elect to "double up" on some research sessions to keep the effort for any session consistent by the Department. This may especially be the case in student driven research projects. For example, if it really only takes 15 minutes to complete a survey for Study X, 20 minutes to complete the judgments required for Study Y, and 15 minutes to complete the memory tasks for study Z, they can be combined into one three-part experience that awards credit equivalent to one hour. Faculty may be required to submit one application that may include details on 2-3 completely unrelated studies.

8.7 MANAGING CONFLICTS OF INTEREST

Conflict of interest, defined as a set of conditions in which judgment concerning a primary interest may be biased by a secondary interest, is inherent to the conduct of research. In any given situation, conflict of interest must be managed through a system of identification, disclosure, containment, reduction, and elimination. While the focus has traditionally been on financial conflicts, which are quantifiable, non-financial interests exist as well. Non-financial interests may clash with the -protection of research participants and should also be disclosed and managed when present.

Management of IRB conflicts of interest will include (1) excusing members from the final deliberation to prevent them from voting on studies in which they have declared a potential conflict of interest; (2) placement of the IRB within the institution in a position of independence to avoid undue influence and bias in reporting structures and policies; and (3) proactive education to increase awareness of existing policies and the potential for conflicts of interest.

Research Personnel

The IRB requires that PIs provide written information in the application regarding any potential conflict of interest relevant to research studies submitted for IRB review. To

ensure that conflict of interest does not compromise the rights and welfare of human participants of research, the IRB will determine: (1) if methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human participants; (2) if other actions are necessary to minimize risks to participants; and (3) the kind, amount, and level of detailed information to be provided to research participants regarding a conflict of interest and any management techniques applied.

IRB Members

No IRB member may participate in the initial review, continuing reviews or modification requests of any research study in which the member has a conflict of interest, except to provide information requested by the IRB. A member with a conflict of interest will be required to recuse him/herself from the room during final deliberation and voting for any research in which the member has a potential conflict of interest due to a role as PI, relationship to the PI, or a financial interest in regards to the research. Such members are excluded from the quorum count for the study being considered. The minutes will reflect by name all individuals not participating due to a conflict of interest and their absence from the room and re-entry. In cases where a reviewer has a conflict of interest, the individual is required to inform the IRB Administrator as soon as possible prior to the meeting and the study is reassigned to another reviewer.

IRB members are permitted to vote on studies submitted by members of their own department or division, because often they are the most knowledgeable about the topic being investigated, but only if the IRB member has no other potential conflicting interest, such as responsibility for the design and oversight of the study. Members who believe they have been involved in attempts by investigators or others to influence the review of a particular study will bring the matter to the attention of the IRB Chair. The member may be advised to recuse him/herself or abstain from the final deliberation and vote if a perceived conflict of interest exists.

Possible conflicts of interest for IRBs may originate at two levels and may include:

- *Individual Level*
    - Member is PI on study under review
    - Member or staff holds significant financial interest in research sponsor
    - Loyalty to colleagues submitting for review
    - Members too closely tied to area of research under review
    - Possible impact of decisions on member's own work (e.g. policy changes)
    - Personal agenda
    - Non-IRB roles

- *Institutional Level*
    - Pressure or desire to protect the institution
    - Concern for institution's reputation or prestige
    - Promotion of research vs. protection of human participants
    - Under evaluation of IRB service

- Potential liability
- Institutional or community values
- Pressure for rapid reviews
- Institutional equity or ownership

Institutional Officials

As academic institutions have increasingly entered into financial and collaborative research arrangements with private industry, institutional conflicts of interest have become a topic of growing concern and increasing public scrutiny. To avoid potential conflict of interest, institutional officials shall not serve as an IRB board member unless a compelling situation exists.

8.8 FORMS AND THEIR PURPOSE

Annual Renewal / Continuing Review

Annual Renewal / Continuing Review forms must be submitted by the anniversary of the approval date for projects that exceed one year in duration.

- A reminder is sent to the PI between 60 and 30 days prior to the anniversary date to renew or close out the protocol.
- If Informed Consent Forms are still being utilized, they also need to be updated.
- If the PI does not contact the IRB by the expiration date and after several reminders have been sent, the Department Chair and Dean of the College will be notified.
- Continuing review of expedited protocols also receive expedited review (unless modifications are made to the protocol that would alter the review status).

Once a project is approved as "exempt" there is no requirement for submission of annual/continuing review forms.

