11-12-2021

Web Capture: Institutional Review Board for the Protection of Human Subjects (IRB)

Office of Research Compliance, University of Maine

Human Subjects

- IRB Overview
- Guidance & Policy
- Regulations
- Training
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Institutional Review Board for the Protection of Human Subjects (IRB)

COVID-19 Guidance for Human Subjects Research

Researchers conducting research with human subjects are encouraged to design their studies to be conducted remotely if at all possible as this is the safest approach for our research participants, researchers and the university community. For those studies which cannot be conducted remotely, face-to-face human subjects research may be allowed it is determined that it can be conducted safely, and must at all times be in compliance with current directives and guidance available on the UMS Information page and the UMaine Information page. The University remains in Research Activity Category 'Lower Level (Mid-Late Phase 3) for Human Subjects Research (HSR), but the guidance has been updated. The full guidance for HSR is available at **COVID-19 Guidance for Researchers**.

Updated 9/13/21

Submit new applications or modifications to: umric@maine.edu

Federalwide Assurance #: FWA00000479

IRB Organization (IORG) #: IORG0000642

Students, employees, and agents of the University who conduct research involving human subjects must comply with the University Policy and Procedures for the Protection of Human Subjects of Research. These procedures exist for the rights and welfare of the people who participate in UMaine research. No systematic investigation of information obtained by observing or interacting with people, or by collecting and examining any form of identifiable private information about people, may be conducted until the Protection of Human Subjects Review Board has approved the research protocol.

Contact for IRB Questions

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Guidance & Policy

Policy

- Graduate School Policy: Graduate students and faculty advisors, please read section 10.2.3 (page 43) Human Subjects Approval, from the Graduate School's Policies and Regulations.
- Policy Concerning the Protection of Human Subjects of Research (PDF): All persons involved with human subjects research should read this policy.
- Revised common Rules Changes (PDF)

Guidance

- Anonymous vs Confidential
- Continuing Review Instructions: For currently approved (non-exempt) studies.
- Data Encryption Requirement: To ensure confidentiality of identifiable, *electronic* data, the Institutional Review Board (IRB) is now requiring **that the electronic key linking participants' identities to their data be encrypted**. See link for additional information.
- Depression and Suicidality in Human Research – Guidance for Researchers (PDF). These guidelines are intended to assist researchers who use measures that screen for depression and/or suicidality.
- Expedited Review Categories: Categories of research that may be reviewed by the IRB through an expedited review procedure.
- Exemption Categories: Listing of research activities that may be exempt from further review.
- FERPA Guidance: Consideration when collecting student records
- Guidelines for Class Projects. These guidelines are intended to assist instructors in

determining when class projects meet the definition of research with human subjects and require review by the University of Maine's Institutional Review Board for the Protection of Human Subjects (i.e., IRB). Please see flow chart (PDF) to assist with the decision-making process. Sample of a course syllabus (PDF) addressing class projects (*used with permission*).

- Human Subject Payment Guidelines
- Information about Oral History Activities: Information to assist individuals in determining when/if oral history activities require human subjects review.
- Informed Consent Guidance/Checklist (PDF): Information about the informed consent process.
- Instructions for Requesting a Modification to Approved Study
- Internal Institutional Data Collection Guidelines
- Reactivating a Closed Study
- Referral Handout Template (Word): Use for studies on sensitive topics where referrals are required.
- Sex, gender, and sexual orientation guidance on demographic questionnaires
- What is GDPR?
- Zoom Guidance for IRB Studies

GRADUATE SCHOOL

POLICIES

AND

REGULATIONS

July 2018

Acknowledgments, by prior agreement between the student and the Graduate Thesis Committee.

5. It is the student's responsibility to secure copyright permissions when necessary (e.g., permission from a journal to use a published paper in the thesis or dissertation).
6. Programs may choose to develop program-wide guidelines on the use of publications in theses or dissertation.

10.2 Approvals Related to Thesis

10.2.1 Thesis Subject

The subject must be formally submitted to the Graduate School at the time the student submits the program of study. Approval of the thesis subject by the student's advisory committee is required.

10.2.2 Completed Thesis

An approved electronic copy of the thesis must be submitted to the Graduate School no later than 24 hours before the final examination. It must have been previously approved by a committee which shall be appointed by the Dean of the Graduate School. The thesis shall be read and approved by no fewer than three (3) persons.

