

# **Investigator Guidelines for Research that Includes Human Subjects**

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## I. Where Do I Begin?

Investigators and key personnel who intend to perform human subject research must seek prospective IRB approval or exemption prior to initiating research. In order to receive an exemption or approval of research all Investigators or key personnel are required to complete the CITI training module on Human Subjects Protections (<http://www.citiprogram.org/>). Upon completion, a copy of the certificate of completion must be filed in the Office of Research Compliance. Investigators cannot have protocols approved or exempted without completing this educational requirement.

There are three possible alternatives relating to the IRB process:

- (1) REQUEST FOR IRB REVIEW
- (2) REQUEST FOR EXEMPTION FROM IRB REVIEW or
- (3) COURSE REQUIRED DATA COLLECTION

The following criteria will guide you to the procedure you need to follow for research review or request for study exemption.

1. Complete a REQUEST FOR IRB REVIEW form ([www.usm.maine.edu/irb/reviewform.htm](http://www.usm.maine.edu/irb/reviewform.htm)) If the investigation meets the definition of "research" (see definitions) in which the purpose of the activity is to contribute to "generalizable" knowledge OR presents greater than minimal risk to the participating subjects. In addition to this form, the investigator must submit a brief protocol summary, all research tools to be used in the study, including recruitment fliers and advertisements, and a copy of the investigator's CV.
2. Complete a REQUEST FOR EXEMPTION FROM IRB REVIEW form ([www.usm.maine.edu/irb/exemptform.htm](http://www.usm.maine.edu/irb/exemptform.htm)) if the study meets the definition of "research" and it does not present more than minimal risk to the participating subjects. Only use this form if the investigation does not include sensitive information or special populations. Please include a brief description of your study with your Request for Exemption form.
3. Complete a COURSE REQUIRED DATA COLLECTION form ([www.usm.maine.edu/irb/studentform.htm](http://www.usm.maine.edu/irb/studentform.htm)) for Classroom Assignments/Educational data collection that involve human subjects if the purpose of these activities is the education of individual students through an inquiry or experiential approach to discover principles or phenomena. In some instances, student research may require IRB review.

## II. What is the Process of IRB Review?

In many instances the process of review is an iterative process that may require several communications between the researcher and the Office of Research Compliance or IRB reviewers before a protocol may be approved or exempted.

### A. Initial IRB Review

Material for IRB review or Request for Exemption should be delivered to the Office of Research Compliance via Mail (178 BioScience Wing, Science Building, Portland Campus ) or electronically at [usmirb@usm.maine.edu](mailto:usmirb@usm.maine.edu).

Once the application is received, an Administrative Assistant will review the application for completeness. If any of the required elements are missing, the investigator will be contacted. Applications that contain all required supporting documents will be forwarded to an IRB analyst for initial screening.

The IRB Analyst will screen all applications to see if the project qualifies for an Exemption under 45 CFR 46.101 or an Expedited review according to Exemption Categories under 45 CFR 46 101(b) or Categories of Expedited review in the federal register 63 FR 60364-60367. Those applications that do not meet the criteria for Exemption or an Expedited review are required by Federal Regulations to be reviewed at a convened IRB meeting. If substantial content (i.e., information required for approval or exemption) is missing, the investigator will be notified for revisions. If the content is complete, the application will be forwarded to the IRB for review or to the Coordinator of Research Compliance for exemption.

### **1. Request for IRB Exemption**

Research that is deemed Exempt will be returned to the researcher within approximately 10 working days of receipt. Exempt studies do not require continuing IRB review. If a study is Exempted from IRB review, no further interaction is necessary with the Office of Research Compliance (unless changes are proposed for the project or adverse events occur).

### **2. Expedited Review**

Protocols that may be reviewed by an expedited review process will be returned to the researcher within approximately 20 working days of receipt. Protocols that do not qualify for an Expedited Review will require a Full Board Review.