The purpose of an annual renewal is to update the IRB about the research activities that have occurred over the past year. The information should summarize:

- Personnel changes,
- Information about the numbers of participants,
- Unanticipated problems,
- Withdrawal of participants,
- Complaints about the research,
- Recent literature that may be relevant to the research,
- Updated informed consent documents and any new proposed consent documents.

If research is no more than minimal risk, the expedited review process may be used to approve the annual renewal. The IRB Administrator also reviews the complete protocol, including any amendments or modifications previously approved by the IRB. The IRB meeting minutes include information about reviewers, concerns, and actions for each protocol that has had an annual renewal. (Changes to procedures or methodologies of an approved protocol must be submitted through the amendment process. The continuing

review date is not changed due to any amendments.)

Expedited review procedures may also be used for annual renewal of previously approved full review projects if:

1. No more new participants are being enrolled, all research-related interventions are complete, and the research remains active only for long-term follow-up of participants or
2. Where no participants have been enrolled and no additional risks have been identified, or
3. Where the remaining research activities are limited to data analysis.

Research activities that are complete but for which the PI wishes to retain identifiable information must also file for an annual renewal before the anniversary date of the approval. The PI should include justification to retain such data and a plan for its use so that identifiable information is kept for only a limited time. Data with identifiers removed may be maintained indefinitely with no more requirements for continuing review and approval, as there is no risk of linking it to the participants that originally participated.

UMass Lowell follows the federal guidelines that require annual/continuing reviews be conducted at least annually for open protocols (with the exception of those that meet Exempt Status Determination).

- The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of the IRB approval.

- If a PI fails to provide annual renewal information to the IRB, the research must stop, unless the IRB determines that it is in the best interests of individual participants to continue participating in the research interventions or interactions.

- No new participants may be enrolled under any circumstances after the approval has expired.

- When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires and the protocol will be administratively closed.

- This type of expiration does not need to be reported to OHRP as a suspension of IRB approval under HHS regulations.

- Researchers who fail to submit the annual/continuing review or final report forms by the expiration date will be notified that the protocol is suspended and no new IRB applications will be accepted for review until all protocols are either brought up-to-date or closed.

- If the lapse exceeds 30 days past the expiration date, a new IRB application may be required to resume the research activities that involve human participants.

The IRB will take into consideration any extenuating circumstances that may have prevented timely submission for the continuing review date. Contact irb@uml.edu to inform us of any problems or concerns.

Application for Exempt Status Approval
This form is used for research that meets one of the six exempt categories, is considered to be of minimal risk, and collects only anonymous information. No further IRB oversight is required for these projects. The IRB designee must make the determination that the status is Exempt and a record of that approval is communicated to the PI.

Approval Renewal
This form should be completed and submitted to the IRB when projects that have already received IRB approval are being submitted to a different funding agency. The project must be essentially identical to the previously approved project with respect to the use of human participants and this form may be submitted with the PI's signature and dated.

Amendment
Projects that require modifications to the approved research project must submit an amendment form to the IRB that explains the reason(s) for the change and attach all related documentation that changes as a result.

- The amendment must be approved by the IRB approval prior to implementation of the change.
- Amendments that are minor and no more than minimal risk can be approved by the IRB Administrator or designee through an expedited process.

Protocols reviewed and approved under either expedited or full review require amendments to be filed for review. Amendments are typically reviewed by the IRB staff for minor modifications but significant changes via amendments are reviewed by either the designated expedited reviewers or the full IRB. Consult the IRB Administrator if you have any questions regarding an amendment.

For changes to projects approved under the Exempt determination, amendments are not required unless the change affects the determination of exempt status. If this happens, the PI should file a new application for expedited or full review. Consult with the IRB Administrator when proposing changes to an Exempt Status approved research project when you are unsure if the amendment may change the status of the research to require expedited or full review.

Examples of revisions that are commonly reviewed through the amendment process include to changes in research staff, instruments (such as survey tools) used, methodology, recruitment site, subject eligibility, or subject characteristics.

Certification of Translation and Back Translation
If a project involves research with populations where English is not their first language, the consent documents and other relevant documents must be translated into that language. A form to identify who conducted the translation and back translation must be submitted to the IRB with the translated and back-translated documents. The form must be completed by two different translators. Two different translators must complete the two different translations. It is recommended that the translated and back-translated forms be submitted as an amendment to the research project after the consent and other project-related documents are approved in final form by the IRB to minimize changes to the translated documents and conserve resources.

