



**The University of Southern Maine
Institutional Review Board's**

Student Handbook on Human Subject Research

August, 2006

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Introduction

The University of Southern Maine (USM) supports a wide range of research activities by its students, staff, and faculty. All USM students are encouraged to engage in research while they are enrolled at USM. In order to ensure that all research activities conducted by USM students meet both national and University standards for ethical and legal practices, all student activities that may include research-like procedures must be reviewed by USM's Office of Research Compliance (ORC). USM's ORC is the only USM entity approved by the United States Department of Health and Human Services' [Office of Human Research Protection](#) (OHRP) to review research proposals. The ORC provides administrative oversight for several Boards that review different types of research, including the Institutional Review Board (IRB), the Institutional Animal Use and Care Committee (IACUC), the Institutional Biosafety Committee (IBC), and the Radiation Safety Committee (RSC).

USM Student Research Involving Human Subjects

In order to help students engage in high quality research activities, all student initiated human subject research must be sponsored by a USM faculty mentor. The faculty mentor is expected to take an active role in the research activities and provide a signature approving the research plans and appropriate ORC forms. All communication about student research is conducted simultaneously through the faculty mentor and the student, who are responsible for sharing the review information with each other. This handbook is designed to help all USM students understand the necessary steps for them to engage in high quality research while attending USM. This handbook covers student human subject research activities not already reviewed by the ORC as student classroom projects. Faculty who plan student classroom projects for research activities should contact the ORC for the correct policy and procedures. The handbook is organized into nine sections:

- Introduction;
- Frequently asked questions (FAQ) about student research;
- Ten steps for student research activities;
- Ongoing review of research;
- Summary;
- ORC staff;
- Additional resources;
- Glossary, and;
- Attachments

Frequently Asked Questions about Student Human Subject Research

What does it mean to conduct human subject research at USM?

Research with human subjects is defined by federal law as any kind of activity that involves "a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge."¹ Though "generalizable knowledge" is the most commonly used criterion, many forms of scholarly work are recognized and regulated as "research". Examples include case studies, ethnographies, oral histories, and other qualitative data collection. Students can get research experience through data collection exercises, independent study, and collaboration with faculty mentors. No matter how research is defined, students at USM have opportunities to get experience conducting research and thereby enter a level of inquiry and learning that goes deeper than classroom participation and textbook reading. Being engaged in such research involves higher than average maturity and commitment and can fundamentally shape a student's life-long interests. Research allows the student to directly participate in the discovery of new information within the arts or sciences, leading to a deeper appreciation of how knowledge is acquired and utilized.

Who is allowed to conduct human subject research at USM?

All undergraduate and graduate students at USM are encouraged to participate in research. However, participation in research is determined by the prospective faculty mentor and is generally influenced by a combination of timing, student maturity, and demonstrated capability. There are three major types of research in which students may participate:

- ***Student Classroom Projects***
 - Student classroom projects are designed and supervised directly by the faculty mentor teaching a class. The criteria for IRB review of student classroom projects are not covered in this handbook because they are the instructor's responsibility. Faculty can obtain information about the IRB review of student classroom projects directly from the ORC.
- ***Existing faculty research programs***
 - Though research programs vary dramatically by college, department, and faculty mentors, a common theme that links all student research involvement can be summarized in the following ways:

¹ See The Common Rule, 45 Part C.F.R. §46.102 (2005)

- Students are expected to demonstrate above average maturity and the ability to handle responsibility.
- Students are usually in good to excellent academic standing, primarily because research work can be extensive and require a significant time commitment. Students are generally advised to establish a strong academic record before becoming involved in research.
- **Student-initiated research**
 - Students often have shown a flair or special interest for a particular area of research through coursework, independent study, or service learning. Students may decide to further their interest through engagement in additional research efforts (e.g., capstone projects, clinical projects, theses, dissertations).

Other more specific requirements for student researchers may be sought by individual departments or faculty mentors. For some human subject research (e.g., direct involvement with children; state/federal contexts) there may be other legal requirements or restrictions.

Why get involved in human subject research at USM?

Research participation can be one of the most gratifying university experiences. Often students discover areas of interest that shape their future post-graduation plans (e.g. graduate school) and careers. Successfully completing a research project of any kind is the culmination of great effort, focus, and creativity. Most students report great pride in their projects or contributions to a research program. However, there are also some very practical, concrete benefits to research participation:

- **Getting into a graduate program:** Admission to good graduate and post-graduate programs is becoming more competitive every year, especially in research oriented programs (e.g., Ph.D, Ed.D.). As an example, if two psychology majors with equal board exams and GPAs are going for the same slot, the one with some research experience (especially with presentations and/or publications) will likely win out.
- **Getting a job:** USM has an excellent record for undergraduate and graduate students with research backgrounds acquiring positions directly related to their research experience. These opportunities come in the form of internships, excellent volunteer opportunities, and career-track positions. Why? Primarily because research (though often academic and intellectual) often involves very

marketable organizational skills, database management, and communication skills (i.e., oral, written, and technological).

- **Career development:** Research at USM can provide experience (as described above) that often helps students, already in part-time or full-time work, clarify strengths and goals for the future, and can directly impact pay and promotion.

What forms of human subject research are available?

The range of research at USM is extremely broad, and is characterized by the diversity of individual faculty. For example, psychological research will tend to be quantitative and statistically based, focusing on behavioral measures, ranging from human development to social processes. Whereas sociological research might have a macro-social approach and involve demographics, social policy, and government or a micro-social approach and involve observations of interactions or interviews with individuals or focus groups. Research goals should be driven by each student's individual interests and aptitudes, especially as they pertain to future graduate school or career plans. Often research assistant positions will be advertised within departments and on USM-wide lists. (See getting paid below).