The "Tentative Thesis Acceptance Form" signed by the members of the advisory committee signifies that the draft thesis has been read and is in appropriate form for the oral defense. The filing of a completed Tentative Thesis Acceptance Form signifies only that the student's committee deems the thesis to be in acceptable form for oral defense. A student may expect that revisions, amendments, or additions may be required based upon the oral examination. In rare instances, serious difficulties may be discovered during the oral examination, which result in major revisions in a thesis or dissertation. (Also see Date of Presentation)

10.2.3 Human Subjects Approval

As required by The University of Maine policy, graduate students who plan to perform research that involves the use of human subjects must comply with The University of Maine Policies and Procedures of the Institutional Review Board for the Protection of Human Subjects (IRB). No research with human subjects shall be conducted until the Institutional Review Board for the Protection of Human Subjects (IRB) has approved the research protocol. Responsibility for ensuring compliance with The University of Maine Human Subjects Review Policy rests with the student's thesis advisor. Evidence of IRB approval, if applicable, must be noted on the student's Final Thesis Acceptance Form.

Student violations of the Human Subjects Review Policy will be handled on an individual basis in accordance with existing University of Maine or college/departmental policy. The inclusion in a thesis or dissertation of data involving human subjects which was obtained through procedures which did not receive prior approval by the IRB will ordinarily not be permitted.

10.2.4 Animal Subjects Approval

Graduate students performing research or testing using live vertebrate animals must obtain the approval of the Institutional Animal Care and Use Committee (IACUC) before initiating such studies. Responsibility for ensuring compliance with The University of Maine Policies and Procedures for the Humane Care and Use of Animals rests with the student's thesis advisor. Evidence of IACUC approval, if applicable, must be noted on the student's Final Thesis Acceptance Form. Student violations of the Policies and Procedures for the Humane Care and Use of Animals will be handled on an individual basis in accordance with existing University of Maine or college/departmental policy. The inclusion in a thesis or dissertation of data involving animal subjects which was obtained through procedures which did not receive prior approval by the IACUC will ordinarily not be permitted.

10.3 Form and Preparation of Thesis

It is expected that each department will guide its own students in the selection of the appropriate manual to be used in order that students will have experience with accepted practice in their own fields. The specific guidelines for thesis and dissertation preparation are available from the Graduate School's website at umaine.edu/graduate.

CAUTION: Do not consult another thesis for guidance. Thesis requirements change.

10.3.1 General

The original copy of the thesis shall be submitted electronically in PDF format to the Graduate School.

The thesis must be standard, double-spaced throughout, except for quotations, footnotes, bibliographies, and illustrations, which may be single-spaced. Each page of the thesis shall have a margin of at least one inch on the left, right, top, and bottom. The only matter which may be outside these imaginary margin lines is the page number. With the exception of the Abstract which are not included in the pagination of the thesis, all pages are assigned page numbers. Small Roman numerals are used for the preliminary pages following the title page. The title page is the only page in the thesis on which a number is

University of Maine
Policies and Procedures for the Protection of Human Subjects of Research
Effective: January 25, 2019
Last Revised: January 25, 2019

Table of Contents

I. Administrative Procedures for Human Subject Research

A. Introduction

Research with human subjects at the University of Maine shall be guided by three general ethical principles: respect for persons, beneficence, and justice. These principles and the rules that may be derived from them shall form the analytical framework for determining whether and how research with human subjects may be conducted. Researchers must respect and protect the rights and privacy and welfare of individuals recruited for and participating in research. More precisely, all human subject research must comply with the US Department of Health and Human Services (DHHS) "Common Rule" 45 CFR 46; 21 CFR 50; the *Belmont Report*; *The Nuremburg Code*; and the *Declaration of Helsinki*.

The University shall maintain and support an Institutional Review Board for the Protection of Human Subjects (IRB), whose function it is to determine whether and how research with human subjects may be conducted, and to educate the community with regard to the protection of human subjects.

No research with human subjects shall be conducted until the IRB has reviewed the research protocol. Before action is taken, proper consideration shall be given to the risks to the subjects, the anticipated benefits to the subjects and others, the importance of the knowledge that may reasonably be expected to result, and the informed consent process to be employed.