Collaborating Institution Authorization Agreement
This form is used by faculty who wish to collaborate with another institution and rely on one institution's IRB for project review and oversight. The agreement assigns one IRB with the oversight authority and often the institution receiving funding (if applicable) will be the IRB of record. The designated institution must also have an IRB with a Federalwide assurance. Signatory officials from each institution must sign the form and it is kept on file with both IRBs. Please contact the Director of Institutional Compliance for more information about collaborative agreements. Annual Reviews and Final Reports must be filed with both IRBs.

Confidentiality Agreement Form (for IRB Members)
This form is signed by all board members to ensure meeting discussions and information reviewed in protocol applications remains confidential.

Confidentiality Agreement For Transcription Services
This form is used by Transcription Services to ensure they agree to maintain full confidentiality in regards to any and all audiotapes and documentation received from the researcher related to the study for which their services are retained. The form outlines how the participants confidentiality and privacy are protected and final disposition of the original materials used for transcription.

Final Report
A final report is required to close out a project upon completion or by the expiration date of the IRB approval. Information included in the final report includes the date of approval, date of last continuing review approval, research completion date, number of participants that have participated in the research project, how the project was conducted, any questions or complaints that arose during the research, statement regarding the status of informed consent forms, and the date when project materials will be destroyed. If the final report is not filed, the IRB Administrator may close the protocol. Research that involves human participants or their identifiable data under the protocol is not authorized to continue. Files are retained for three years past the closing date or longer as required by the funding agency and then destroyed.

IRB Member Review Forms
IRB member review forms for expedited review, amendments, and annual renewals are available from the website. IRB members must specifically designate approval for alterations to consent for research activities that request any type of waiver to the consent process and the forms are designed to easily allow for this type of approval.

Individual Agreement Authorization
This form is for use by individuals who are collaborating on a UML research project but have no affiliation with another IRB. The individual must meet all of the training and other requirements for researchers conducting human subject research at UML. The form is signed by the appropriate signatory official at UML and the individual.

Self-Report of Noncompliance by PI
This form is used to report an incident of noncompliance with a protocol or with UML IRB Policies and Procedures. This form is used to notify the IRB of some type of variation from the approved protocol not of an adverse or unanticipated event. An amendment form should also be submitted to request a formal review and approval for the modification after it is reported on the noncompliance form.

Administrative Oversight Report
These forms are used to report either information that should have been reviewed and approved by the IRB but the PI followed all appropriate procedures but did not notify the IRB through the amendment process. This form is for minor oversight reporting such as adding new staff to a project.

Video/Photo Publication Release
This form is used for any video or photographic images that are collected during the approved research project and indicate the participant has agreed to the use of the image for publication. This release must be obtained for anyone who is visibly recognized in the photograph or video. The PI must obtain this information with the other research-related consent information.

9.0 COMPLIANCE REPORTING AND INVESTIGATIONS

Research conducted at UML is expected to follow UML Policies and Procedures and adhere to federal regulations regarding the protection of human participants, regardless of who is conducting the research. A Compliance Hotline has been established at 978-934-3100 for anonymous reporting of any suspected noncompliance. Anonymous reports of noncompliance may also be submitted through the U.S. Mail or intercampus mail. The OIC Director is also available to discuss any concerns and will keep the informant's information confidential. Concerns will be investigated following the procedures outlined below.

Failure to comply with federal regulations or UML Policies and Procedures may result in the following disciplinary actions or sanctions:

- Suspension or termination of IRB approval of specific research protocols or of all research involving human participants in which the investigator participates
- Institutional or individual action by the FDA or OHRP, which may include withholding approval of all new UML studies by the IRB, not allowing any new participants to be added to ongoing studies, termination of all ongoing studies (unless doing so would endanger any participants), and /or notifying relevant state, federal and other interested parties of the violations
- Individual disciplinary action for failing to secure IRB approval before commencing human participant research will be reported to the Director of Institutional Compliance and IO for disciplinary action
- Suspension or termination of project support by DHHS
- Loss of indemnification from liability by the institution for adverse events if a PI fails to follow approved procedures

NOTE: A copy of **ALL letters of warning** must be sent to the Director of Institutional Compliance within two working days after receipt. A copy of **ALL responses to audits and/or letters of warning** must also be sent to the Director of Institutional Compliance and reviewed by the IO **prior to being sent** to the regulatory agencies.