How do I get involved in human subject research at USM?

Students engaged in research at USM are not part of an exclusive, secretive club! For many, student research may even be part of required course work. However, participation in independent study or faculty research programs usually happens in two ways:

- **Joining an existing research program:** This type of involvement can occur either by invitation of a faculty member, or by a student approaching a faculty member to explore the possibility of working as a research assistant. In the former case, it would usually occur when a faculty member individually recruits students with high academic standing from a class. Typically, when a student joins an existing research project, the ORC or IRB approval will have already been obtained, thus the student may not be directly involved in the initial review. However, if the faculty member's research extends beyond the initial approval period or undergoes a change in design the student may be involved in preparing the necessary IRB application packet for continuing review or for revision/amendment.

- ***Student-initiated research:*** This process is fully described in steps 1 through 10 of the next section of this handbook (see page 11). This may be a project that a student wishes to pursue for his or her own interest, but may also be for academic credit within the Independent Study program (e.g., PSY400 – Independent Study) or Honors Program. It is a good idea to set up a meeting with a faculty mentor under whose supervision you would like to work. Informal "brain-storming" sessions are great for generating research ideas and getting a good sense of appropriate scope and duration of a research project. Once a research proposal is fully articulated and approved (first by the faculty mentor, then eventually by the USM IRB), it can commence.

Can I get paid for research activity?

Often, yes. Some faculty members have grants that fund research projects and allow students to be paid for lab work, data collection/input, and occasionally for higher responsibility roles such as research design and even manuscript co-authoring. Some research positions are funded with work-study; however, one must not assume paid research positions at the undergraduate level.

What should I expect from the student-faculty relationship?

This is one of the most important considerations in student research, but also the most ambiguous. When students are participating in research as part of a course requirement, then the role of the faculty member is to very clearly define the activity and assessment criteria, and take responsibility for protection of human subjects. Usually in these cases, a joint or group IRB proposal is drafted for the purpose of class data collection. Students become more proficient with research design and more familiar with the literature in their area of interest, as they reach their junior and senior years, and certainly within the first year of a graduate program. As a result, the relationship with the faculty mentor tends to naturally become more collaborative, with more responsibilities shared with the student. As with other aspects of research, departments differ greatly on the extent to which students become more closely affiliated with the work of faculty. At USM, student-faculty relationships range from students working in a lab or research setting as an assistant with clerical or administrative duties, all the way to co-principal investigator, with responsibilities for research design and manuscript preparation. No matter what level of involvement a student has with a faculty mentor, a few key commonalities apply:

- **Independence:** Students should expect to work gradually toward independent research (either for academic credit or to take on part of a faculty mentor's research program) in a way that is consistent with their maturity level and proficiency.
- **Expectations:** Students should expect a clear division between coursework they may currently have with a faculty mentor, and the actual research responsibilities. It would be inappropriate for a faculty mentor to allow performance in one context to bias his/her evaluation of the student in another. Similarly, a faculty mentor should be sensitive to the academic needs of a student and not overload him or her with work in the research setting.
- **Boundaries:** Another issue that pertains to the research setting as much as to any other student-faculty interaction is the setting of boundaries. Students must feel secure that they will not be asked to take on responsibilities that are inappropriate, or are out of the scope of their research role (e.g., a student should not be expected to run personal errands for a researcher).
- **Recognition:** Students often contribute enough to the research program that they expect to be included as a co-author on publications or conference presentations. This can be a tricky, potentially problematic issue. The key to avoiding disappointment or resentment is to always establish, *in advance*, a transparent, predictable set of criteria for being included on published work. Below are direct questions that any research student should feel comfortable asking a faculty mentor:
 - "If I design and implement a study, collect the data and write up the results, can I be first author? And if so, do you expect to be added as a second author?"
 - "If I have worked in your lab managing databases, running subjects, etc. will I be added as a junior author (i.e., second author)?"
 - "What level of involvement in the current research will allow me to be considered as an author for future publications/presentations?"
- **Equity and fair practice:** As with any other university setting, students should always feel secure that they will receive fair pay or recognition for work, commensurate with their effort and level of ability. There should never be any bias on grounds of sex, sexual orientation, race, or ethnicity. Students should expect to be treated with respect, without fear of sexual harassment or inappropriate pressure within the student-faculty relationship. If questions arise

on these issues, the student should address concerns with the faculty mentor. If he or she does not respond, or if the problem becomes worse, then the student should immediately seek help from a department chair or other University official.

How is research defined?

Although USM welcomes many different forms of inquiry by students, other organizations have developed specific definitions of research and related terms. Under federal regulations that govern research compliance, definitions of research and related terms have been developed to help researchers know when their activities need to be reviewed. Specifically, the terms *research*, *research subject to regulation*, *human subject*, and *intervention* are defined in federal statutes². These definitions are as follows:

- ***Research:*** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- ***Research subject to regulation:*** Similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (e.g., Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (e.g., Wage and Hour requirements administered by the Department of Labor).
- ***Human subject:*** A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- ***Intervention:*** This process includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place,

² See 45 C.F.R. § 46.102

and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

USM does not restrict students from engaging in research, however the intent is to support high-quality and ethically sound student research. USM undergraduate and graduate students must be aware that all proposed research activities, including student classroom projects, that include animals or humans as subjects, biologically sensitive materials, or radiation must be reviewed by USM's ORC. In the case of research that includes human subjects, all student research plans need to follow a ten step process for IRB review. **Importantly, these steps must be followed prior to the start of any research activities by students that include human subjects.** The steps are outlined in the next section of the handbook.