The University of Maine shall acknowledge and accept responsibility for protecting the rights and welfare of human subjects of research. University Policies and Procedures for the Protection of Human Subjects of Research apply to all activities which include research with human subjects and:

- are sponsored by the University; or
- are conducted by or under the direction of any faculty, staff member, or student of the University in connection with his or her institutional responsibilities; or
- are conducted by or under the direction of any faculty, staff member, or student of the University using any property or facility of the University; or
- involve the use of the University's nonpublic information.

The University of Maine shall encourage and promote constructive communication among research administrators, department chairs, deans and directors, research investigators, research staff, human subjects, and University

officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

The University of Maine shall comply with all federal, state, and local regulations pertaining to the protection of human subjects.

B. Student Class Projects

1. Class projects that involve systematic collection of data and for which the design or objective is to develop or contribute to generalizable knowledge are considered research and require IRB review.

2. Class projects that are designed: a) solely with the objective of providing students with training about and experience with research methods, **and** b) where data will not be used outside of the classroom context, **and** c) where data will be destroyed upon completion of the project, are not considered research and do not require IRB review. **However**, if the instructor allows a student to design a class project that involves protected populations or sensitive information, IRB review and approval are required. (See document, Guidelines for Class Projects for additional information.)

C. Research Activities that May Be Exempt from Further Review

Exempt - The Common Rule outlines certain types of research that are exempt from Institutional Review Board (IRB) oversight: 45 CFR 46.104(d); 21 CFR 50 and 56 [US Food and Drug Administration (FDA research)]. Only the IRB can determine if a proposed project qualifies as exempt from further review. Principal Investigators (PI) whose research is judged exempt from further review are not required to have any further interaction with the IRB unless adverse events occur, or there is a substantial change to the protocol.

Exempt Categories:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service

programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) 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.

D. Definitions

Adverse Event, Serious: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.

Serious Adverse Events include those that:

- Are fatal or life threatening;
- Result in significant or persistent disability;
- Require or prolong hospitalization;
- Result in a congenital anomaly/birth defect; or
- Represent other significant hazards or potentially serious harm to research subjects or others, in the opinion of the investigators.

Unexpected Serious Adverse Events are those that have not been described in the:

- Package insert for a given drug or investigator's brochure (for FDA investigational agents);
- Approved protocol; or
- Informed consent document. [21 CFR 312.32(a)]

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;
- Unusual attrition of human subjects;
- 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.

Certificate of Confidentiality: A discretionary document issued by the National Institutes of Health (NIH), which helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Further information is available at http://grants1.nih.gov/grants/policy/coc/.

Coercion: To bring about participation in research by force or threat, actual or perceived, or through any other imbalance of power.

Common Rule: The federal regulation that is the primary source of human subjects' protections. This is the common reference for 45 CFR 46, PROTECTION OF HUMAN SUBJECTS.

Generalizable Knowledge: Currently, US DHHS Office of Human Research Protection (OHRP) **does not** have a formal position on what does and does not constitute "generalizable knowledge" beyond the language of the Common Rule. The University of Maine adopts the following definition of generalizable knowledge:

Generalizable knowledge is information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

Thus, a case study, designed to illuminate the course of a single individual's experience generally **will not** be considered to be developing or contributing to generalizable knowledge. A series of case studies, intended to lead to improvements in the management of a particular circumstance or condition, generally **will** be considered generalizable knowledge.

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

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Institutional Review Board (IRB): A research review committee whose primary purpose is to review all research involving human subjects and to provide oversight of human subjects' protections.

Interaction: A communication or interpersonal contact between investigator and subject for research purposes.

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

Key Research Personnel: Persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects'

identifiable data or biological samples (*e.g.*, tissue, blood, urine, plasma, saliva), or use subjects' personal information.

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 living or during the performance of routine physical or psychological examinations or tests." [45 CFR 46.102(i)]

Minor: An individual under the age of 18 years.

Minor Changes: Minor changes have no substantive effect upon an approved protocol or reduce the protocol risk already approved by the IRB. Examples of minor changes are:

- Changes in research personnel that do not alter the competence of the research team to conduct the research, or
- Minimal changes in remuneration.

Principal Investigator (PI): Any University of Maine faculty, staff member, or student so designated in a protocol who is the primary person responsible for all aspects of the research project and assumes all responsibilities for the results.