9.1 DEFINITION OF NONCOMPLIANCE

Noncompliance is defined as research that is not conducted in accordance with institutional policy or federal regulatory requirements for human participant protection. Protocol deviations and variances from the protocol do not fall within these definitions until they meet the description for being serious and/or continuing. Noncompliance may be designated as:

- Non-serious and non-continuing for incidents that are isolated and a result of an unintentional mistake, oversight, or misunderstanding, or
- Serious and/or continuing for practices that appear to cause injury (physical, psychological, emotional, etc.) or any other unanticipated problems involving risks

to participants and/or others or constitute serious to continuing noncompliance with IRB determinations or federal regulations.

9.2 ADDRESSING ALLEGATIONS OF NONCOMPLIANCE

The IRB may be notified of noncompliance in several ways including new applications, continuing reviews, internal audits, FDA audit reports, adverse event/safety reports, or reports from collaborators, employees, participants, family members, community members, or any other source. Each complaint or concern is taken seriously and reviewed in a consistent, prompt, and professional manner. Efforts will be taken to maintain confidentiality and communicate information in a factual and objective manner.

9.3 PRELIMINARY DETERMINATION OF SUSPENSION OR NON-SUSPENSION

The IRB Administrator and the Chair determine if immediate suspension of study procedures and/or study enrolment is required for the project in question, as well as for other projects under the same investigator. The initial decision is based on preliminary review of available information, communication with the PI(s) involved in alleged noncompliance activities, and the seriousness of the allegations. The PI(s) in the allegations and all associated research staff, Department Head, and IO are notified in writing about any suspension. Federal funding agencies are notified, if applicable. Further fact-finding and timely review by a convened IRB determines the length of any suspension.

9.4 INVESTIGATIONS AND ACTIONS

The Director of Institutional Compliance conducts an investigation within 5 working days of the recognized concern. The purpose is fact-finding and may involve examination of study records, discussion with the research team, other personnel, research participants, witnesses, the complainant (if not anonymous), and others as appropriate. The information is compiled in collaboration with the IRB Chair and a determination is made as to whether the noncompliance is either non-serious and non-continuing or serious or continuing and warrants investigation by the IRB.

Non-serious and Non-continuing

If the noncompliance activity is determined to be non-serious and non-continuing, the issue may be resolved between any combination of the Director of Institutional Compliance, IRB Administrator, IRB Chair, PI, and respective Department Dean and Chair or other appropriate authority supervising the PI. The IRB Administrator will document the outcome of all communication in writing, which will include any sanctions or corrective actions required on the part of the PI and the timeline for resolution. The final report is sent to the PI, research staff, and others as appropriate. The PI must acknowledge receipt of the report in writing within 5 working days of the date the report is issued. The complainant will be provided information by the IRB Administrator as appropriate. Investigation communication records will be kept on file by the Director of Institutional Compliance under restricted conditions to keep the report confidential. The IRB will be kept apprised of non-serious and non-continuing noncompliance actions as they arise.

Serious and/or Continuing Noncompliance
The Director of Institutional Compliance and the IRB Chair address the possible need for suspension of study procedures and/or study enrollment for the project in question, as well as for other projects under the same PI, pending review by a convened IRB. The PI(s) involved in alleged noncompliance activities is/are notified and provide with an opportunity to discuss the allegations. If research activity suspension is warranted, the PI(s), associated research staff, Department Chair, and IO are notified in writing about any suspension and federal regulatory agencies are notified if applicable. In cases of externally funded programs, the sponsor and the UML's Grant and Contracts Administrator are also notified. A written report summarizing the findings of the investigation is sent to the PI(s) involved and the associated research staff. The PI(s) involved in noncompliance activities is/are required to respond to the findings within 5 working days from the date the report is issued, unless an extension is requested in writing and granted by the Director of Institutional Compliance. The PI and the complainant (if not anonymous) will be invited to attend the next convened IRB meeting to address the allegations. If urgent, an emergency IRB meeting may be convened to discuss the issue.