Steps Required for Conducting Research with Humans

In order for students to develop strong research skills that will be useful in their future work endeavors, training and support by faculty are essential. For this reason, all USM student research **MUST** be supervised by a USM faculty mentor. Together, the student and faculty mentor co-develop and work through the steps required for successful completion of the research. When the study includes human subjects, the research proposal must be reviewed by the IRB. To help students and faculty prepare materials for IRB review, a 10-step process for research proposal development and review has been developed. The steps in the IRB review process for student-based human subject research are depicted in flow chart in Figure 1 (see Attachment C).

Training for protection of human subjects

Personnel who participate in collecting or handling data from human subjects in the study must complete approved training. The National Institutes of Health (NIH) has an online training program that students and faculty must complete to become aware of the historical, social, and legal components of human subjects protection. This training can be accessed via the [NIH website](#), as well as from the link on the [USM IRB website](#) at <http://www.usm.maine.edu/orc/irb/>. Once the training is completed, a certificate verifying the training should be saved and printed. This certificate must be sent to the USM ORC with the submission forms.

Ten Step Process

1. Idea

The first step in student research is an idea. Students of all levels can generate ideas that may lead to research activities. The idea and planning stage of the research process should be guided by prior research in the student's field of study. In order to move forward, student research ideas need to be organized into a research proposal.

2. Student draft proposal

All student research needs to be outlined in a written proposal of the research. The research question(s), design, subject(s), method, procedures, and time frame should be described in the proposal. Proposals can be written in the format that is common for research in the discipline of study; however, certain information about the study is required for all IRB reviews. Specifically, proposals

must include descriptions of the research questions, study participants, and materials and procedures to be used. The forms and required information that need to be included in the proposal can be found on the ORC website at:

<http://www.usm.maine.edu/orc/irb/>. All research proposals must be submitted with a separate Research Proposal Summary that includes the required content and follows the designated format indicated on the form being used (e.g., on the IRB Exempt form [see #9] and on the IRB Review form [see #5]).

Students and faculty should be aware that there are a number of different forms that the ORC uses for research proposal submissions. These forms help the ORC staff identify what type of research is being proposed and whether the proposal is for initial, amendment or revisions, or continuing review. Below are the names of important ORC forms. These forms can be obtained directly from the [ORC website](#).

- [Request for IRB Review](#)
- [Request for Study Exemption from IRB Review](#)
- [Request for Student Classroom Projects Form](#)
- [IRB Continuing Review/Study Completion Form](#)
- [Protocol Revision or Amendment Form](#)
- [Adverse Event Report Form](#)

If you are uncertain which form you need to submit or have any questions in general about the process, please contact the ORC office at usmirm@usm.maine.edu or 780-4368. Please note that only complete research proposals will be reviewed and the ORC will return incomplete, incorrect, or handwritten submissions to the faculty mentor unread.

3. Faculty mentor reviews proposal

Once the student has drafted the research proposal, it is reviewed by a faculty mentor. Students cannot submit research proposals on their own. All student-initiated research must be sponsored by a USM faculty mentor. The faculty mentor is responsible for reviewing and approving the research design as sound and appropriate for the proposed study. It is up to the faculty mentor to review the proposal carefully and arrange for any changes in the research proposal and IRB submission forms before signing the request for IRB review.

4. Student and faculty mentor revise proposal

Since most successful research initiatives undergo multiple revisions before a final study is conducted, it is expected that the initial student draft of a research proposal will require changes. The faculty mentor should communicate what design

changes are needed directly to the student and together with the student revise the written research proposal.

5. Faculty mentor approves research proposal

Once the student and faculty mentor have agreed on the final version of the research proposal, the IRB review forms can be completed and signed. The correct IRB review form must accompany all research proposals submitted for review. All IRB forms are available on the ORC website at:

<http://www.usm.maine.edu/orc/irb/forms.htm>.

The student and faculty mentor need to complete the correct form to match the research proposal. Submission of the research proposal and completed ORC forms will help prevent delays in the review process. Both the student's and faculty mentor's names should be listed on the research proposal and IRB forms as co-principal investigators. Both the faculty mentor and student sign the IRB form that accompanies the research proposal submitted for review.

6. Proposal is submitted to USM Office of Research Compliance

As soon as the research proposal has been approved by the faculty mentor, and the IRB forms have been completed and signed, the total research application can be submitted to the IRB for review. The research proposal and IRB forms should be submitted in both hard copy and electronic (e-mail) format. E-mailed research proposals and IRB forms may be submitted to usmirb@usm.maine.edu. Hard copies can be sent via campus mail to the Office of Research Compliance at:

178 Science Building, New Wing
5th Floor
Portland Campus

In situations where a student joins a research project after it has already been reviewed by the IRB, a *Protocol Revision and Amendment* form will need to be submitted to the ORC, by the faculty mentor, in order to list the student as a new associate and to assure the ORC that the student has an up-to-date NIH certificate. All researchers must complete appropriate NIH human subjects training. Copies of the completed/updated NIH training certificates are required from the student and the faculty mentor, as well as a copy of the faculty's current curriculum vita (CV), with each to be sent to the ORC. A student CV is not required. A faculty CV is required and is kept with individual research protocol applications, therefore a copy of a faculty CV is requested with each new protocol submission.