### **3. Full Board Review**

The ORC will make every effort to disseminate protocols for Full Board Review, if the protocol is submitted to Office of Research Compliance at least 30 working days prior to a scheduled IRB meeting. The investigator will receive the results of the Full Board Review within 5 working days from the meeting date. These deadlines only apply to research projects submitted to the IRB as complete applications.

#### The IRB may:

1. Approve the research as submitted.
2. Approve the research contingent upon specific revisions.
3. Table the protocol for substantive changes.
4. Disapprove the research.
5. Suspend or terminate research that has not followed IRB conditions of approval or is not in compliance with USM Research Policy.
6. Monitor the research for compliance with IRB recommendations. All basic monitoring has been delegated to the ORC.

The IRB Chair or the IRB designee will convey the committee's decisions in writing to the investigator.

**Approval:** If the protocol is approved, a copy of the submitted documentation will be returned to the investigator in addition to a letter of approval. All forms submitted as research tools (surveys, advertising for subject recruitment, consent forms), once approved must be altered to reflect the IRB approval date and expiration date (in most cases 1 year from the approval date). Investigators may not use expired instruments.

**Approval with Revisions:** If the protocol is approved contingent upon minor revisions, the investigator will be sent a copy of the protocol and a letter that describes the needed revisions. After revisions are made, the investigator must send 2 copies of the revised protocol to the Office of Research Compliance. If the revisions are satisfactory, the Chair of the IRB or the Coordinator will initial the changes and enclose a signed letter indicating approval of the minor revisions. Once approved, all forms submitted as research tools (surveys, advertising for subject recruitment, consent forms) must be altered to reflect the IRB approval date and expiration date (in most cases one year from the approval).

**Tabled Protocols for Major Revisions:** When a proposal is tabled it must be resubmitted to the IRB and treated as a new proposal.

If an investigator disagrees with the revisions or specifications or IRB decisions, the investigator may bring his or her concerns to the attention of the Chair, primary reviewer or the Coordinator of Research Compliance for a due process investigation.

## **B. Continuing Review Procedures**

Protocol approval automatically expires at the end of the IRB approval period. If a researcher would like to continue research activities past the approval period, the researcher must request continuing review. A Request for Continuing IRB Review may be found on our Applications/Forms web page . Continuing review procedures should commence thirty working days prior to the IRB approval expiration date. Investigators must submit a brief summary of the research activities, including the number of subjects enrolled in the study to date, any unexpected events, any findings of the research, and an update of the initial literature review. The researcher should deliver a copy of the continuing review summary to the Office of Research Compliance or email it to [usmirb@usm.maine.edu](mailto:usmirb@usm.maine.edu).

Federal Regulations require review of research at least annually, consequently the date of approval always begins from the date of review and extends at the maximum one year from the review date. Because of this Federal Review Requirement, the IRB is not able to make approval dates consistent with project timelines.

## **C. Changes After IRB Approval**

Substantial changes in IRB protocols, including approved instruments, consent forms, or advertisements, require IRB approval before use. Investigators may initiate approval for

changes by submitting a Protocol Revision and Amendment form (PRAF). Minor typographic errors may be corrected by the investigator, but the investigator must provide the altered forms to the ORC using the Protocol Revision and Amendment form. From time to time, the ORC may contact the investigator to verify use of approved IRB documents.

#### **D. Withdrawal or Completion**

Protocol approval automatically expires at the end of the IRB approval period. When a study is withdrawn or completed prior to the IRB approval period, the ORC requests that the investigator notify the IRB in writing and indicate provisions to protect confidential information or indicate plans for destroying it. All records of IRB communications must be kept on file for three years following termination or completion of research studies. Protocols are considered to be active if data analysis or handling of data is ongoing. To withdraw or complete an IRB protocol, complete the IRB Continuing Review/Study Completion form.

#### **E. Report of Unforeseen and Adverse Events**

All adverse events of physical or psychological harm, threats to privacy or safety of human subjects must be immediately communicated to the Office of Research Compliance. In addition, unanticipated research events in federally sponsored research will be disclosed to the Department of Health and Human Services via the Office of Research Compliance. In the event of research misconduct in projects sponsored by the Public Health Service, the Office of Research Integrity will be informed of misconduct committee proceedings.