The IRB reviews the outcome of all documented communication and discussions concerning the noncompliance and determines if further information is required. A vote is taken at a convened meeting as to whether noncompliance occurred. If noncompliance is determined, the IRB also votes on the appropriate course of action, which may include:

- Suspension or termination of IRB approved protocols that are found to be noncompliant with UML Policies and Procedures, state laws, and/or federal laws or regulations
- Other sanctions including but not limited to compliance audits, letters of reprimand, additional training, and restrictions on serving as a PI on protocols that enroll human participants

All communication is documented and retained in a secure site by the Director of Institutional Compliance. In addition, the IRB Administrator, on behalf of the IRB, sends written notification of the IRB's determination and required actions to the PI involved in the allegations, the associated research staff, Department Head, and Institutional Official. In cases of externally funded programs, notice is sent to the sponsor and to the Grants and Contracts Administration when any action includes suspension or termination. Federal regulatory agencies are notified if applicable and others as deemed necessary by the IRB.

9.5 APPEAL OF IRB ACTIONS

The IRB action on a noncompliance event is final and not subject to appeal.

9.6 RESEARCH MISCONDUCT

In cases that involve allegations of research misconduct, the IO is notified immediately. This does not preclude the IRB Chair or any member of the IRB from independently contacting the IO about any allegation of research misconduct. Inquiries or investigations into research misconduct do not preclude IRB reviews and actions.

10.0 ADDITIONAL RESOURCES

10.1 GENERAL IRB INFORMATION

Institutional Review Board: Management and Function, 2nd Edition. Edited by Elizabeth A. Bankert and Robert J. Amdur. 2006. Jones and Bartlett Publishers, Sudbury, MA.

U.S. Department of Health and Human Services, Office for Human Research Protections, http://www.hhs.gov/ohrp/

University of Massachusetts Lowell, Office of Institutional Compliance websitehttp://www.uml.edu/Research/OIC/default.aspx

10.2 ETHICAL CODES

Nuremberg Code http://www.hhs.gov/ohrp/archive/nurcode.html

Belmont Report, Ethical Principles & Guidelines for the Protection of Human Subjects of Research
http://www.hhs.gov/ohrp/policy/belmont.html

World Medical Association Declaration of Helsinki
http://www.wma.net/en/30publications/10policies/b3/

10.3 INFORMED CONSENT

Seattle Children's Hospital. Multiple resources including:

- Glossary of alternative words for terms used in medical and research settings
- Language Resource Text provides language below the 8th grade reading level for commonly used concepts and terms found in IRB forms.

http://www.seattlechildrens.org/research/forms-policies/irb/assent-consent-forms/

Stanford University. Definitions and Lay Glossary of Medical Terms
http://humansubjects.stanford.edu/new/resources/definitions_glossary/index.html

University of Michigan. Simplification Guide to Medical Terms
http://med.umich.edu/irbmed/guidance/simplificationterms-B-C.html#C

10.4 ORAL HISTORY

Oral History Association. Human Subjects and IRB Review
http://www.oralhistory.org/resources/do-oral-history/oral-history-and-irb-review/

Columbia University. IRB Review of Oral History Projects
http://www.columbia.edu/cu/irb/policies/documents/OralHistoryPolicy.FINAL.012308.pdf

10.5 ORGANIZATIONS

Public Responsibility in Medicine and Research (PRIM&R) is committed to the consistent application of ethical precepts in both medicine and research. https://www.primr.org/

10.6 U.S. GOVERNMENT (FEDERAL) REGULATIONS

Protection of Human Subjects, 45 Code of Federal Regulations 46
http://www.gpo.gov/fdsys/pkg/CFR-2009-title45-vol1/content-detail.html

Food and Drug Administration (FDA)

21Code of Federal Regulations Part 50
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

- Part 50 Human Subjects
- Part 56 Institutional Review Boards
- Part 600 Biological Products
- Part 312 Investigational New Drug Applications
- Part 812 Investigational Device Exemptions

Health Insurance Portability and Accountability Act (HIPAA)
http://www.hhs.gov/ocr/privacy/index.html

10.7 U.S. GOVERNMENT AND STATE GUIDANCE

Office of Human Research Protection (OHRP): Dear Colleague Letters
http://www.hhs.gov/ohrp/archive/policy/archive.html

FDA Information Sheets (1998 edition), Guidance for Institutional Review Boards and Clinical Investigators
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm

Office of Research Integrity http://ori.dhhs.gov/

International Compilation of Human Subject Research Protections
http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html

Risk Assessment Information (NSF FAQs) http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp

Massachusetts Laws About..... http://www.lawlib.state.ma.us/subject/about/index.html