7. ORC determines IRB level of review

As soon as a research proposal is submitted to the ORC, it is assigned a protocol number. Each submission is referred to as a “protocol” and the ORC staff will refer to the protocol number when communicating about the submission. The protocol number helps the ORC keep track of submissions and communicate about them without revealing confidential information during the review process. Once the protocol is assigned a number by the ORC, a determination will be made as to the appropriate type of review to be conducted. Consistent with U.S. legal standards regarding IRB reviews, the ORC will first determine if the proposed activities constitute research as defined by federal regulations. If the proposed activities do not fit the criteria for research, the ORC will issue a formal letter to the faculty mentor and student indicating that the proposal needs no additional review by the ORC. If the proposal fits the criteria for research activities, there are three levels of review that can be conducted for an initial research proposal. These are:

- Exempt
- Expedited
- Full Board Review

The ORC staff will read the submitted research proposal and determine which level of review is needed. The only legally authorized entity at USM that can determine what is or is not research (as defined in 45 C.F.R. §46.102 (2005)), for purposes of regulatory compliance and human subjects protection, is the ORC/IRB. No other person, group, department, or entity has the legal authority to make such a determination.

Research that involves minimal risk to human subjects and meets certain regulatory guidelines may be exempt from additional review and such exemptions are granted by the ORC. Other research that also includes minimal risk to the subjects may, however, require an expedited review. Expedited reviews include review by both ORC staff and one or more IRB members. Research that involves greater than minimal risk to the subjects and/or includes certain protected subjects such as prisoners may require full review by the IRB. A summary of the levels of review for research proposals involving human subjects can be found on the ORC website at: <http://www.usm.maine.edu/orc/irb/process.htm>. Once the IRB determines what type of review is needed the proposal is sent on to the parties who will conduct the review. The faculty mentor will be notified of the type of review to

be conducted. Approximate time frames for completion of reviews, depending on the level, are available on the IRB Website.

8. Review conducted

The review is conducted according to the requirements set forth in relevant federal and state laws and USM Policies, Procedures, and Guidance For Human Subjects Research. The reviewer, or the entire IRB if a full board review, will consider the features of the proposed study and whether they meet the federal requirements. In some cases, a reviewer may request additional information prior to completing the review. When necessary, the ORC will contact the faculty mentor and student to request specific information about the research proposal; the faculty mentor is responsible for obtaining the requested information and submitting it to the ORC in order for the review to be completed.

9. Faculty mentor notified of review results

After the level of review has been determined (i.e., Not Human Subject Research, Exempt, Expedited, or Full Board) and the review process has been completed, there are three types of decisions that can result. The ORC staff will notify the faculty and student of the results of the review. The three potential decisions are:

- Approved as Written
- Approved with Conditions
- Not Approved

If a proposal is approved as written, then the faculty mentor can notify the student and the research can begin according to the planned time frame. Approvals are given for no more than 12 month time periods. If a proposal is approved with conditions, then the research can begin only after the stated conditions are met. If a proposal is not approved, then none of the research can be conducted. In such cases, the faculty mentor should meet with the student and discuss revising the proposal to meet ORC requirements. If the student and mentor decide to re-submit a proposal, the process would include the same 10 steps as the initial research proposal.

10. Research begins

Only after a proposal has been approved by the ORC can the student's research begin. Research initiated prior to ORC approval is subject to potential termination by the ORC. Any data collected before or after the time period approved by the ORC is subject to potential confiscation by the ORC. Both the student and

faculty mentor who engage in research activities not approved by the ORC, are subject to any applicable USM and/or federal penalties.

Ongoing Review of Research

Once a study has been approved by the IRB, the research can begin. The approval is based on the condition that the research activities will be carried out exactly as stated in the proposal. If the student and faculty mentor want to change the stated research activities in any way, they must submit a [Protocol Revision or Amendment Form](#) (PRAF). The PRAF includes descriptions of any protocol changes. The PRAF must be reviewed in the same manner as was the initial research proposal. No changes in the research activities can occur until a PRAF has been submitted, reviewed, and approved. PRAF forms must be submitted any time an approved research proposal is changed.

Researchers must submit a proposal for continuing review and approval of research that will last longer than the initial approval period. Usually, the IRB approves research proposals for a period of up to one year, however, sometimes shorter approvals may be granted. For example, if a study has multiple stages, the IRB may want to review the research proposal at the end of each stage, even if the stage is a few weeks or months long. Within 60 days of the end date of the initial approval, the faculty mentor and student will be notified by e-mail and must submit the [IRB Continuing Review/Study Completion Form](#). This form must also be completed when the study is terminated, even if the termination occurs during the initial year of approval. Researchers are also required to notify the ORC if something harmful, undesirable, or unexpected happens as a result of research activities. When a harmful, undesirable, or unexpected incident happens as a result of research, it is known as an adverse event. When this happens, the faculty mentor and student must submit the [Adverse Event Report Form](#) to the ORC. In short, the ORC needs to know when the study starts, when it ends, if you want to make changes, and if an adverse event happens during the study.

Summary

Specific steps must be completed before, during, and after a study for a research proposal involving human subjects is reviewed by the ORC. These required steps are part of the federal regulations governing research at public universities. The three major submission requirements are:

- Completion of [computer-based training](#) in the protection of human subjects by the student(s) and faculty mentor(s);
- Submission of all required and signed forms and supplemental documentation to the ORC, and;
- Submission of a research proposal that summarizes the planned study.

**Office of Research Compliance
(ORC)**

Administration:

- ◆ William R. Harrison, Director
 - 780-4684
- ◆ Ross Hickey, Human Protections Administrator
 - 780-4340
- ◆ Deborah Briskey, Operations Specialist
 - 780-4268

ORC Drop Box:

- For signed paper submissions
- Located at 178 New Science Wing (On the left wall at the inside entrance)

Send Electronic submissions:

- usmirb@usm.maine.edu

Additional Resources

National Institutes of Health. (2006). Researcher Computer-based Training. Retrieved April 3, 2006 from:

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

United States Department of Health and Human Services. (2006). Office for Human Research Protections. Retrieved April 3, 2006 from: <http://www.hhs.gov/ohrp/>.