### **III. Guidelines for Student Research**

Students who are using human subjects in thesis, dissertation studies, or other individual research projects, must follow the same guidelines as faculty in submitting their proposals for approval by the Institutional Review Board. In the case of undergraduate and graduate research courses, in which students are required to learn and practice research methods, the situation is more varied. The following guidelines are intended to help faculty, and their students, in these courses to determine whether review is required, and if it is, how to prepare for it.

#### **A. Student Research that May be Eligible for Exemption from IRB Review:**

1. Student research that is not intended to produce "generalizable" information shared beyond the research class, and that does not include sensitive information, pose greater than minimal risk, or study a special population.
2. Data collected in connection with a class that is undertaken for the purpose of learning research techniques, or professional skills (e.g., patient evaluations for nursing students, law student research techniques, and student counseling techniques).
3. Observation of students performed in commonly accepted educational settings provided the evaluator does not interact with the student (including observation of minors). Studies that focus on normal educational practices, curriculum, instructional techniques, or management strategies are exempt provided that the information is not shared beyond the USM class or the research context.

4. Study of existing data files in which subjects cannot be identified.

Course instructors may request an exemption for these studies. Complete a Course Required Data Collection Form and submit it to the Office of Research Compliance.

### **B. Student Research that Must be Submitted for IRB Review**

1. The information that is being collected will be disseminated to the general public.
2. Studies that include the interaction or intervention with "special populations."
3. Studies that collect "sensitive information."

Complete a Course Required Research form for the class assignment and a Request for IRB Review for each study. Student research projects require a faculty sponsor who will be fully responsible for adherence to USM Policies and Procedures for Human Subject Research.

### **C. Note to Instructors**

Even if student inquiry does not require full review, all research courses should ideally include basic information about the existence of and reasons for government regulations designed to safeguard human research subjects. Students should be familiar with the concepts of risk/benefit analysis, confidentiality, and informed consent.

If course-related research requires review, each student should fill out the Request for Review Form; the professor should collect these forms and send them as a group to the IRB with a cover letter describing the assignment. Note that all student research, whether reviewed or not, must be supervised by a faculty member who is responsible for the student's research conduct; this includes adherence to USM Policy and Procedures for Human Subject Research and research ethics.

## **IV. Definitions**

**Research:** Research is defined as a systematic investigation designed to contribute to or develop "generalizable" knowledge (intended to be shared with the general public). This includes research obtained by an investigator through interaction or intervention with a human subject or any research on human subjects that includes identifiable private information. This does not include research in commonly accepted educational settings that does not generate information used beyond the institution (such as course evaluations) unless the subjects can be identified and the information obtained poses a risk to the subject greater than that encountered in daily life.

**Intervention:** Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for data collection purposes.

**Interaction:** A communication or interpersonal contact between investigator and subject for purposes of data collection.

**Minimal Risk:** Risk that is not greater than that encountered in every-day life.

**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, as well as information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

**Sensitive Information:** Includes information that may pose a risk to the subject: psychological, social, medical, legal, economic or quality of life. The following categories exemplify these risks.

Categories of Sensitive Information:

1. Information relating to sexual attitudes, preferences, or practices.
2. Information relating to the use of alcohol, drugs or other addictive products.
3. Information pertaining to illegal conduct.
4. Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
5. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination.
6. Information pertaining to an individual's psychological well-being or mental health.
7. Genetic information

**Special subject populations:** Certain populations have additional protections under the Common Rule. Studies that include special subject populations must follow a more rigorous review by the IRB. (Researchers are reminded that USM policies have been written to comply with the Federal Rules that provide additional protection for these populations.)

Subject populations with added protections:

1. Minors (under 18 years)
2. Pregnant women
3. Fetuses or products of labor and delivery
4. Prisoners
5. Individuals with a diminished capacity to give informed consent

## **V. Guidelines for IRB Protocol Summary**

In order to review research involving human subjects, the IRB requires completion and submission of a 3 page form (Request for IRB Review) AND a research protocol summary. The following guidelines are designed to help researchers develop a comprehensive yet succinct research protocol to facilitate timely review by the IRB. (Capstone, thesis, dissertation, grant, and funding proposals cannot be submitted as, or in lieu of, research protocols as they do not contain all the required information.)

