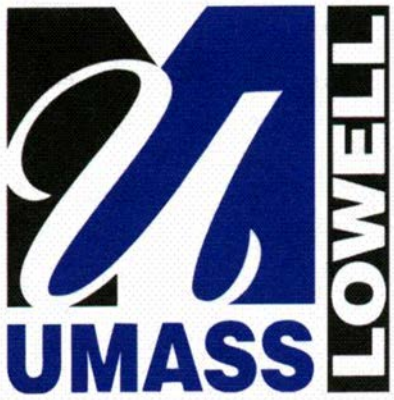

INVESTIGATOR GUIDELINES

For the

INSTITUTIONAL REVIEW BOARD

February 2013

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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.

INVESTIGATOR GUIDELINES

These guidelines are one section of the complete UMass Lowell IRB Policies and Procedures. (The Policies and Procedures include additional information about institutional policy, regulatory requirements, when to use the various types of forms, IRB administrative procedures, and compliance reporting processes.) The Guidelines are intended to provide investigators (faculty, staff, and students) with the details relevant for preparation and submission of IRB applications. The Guidelines should be used to communicate information to improve understanding of what is required by the IRB for human subject research applications, improve the quality of application submitted, and reduce the turn-around time for approval of applications submitted for IRB review. For additional information and forms, go to http://www.uml.edu/Research/OIC/default.aspx. Send all questions and application information to IRB@uml.edu. (Definitions of terms and websites for additional resources are at the end of this document.)

A. 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.

B. 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.
(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.

Program Evaluation

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.

Research Using UML Directory and Non-Directory Information

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 Enrollment, 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 subject 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.

Research Using a Student "Subject Pool"

The Psychology Department currently requires students in the General Psychology course to obtain four credits of research experience, which may be obtained by participating in IRB-approved studies conducted in the department under the supervision of faculty. This section applies to the Psychology "Subject Pool" as well as any such arrangements as may be made by other departments. Note: 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.

Because research participation cannot be coercive, an alternate method of fulfilling that academic requirement must also be made available to students. In addition, 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," i.e., for failing to attend a research session without cancelling his or her appointment in advance. This includes giving the student a failing grade for the no-show or increasing the number of research participation credits to be required of the student.

It does 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 for the requirement, 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 the alternative research experience once those four opportunities have been used. These procedures should be clearly outlined and provided to students in writing.

Use of online participant recruitment tools, such as SONA, requires that information posted on the system be provided to the IRB in the application for approval. In order 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 a full review IRB application must be submitted and approved before they may be included in any study*. Age guidelines should be clear on any recruitment tools, including SONA listings.

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.

Research, but 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.)

C. APPLICATION CATEGORIES 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.

Researchers who clearly explain all procedures in the protocol applications will increase the likelihood of quicker approval. In many cases, applications are submitted that are vague in key areas that reviewers need to evaluate in order to 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.

1. 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.

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.

2. Expedited 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 x6012, 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.

3. 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.

Pre-Review Process for Full Review Applications

The IRB Administrator screens full review applications to evaluate whether more details are required before scheduling the protocol for full review. The IRB Administrator will work with the PI to improve the application before it is sent out and scheduled for a full review meeting.

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 submitted for the next full board meeting as soon as revisions addressing the pre-review concerns are completed.

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.

Notification and Appeal of IRB Decisions (all review types)
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. The Chair will review the appeal and his/her determination is final. The IO may not overturn any IRB decision.

D. MISCELLANEOUS INFORMATION FOR IRB APPLICATIONS

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.

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

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.

Use of UML Faculty and Students for Research 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.

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.

Are they Anonymous, Confidential, or De-identified Data?
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.

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.

Recruiting Participants from "Subject Pools"

Regulations do not allow an institution to levy any punitive damages to students from non-participation in research activities that recruit participants from standing "Subject Pools," which are commonly used in Psychology to provide students in General Psychology with The incentive for these students is generally credit for a required component of their course. However, because regulations state that

research must be voluntary, there must also be alternative methods available to fulfilling that course requirement. Because research is also prohibited from being punitive, penalties cannot be imposed on students who fail to show up for appointments. (See also, p. 23-24). Note: 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.

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.

E. 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.

- **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. 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.

F. INFORMED CONSENT PROCESSES AND TYPES

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.

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

Signed Consent Documents and Retention

After IRB approval, the IRB Administrator signs and dates the approved consent form and returns it to the PI. The PI should then sign the approved form 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 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.

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."

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

Confidentiality/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.

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.

"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.

Adverse Event and Unanticipated Incident 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)).

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.

ADDITIONAL RESOURCES

Ethical Codes
Nuremberg Code
http://ori.dhhs.gov/education/products/RCRintro/c03/b1c3.html

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

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979.
http://www.hhs.gov/ohrp/archive/documents/19790525.pdf

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

Informed Consent
Boston Children's Hospital. Variety of resources for children and parents across languages
http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/mainpageS2206P14.html

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

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

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/

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

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

Office of Human Research Protection (OHRP): Guidance Topics by Subject
http://www.hhs.gov/ohrp/policy/

OHRP Compliance Activities: Common Findings and Guidance
http://www.hhs.gov/ohrp/references/findings.pdf

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

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

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

Revised Expedited Review Criteria (1998)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110

Food and Drug Administration (FDA) http://www.fda.gov/

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

Institutional Review Boards, 21 Code of Federal Regulations Part 56
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=56

Biologic Products: General, 21 Code of Federal Regulations Part 600
http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&tpl=/ecfrbrowse/Title21/21cfr600_main_02.tpl

Investigational New Drug Application, 21 Code of Federal Regulations Part 312
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=312

Investigational Device Exemptions, 21 Code of Federal Regulations Part 812
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?cfrpart=812

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