University of Southern Maine. (2006). Office of Research Compliance. Retrieved April 3, 2006 from: <http://www.usm.maine.edu/orc/>.

Glossary of Important Terms

Adverse Research Event: Adverse research events include a wide spectrum of events.

Adverse events include, but are not limited to, physical or psychological harm or injuries, threats to privacy or safety, and unusual attrition of human subjects. They also include breaches of confidentiality or emotional harms such as the emotional distress that could be triggered by questions about traumatic life events or a subject's complaints about the experimental procedures or the conduct of the investigators.

Biosafety: The safety procedures associated with the research and/or production of biological products such as radioactive materials.

Case Study: An exploration of a "bounded system" or contemporary phenomenon within its real life context, especially when the boundaries between phenomenon and context are not clearly evident.

Co-author: Any individual, who with the agreement of the author may add his or her name on that individual's publication or presentation as a collaborator. Designation as a co-author usually indicates sustained involvement with the project.

Ethnography (or ethnographic study): An approach to inquiry in which the researcher studies human behavior in a natural setting rather than in a laboratory, for purposes of understanding the culture of that particular population. Research may involve observations and/or interviews with people in that setting. Since human participants are involved, the research must be prospectively reviewed and approved by the USM IRB before the research project begins.

Exempt Review: An IRB reviewable research study, typically handled at the administrative level by the Human Protections Administrator (HPA). Exempt research does not require continuing yearly review, however, any revisions to the project still must be submitted for review to the IRB. A protocol qualifies for an exempt review when the following criteria are met:

- Involves minimal risk to human subjects;
- Falls into one of the designated exemption categories set forth in: The Common Rule, 45 C.F.R. § 46.101 (2005).
- Does not involve identifiable or sensitive information; and
- Generally does not involve special subject populations (such as children, prisoners, mentally challenged, etc.)

Expedited Review: An IRB reviewable research study that is typically reviewed by one IRB member and the Human Protections Administrator (HPA). A protocol qualifies for an expedited review when the following criteria are met:

- Involves minimal risk to human subjects;
- Does not involve the identification of human subjects or their responses in a way that would place them at risk of criminal or civil liability or a diminished quality of life.
- Falls into one of the designated expedited review categories set forth in: 63 Fed Reg. 60364-60367 (1998);
- May involve identifiable or sensitive information;
- May involve special subject populations;
- Research overlapping with other regulations (for example HIPAA, FERPA) will typically be reviewed at the Expedited level.

Full Board Review: An IRB research study that is initially reviewed by the Human Protections Administrator (HPA) and then reviewed by the fully convened IRB when:

- Involves greater than minimal risk to human subjects;
- Involve identifiable and/or sensitive information; and
- Involve special subject populations.
- Research overlapping with other regulations (for example HIPAA, FERPA) and that involves identifiable/sensitive information will typically also require Full Board review.

Generalizable Knowledge: Knowledge produced by a project or study which is intentionally shared with others, be it at a poster presentation, at a conference, or in a publication. For example, a "Thinking Matters" presentation would be considered "generalizable knowledge".

Student classroom projects which are not intended to be shared outside the classroom are usually not considered "generalizable knowledge". However, when a third party not affiliated with a course attends a classroom presentation, or, receives information from the project, the researcher has contributed to or developed "generalizable knowledge".

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains

- Data through **intervention*** or **interaction**** with the individual, or
- Identifiable **private information*****.

***Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

****Interaction** includes communication or interpersonal contact between investigator and subject.

*****Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Note: For research involving health or medical information (and/or the electronic transmission of this type of information) the definition of "private information" is not the same as the definition of "protected health information" (PHI) as defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Independent study: In-depth individual projects under the guidance of a faculty member. A course of study that is not part of regular department offerings.

Mentor: An individual (e.g., faculty member, advisor) who provides guidance and recommendations to a more junior person for courses of action and behavior.

Minimal Risk: 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.

Oral History: A technique in which the researcher conducts a series of interviews with participants, which may be recorded, or observes a particular historical event or period. Often, the intention is that the archived data becomes available to the public at a specified future time in order to convey historical insight.

If the archived data will be made publicly available then the research must be prospectively reviewed and approved by the USM IRB before the research project begins. The IRB requires that the researcher make provisions for obtaining informed consent from all participants and document the process. Participants in oral history

projects should be allowed to review the material prior to public archive and decide if they do not wish any or all of the oral history archived.

Principal investigator: The lead investigator with primary responsibility for the project.

The Principal Investigator (PI) is the individual responsible and accountable for designing, conducting, and monitoring a protocol. The PI must be a suitably qualified member of the senior, junior, or research staff. The PI assumes full responsibility for the treatment and evaluation of human subjects and the integrity of the research data.

Qualitative Research: The investigation of phenomena in a non-quantitative, in-depth, and holistic fashion, through the collection of rich narrative materials. Examples of data collection include observation, interviews, and document analysis.

Quantitative Research: The investigation of phenomena that lend themselves to test well-specified hypotheses through precise measurement and quantification of predetermined variables that yield numbers suitable for statistical analysis.

Risk: Measure of the association between exposure and outcome (including incidence, side effects, toxicity).