General Guidance

1. Use the format stated below.
2. Use the recommended topic headers.
3. Keep the Research Protocol Summary under three pages (references, informed consent/assent documents, and copies of questionnaires, guiding questions, survey instruments, tests, letters of support, etc. do not count toward the three-page limit). Write your summary in such a way as to be understood by readers outside of your field of expertise.

## **A. Research Protocol Summary Topic Areas and Recommended Format**

1. Introduction: Summarize the background, nature, rationale and significance of the proposed study.
2. Specific Aims: In outline form, state clearly the objectives of the research.
3. Methods of Data Collection and Analysis: Describe all the activities in which subjects will participate (e.g., completing a survey, taking a test, answering questions in an interview, completing a specific task, completing tasks on a computer, running on a treadmill, etc.). Describe the methods of data recording (videotapes, audiotapes, photographs) and explain the rationale for doing so. Subjects (and their guardians, if applicable) should be given the opportunity to review their audiotapes, videotapes, or photographs before inclusion in the final data, and researchers must honor requests to edit a subject from a presentation. Attach a copy of the data collection instruments. Explain how the data will be analyzed or studied (i.e. quantitatively or qualitatively). Explain how the interpretation will address the research questions. Explain how data will be reported (i.e. aggregated, anonymously, pseudonyms for participants, etc.). If data is collected at another institution, the investigator must include permission for data collection from the appropriate institution.
4. Subject Population, Research Setting, and Subject Recruitment Procedures: Describe the target subject population and the setting where the study will be conducted. Include a description of how subjects will be recruited or contacted. Explain who or what will be the source of subjects and include criteria for subject inclusion/exclusion. Please provide specifics about equity of subject selection. Explain the compensation provided to subjects for their participation in the research study (i.e. money, goods, course credit, etc.), and how and when it will be provided. If you are conducting research in a classroom environment, state what alternative activities will be available for students not participating in the research. Describe procedures for reducing peer pressure or stigmatism for non-participants, if applicable.
5. Informed Consent Procedure: Attach a copy of the consent form and describe the procedures for obtaining consent. Explain how the assent or consent will be secured. Describe procedures for obtaining informed consent/assent. Describe special provisions for individuals who might have trouble comprehending the consent information. If participants do not speak English, contact the Office of Research Compliance for guidance.
6. Provisions for Subject and Data Confidentiality: Describe how the privacy of subjects' responses will be protected (i.e. responses will be anonymous, assigning pseudonyms, assigning codes, etc.). If you plan to identify participants, contact the Office of Research Compliance for guidance. Describe where the data will be stored and who will have access to it. Describe what will happen to video and/or audiotapes after transcription. Will they be destroyed or used later for research purposes?
7. Statement of potential research risks to subjects (e.g., breach of confidentiality, treatment complications): Research risk is the probability of harm occurring as a

result of participation in research. For any project involving more than minimal risk, please contact the Office of Research Compliance for guidance. Describe any risks to subjects that are reasonably foreseeable, even if unlikely, and the safeguards in place against these risks. Risks may include psychological, social, economic, physical and legal risks.

8. Statement of Potential Research Benefits to Subjects (Monetary compensation is not a benefit of participation): Benefit is a valued or desired outcome or advantage. Describe any direct benefits participants could potentially accrue or benefits the subject class/population may accrue. If there are no benefits, explain. Explicitly address how risks compare to benefits.
9. Investigator experience: Briefly describe your experience with the proposed subject population and enclose a current copy of your C.V.