Service Learning: An educational method by which participants learn and develop through active participation in service that is conducted in and meets the needs of a community. Service learning is coordinated with a school or community service program and with the community. It is integrated into and influences the lifelong learning of a participant and includes structured time for the participants to reflect on the service experience.

Attachments

- A. USM-IRB Application Checklist
- B. Sample Consent Forms
- C. Figure 1 – Flow Chart

USM IRB APPLICATION CHECKLIST
(A review will not be started until application is complete.)

Applications for IRB Review must include the following elements to be considered complete:

- Request for IRB Review** form (or other appropriate USM IRB Review form)
- Research Proposal Summary** (must be in the same format listed below, using lay language, as brief as possible, and not to exceed 3 pages **(Important Tips – see below)**)
 - A. Introduction
 - ➔ References/Brief Literature Review
 - ➔ Should show thoughtful consideration of the research topic, particularly if the study involves greater than minimal risk
 - ➔ Should be current and should reflect recent advances or changes in the field of inquiry.
 - B. Specific Aims
 - C. Methods of Data Collection and Analysis (Qualitative and Quantitative)
 - D. Description of the subject population, research setting, subject recruitment procedures
 - E. Informed Consent procedure
 - F. Provisions for subject and data confidentiality
 - G. Statement of potential research risks to subjects (e.g. breach of confidentiality, treatment complications)
 - H. Statement of potential research benefits to subjects (Monetary compensation is not a benefit of participation)
 - I. Investigator experience (Attach a current copy of your C.V., unless one is on file with the IRB already)
- Copies of all advertisements/flyers** used for recruitment of subjects
- Copies of all questionnaires, guiding questions, survey instruments, tests,** etc.
- Other pertinent documentation** **(Supplementary Information – see below)**
 - Debriefing scripts/forms
 - Grant application (complete application, including grant face page)
 - Section of the thesis or dissertation that describes the human subjects portion of the research
 - Complete Research Proposal (if study needs Full Board Review or if requested by IRB)
 - Letters of cooperation from any cooperating groups, schools, etc.
 - For research conducted in foreign countries, documentation of local approval (e.g. approval by a local ethics review committee) AND the informed consent document(s) to be used in the foreign country.

- Other institution IRB approvals of research studies to be conducted by USM faculty/staff/students or at USM facilities when the Principal Investigator is from the other institution.

Note:

Supplementary Information

- Grant application, including face page (if project is funded)
- Complete Research Proposal (for thesis or dissertation or for any study requiring Full Board Review)
- Debriefing scripts/forms, when applicable
- Letters of cooperation/authorization from cooperating groups/agencies, including HIPAA authorization and Business Associate Agreement; school permission requiring FERPA or PPRA; permission to use archived data, etc.
- For research to be conducted in foreign countries, documentation of local approval **AND** translations of informed consent documents to be used
- For research conducted by researcher from an institution other than USM or by USM researcher in cooperation with other institutions, copy of other institutional IRB approval letter
- Check document for **grammar and spelling**

Note:

Important Tips

- Title document "Proposal Summary"
- Use headings: A. Introduction, B. Specific Aims, etc
- Provide brief, thoughtful responses under each topic heading, using lay language
- Demonstrate preparation by referring to research context or by including brief literature summary
- Describe only data collection activities involving human subjects
- List each human subjects data collection activity separately with appropriate methodology
- Use informed consent and other templates provided on ORC website as ***guidance*** for *individualizing your documents*
- Check document for **grammar and spelling**

University of Southern Maine

SAMPLE FORMAT CONSENT FORM

INSTRUCTIONS:

- The format may be modified or expanded, but the consent form is to contain all the elements included below.
- Please use language which the average lay person is likely to understand or which is appropriate for the age of the subjects (specifically on child assent forms).
- **If the research is being conducted at USM**, the heading should reference USM, along with the specific division and department where the protocol will take place.
- **Please note sections that may not always be applicable in a consent form have been marked as such.** Please be careful to remove these sections if they do not apply in your protocol so as to avoid confusing your participants.

Statements in *italics* are instructions for you. They concern information required as part of your consent form. These instruction statements should not be automatically inserted into your consent form. Instead, you should read the instruction and then draft a statement that is tailored to your specific protocol.

REMINDER: Please check the following items prior to submission:

1. Readability
 - Wherever possible, use a readability analysis to ensure the reading level is no higher than eighth grade;
 - Justify left margins and make right margins ragged;
 - Whenever possible, avoid using words with more than three syllables, and
 - Be careful to balance white space with words in the layout of the consent form.
2. Grammar:
 - Make sentences as direct and concise as possible;
 - Whenever possible, replace technical, i.e. scientific and/or medical term, with terms a lay person will likely understand;
 - When it is necessary to use a technical term, provide a definition of the term;
 - Use active voice as opposed to passive voice, and
 - Use personal pronouns to increase personal identification for participants.
3. Font size:
 - Use font that is "easy to read";
 - Use at least a 12-point font size, and
 - **Researchers working with elderly or visually impaired persons should use a minimum of a **14-point font for their informed consent forms.****

Informed Consent for Participation as a Subject in a Research Study

YOUR HEADING HERE

Introduction:

- You are being asked to be in a **research** study of [*insert a general statement about your study here*].
- You were selected as a possible participant because [*explain how your subjects are identified, and include any exclusionary criteria*].
- We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Note: *Research* - A statement that the study involves research must be included in your consent form.

Purpose of Study:

- The **purpose** of this study is [*explain your research question and your purpose in easily understood language*].
- Participants in this study are from [*note what area(s) they are from*].
- The total number of subjects is expected to be [*insert number*].
- *If you and/or members of the investigative team have a consultative or financial interest relating to the study please precisely state the nature of the relationship to the participants. Examples include:*
 - *A paid (or unpaid) consultant to the company sponsoring this study;*
 - *Paid membership on the advisory board;*
 - *Receiving payment for lectures from the company sponsoring the study;*
 - *Have stock in the company that is sponsoring the study;*
 - *Hold a patent for the product being investigated in this study.*

Note: *Purpose* - You must include an explanation of the purpose of the study.

Description of Study Procedures:

- If you agree to be in this study, we would ask you to do the following things:
 - [*Explain procedures and tasks; identify any procedures that are experimental*].
 - [*State the expected **duration** of the subject's participation*].
 - [*Explain any alternative procedures or courses of treatment available to the subject. If not applicable, please inform the participants there are no alternate procedures or courses of treatment offered to them for this study*].

Note: *Duration* - Describe the length of time for participation, frequency, and the expected end of the study.

Risks to Being in Study:

- [*OPTIONS: select one*]
 1. The study has the following risks: [*Please describe any, and/or, reasonably foreseeable risks or discomforts to the subjects*].
 2. [*If there are none, please inform the participants that there are no foreseeable risks or discomforts*].

- *[For research involving more than minimal risk, you must include a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable].*
- If you experience an emergency physical or emotional harm as a direct result of your participation in this research, you will receive care from *[insert name or facility, etc.]*. *[Insert statement as to how care will be paid for]*. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Benefits of Being in Study:

- The benefits of participation are *[explain benefits of participation that will be gained by the participants and/or others]*.
- *[If there are no expected benefits, state that there are no direct benefits to participating in this study.]*

Payments:

[OPTIONS: select one]

1. You will receive the following **compensation/reimbursement**: *[explain amount of payment or other reimbursement information (e.g., class points, tokens, donations, etc.), when payment and/or reimbursement will occur, and if any anticipated prorated payments to the subject will be required]*.
 - *[If payment is made in money or gifts, include the following statement]:*
Legally, you can be paid only if you are a U.S. citizen, a legal resident alien (e.g., possess a "green" card), or have a work eligible visa sponsored by the paying institution

Note: *Compensation/reimbursement - Examples of compensation/reimbursement are:*

- *Extra credit points added to a course grade for students who participate in the study;*
- *A raffle ticket for a chance to win a prize in a drawing;*
- *A transportation reimbursement provided to participants for fuel and vehicle wear and tear;*
- *A gift certificate to a local business.*

2. You will not receive any compensation/reimbursement for your participation in this study.

Costs: [If Applicable]

[OPTIONS: select one]

1. There is no cost to you to participate in this research study, however, the cost of *[insert lab test, procedure, etc.]* will be billed to your insurance company and we will accept as full payment whatever they pay us.
2. How much you will have to pay depends on whether or not you have medical insurance and what costs your insurance will cover. You or your insurance carrier will be responsible for the costs of *[insert what tests, treatments, visits, etc.]*.

Confidentiality and Privacy of Data:

Note: *Confidentiality - A statement describing how confidentiality of records, that identify the subjects, will be maintained must be provided to the participants.*

- The records of this study will be kept private. *[Please outline for the participants how this will be kept private. Explain where the data will be kept secure after it is collected; what, if any, identifying information will be collected; who will have access to the data and what will happen to the collected individual data once the study is completed].*
Examples include:
 - *Research records will be kept in a locked file in the office of the Principal Investigator;*
 - *The individually collected data will be destroyed after the study is completed;*
- Access to the records will be limited to the researchers; however, please note that sponsors, funding agencies, regulatory agencies, and the Institutional Review Board may review the research records. *[Please note that absolute confidentiality should not be promised to participants].*
- In any sort of report we may publish, we will not include any information that will make it possible to identify a participant.
- *[If you know how you will be publishing your results, please disclose this information to the participants. Examples of publishing include a "Thinking Matters" presentation, a Muskie Capstone project, a journal article and a report to a third party agency].*
- *[If audio or video tape recordings are made, explain specifically who will have access to them, if they will be used for educational purposes, and when they will be erased/destroyed].*
- *[If the study will include the use of an on-line survey, or, will transfer collected data over the internet, explain to the participant what measures will be used to keep the transferred data secure].*

Voluntary Participation/Withdrawal:

- Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University *[or with other cooperating institutions (insert name)].*
- You are free to withdraw at any time, for whatever reason*.
- *[When applicable]* There is no penalty or loss of benefits for not participating or for discontinuing your participation. *[For studies with students, state that the subject does not jeopardize grades nor risk loss of present or future faculty/school/University relationships]. [For medical studies, state that the subject does not risk loss of present or future care they would otherwise receive]. [Explain any consequences (e.g., adjusted monetary benefits) due to early withdrawal].*

*You will be provided with any significant new findings that develop during the course of the research that may make you decide that you want to stop participating.

Dismissal From Study: [If Applicable]

[OPTIONS: select one]

1. If you do not follow the instructions you are given you will be dismissed from the study.
2. If the study sponsor decides to stop or cancel the study you will be dismissed from the study.

Contacts and Questions:

[Note: Student researchers are required to have a faculty mentor listed as Co-PI on their submissions.]

- The researchers conducting this study are [*insert name(s) of investigators, including the PI*]. For questions or more information concerning this research you may contact her/him/them at [*telephone number and email address of researcher and/or faculty mentor*].
- If you believe you may have suffered a research related injury, contact [*specify name of researcher or your faculty mentor if PI is a student*] at [*telephone number and email address*] who will give you further instructions.