## **VI. Guidelines for the Informed Consent Procedure**

Informed consent is a process involving the exchange of information between subjects and investigator to provide subjects with sufficient information to make informed choices about either beginning or continuing participation in a research project. Informed consent should be ongoing throughout the research project and should not be regarded as simply a "form"; the consent document is merely a tool to assist the investigator. The IRB is aware that in some types of studies, informed consent interferes with confidentiality, or may confound the results of the study. In these cases, some elements of the consent form may be waived by the IRB, but only in low risk studies, and only with proper justification from the researcher.

### **A. Legally Effective Informed Consent Requires:**

- Disclosure of relevant information to prospective subjects about the research
- The prospective subjects' comprehension of the information
- The prospective subjects' voluntary agreement, free of coercion and influence, to participate

### **B. Required Elements of the Consent Documentation (Consent Form):**

The IRB and the ORC are aware that some categories of research that do not require all of the above provisions of consent. These categories of research include; 1) public service benefit programs, if the consent form would be the only personal identifier and as a result, a signed consent form would diminish confidentiality, and 2) research that cannot be practically performed with full consent, and the risk to human subjects is minimal.

Except for the categories noted above, to be eligible for approval each consent procedure must include the following elements;

1. A statement that the study involves research.
2. The purpose of the research in lay terms (in language understandable to the subject).
3. An explanation of the purpose of the research.
4. The expected duration of the subject's participation.

5. A brief description of the procedures to be followed.
6. The time commitment of participation.
7. The risks and benefits associated with the participation.
8. Approximate number of subjects involved in the study.
9. A statement of confidentiality that provides the subject with a contact at the institution who may be reached if injury occurs or confidentiality is breached (this should be someone other than the researcher).
10. A statement that participation is entirely voluntary and may be discontinued at any time.
11. A statement that withdrawal from participation will not result in denial of entitled benefits.
12. Invasive biological, clinical or behavioral interventions require specific descriptions of the procedure.
13. The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness.
14. The consent form must have an expiration date for IRB approval.
15. Individuals with added protections require both permission of a legal representative and assent of the individual.

### **C. Tips for Informed Consent Documentation**

When developing an informed consent document, researchers need to consider their audience in relation to the comprehension of the information presented. The following tips are to help researchers develop clear, easy-to-read, easy-to-understand informed consent documents.

#### Content:

1. Make sentences short, simple, and direct.
2. Use title, subtitles, and other headers to organize the text and break it into short sections.
3. Present study purpose at the beginning of the document.
4. Use words familiar to the reader, i.e. "cholesterol" instead of "blood lipids."
5. Use non-scientific/non-medical terms where possible. If it is necessary to use scientific, medical, or legal terms, clearly define them.
6. Stress or highlight important points.
7. Avoid using words containing more than three syllables where possible.
8. Use words and terminology consistently throughout the document.
9. Use verbs in the active voice versus the passive voice, i.e. the subject is the doer of the act.
10. Use personal pronouns to increase personal identification.
11. Stress or highlight important points.
12. Be as concise as possible.
13. If possible, conduct a readability analysis to ensure reading level is no higher than seventh grade.

#### Appearance:

1. Use a font that is easy to read.
2. Use at least a 12-point font size.

3. Use upper and lower case letters.
4. Justify left margins and make right margins ragged.
5. Employ underlining, bolding, and boxing text to give emphasis rather than capitalizing or italicizing.
6. Avoid large blocks of text. Balance white space with words and graphics in the layout.

When reviewing the informed consent document, researchers should ask themselves the following questions:

- Is the document written at a reading level understandable to the audience?
- Is the document formatted well? Does it have headings that break the text into short sections?
- Does the document present all the necessary information in an easy-to-understand manner?
- Can the document be shortened without compromising clarity or other requirements?

Researchers might also have individuals they know but who are unaffiliated with the study, such as friends or family members, review the consent form in regard to the questions above.

#### **D. Examples of Informed Consent Documents**

Research Involving Children  
Oral History Research  
Anonymous Surveys

#### **Additional Information**

For more information on the USM Institutional Review Board or institutional requirements regarding research involving human subjects, contact the Office of Research Compliance at 780-4268, 178 Science Building, New Wing, Portland Campus. All application materials are available on our Web site.