Note: *Faculty mentor - The faculty mentor is expected to take an active role in students' research activities and provide supervision throughout the duration of their research study.*

- If you have any questions about your rights as a research subject, you may contact: Director, Office of Research Compliance, USM at (207)780-4517, or usmirb@usm.maine.edu, or TTY (207)780-5646.

Copy of Consent Form:

- You will be given a copy of this consent form and one will be kept in our records file for future reference.

Statement of Consent: - *Please carefully read through these options before making your decision. Some of these may **not** apply.*

Please select the appropriate statement of consent from the list below:

- For Adult or older child(12-17 years) Consent/Assent (Full form): I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form.
- For Adult or older child(12-17 years) Consent/Assent (Short Form): I have read (or have had read to me) the contents of this consent form. An explanation of the research has been given to me and I have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form.
- For Child Assent: This form was read to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.
- For Parental Permission/Consent: I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for my child to participate in this study. I have received (or will receive) a copy of this form.

Signatures/Dates: - *Please carefully read through these options before making your decision. Some of these may **not** apply.*

[OPTIONS: select one]

1. For Adult or Subject's Legal Representative or older child consent (Full Form):
 Study Participant (Print Name): _____
 Participant or Legal Representative Signature : _____ Date _____

2. For Adult or Subject's Legal representative or older child consent (Short Form):

Study Participant (Print Name): _____

Participant or Legal Representative (Signature): _____ Date _____

Witness/Auditor (Signature): _____ Date _____

3. For Child Assent:

Study Participant (Print Name): _____

Witness/Auditor (Signature): _____ Date _____

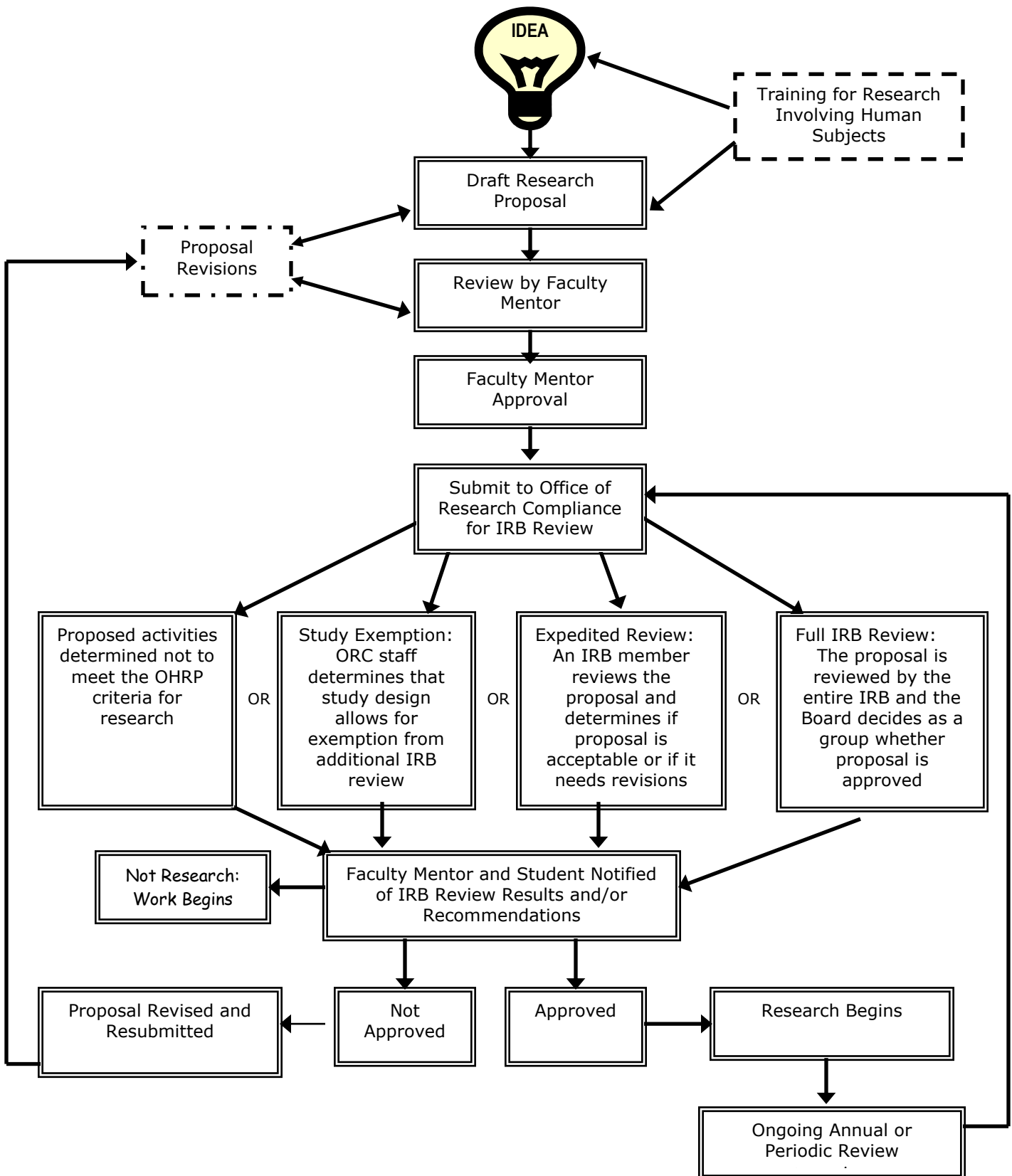
4. For Parental Permission/Consent:

Study Participant (Print Name): _____

Parent/Guardian (Print Name): _____

Parent/Guardian (Signature): _____ Date _____

Figure 1 – Flow Chart



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Also Contributing:

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