Prisoner: Any individual, regardless of age, involuntarily confined or detained in a penal institution or a parolee detained in a treatment center as a condition of parole. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This definition also includes data from non-publicly available databases and secondary sources. The University of Maine extends the term "prisoner" to include persons on pre-trial supervised release, on community supervision or on probation, or who is in any court-ordered deferred prosecution or diversion program.

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Protected Population: (Also referred to as protected subject group). These groups of potential research subjects have specific regulatory compliance requirements and receive special protections under the Common Rule and/or other federal regulations. These groups include (but not restricted to):

- Children/Minors (under the age of 18)
- Prisoners (now includes non-publicly available secondary data)
- Pregnant women
- Fetuses and products of labor and delivery
- People with diminished capacity to give consent
- Mentally or physically challenged individuals

Protocol: Any type of research project that is submitted for IRB review (also known as a research project, proposal, submission, *etc*.).

Protocol Violation, Major: A major protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the IRB and the actual activities being performed. Major protocol violations include violations that:

- Cause or pose a significant risk of substantive harm to research participants;
- Damage the scientific integrity of the data collected;
- Show evidence of willful or knowing misconduct on the part of the investigator; or
- Demonstrate a serious or continued noncompliance with federal, state or local research policy, laws, or regulations.

Protocol Violation, Minor: A minor protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the IRB and the actual activities being performed. Minor protocol violations include violations that:

- Have no substantive effect on the risks to research participants;
- Do not impact the value of the data collected (meaning the violation does not confound the scientific analysis of the results); and
- Do not result from willful or knowing misconduct on the part of the investigator(s).

Research: The University of Maine takes as its starting point the federal definition of research set forth in the Common Rule, [45 CFR 46.102(d)]:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities). ***Please note that risk assessment plays no role in the determination of whether a proposed activity constitutes research. See also the definition of generalizable knowledge, above.***

For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Research Misconduct (42 CFR §93.103): means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them as if they were real.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

Sensitive Information: According to the NIH Certificate of Confidentiality Kiosk, sensitive information is that which, if disclosed, may reasonably pose a risk to the subject's psychological, social, medical, legal, or economic well-being or quality of life. Categories of sensitive information include (but are not limited to):

- Sexual attitudes, preferences, or practices
- Use of alcohol, drugs, or other addictive products
- Information pertaining to illegal conduct
- Information that if released might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination
- Health and medical information contained in a medical record, chart, or insurance file (this category may also require a HIPAA review)
- Information pertaining to an individual's psychological well-being or mental health (this category may also require a HIPAA review)
- Genetic information or tissue samples (this category may also require a HIPAA review)

Signatory/Institutional Official: The signatory/institutional official (IO) is the highest institutional official who has the legal authority to represent the University of Maine's Assurance filed with the OHRP, and is responsible for the provisions of this policy. At the University of Maine, the signatory/institutional official is the Vice President for Research.

Specimen: Specimen is used to refer to biological specimens (*e.g.*, blood or tissue samples), as well as to other types of data "specimens" that could be stored for use in future research (*e.g.*, audio tapes, video tapes, *etc*.).

Substantive Changes Affecting Risk: Substantive changes are changes that may increase the research population's risk or are of questionable risk. Examples of substantive changes that are considered to increase the risk to the study/individual include, but are not limited to:

- Increasing the length of time a study participant is exposed to experimental aspects of the study.

- Changing the originally targeted population to include a more at-risk population (*e.g.,* previous exclusion for those with renal failure are now allowed to enroll, or adding children or pregnant women to the study).
- Adding an element that may breach the confidentiality of the subject such as tissue banking or genetic testing.

Undue Influence: Inappropriate remuneration or any other form of compulsion offered to an individual that may unfairly compel that individual to participate as a human research subject.

Unanticipated Problem: Any event that is not expected given the nature of the research procedures and the subject population being studied, and places subjects or others at greater risk or harm/discomfort related to the research than was previously known or recognized. An event which was previously unforeseeable based on the information provided to the IRB.

Written or in writing: refers to writing on a tangible medium (e.g., paper) or in an electronic format.

E. Responsibilities of the Principal Investigator

The individual faculty, staff member, or student of the University who conducts or directs research with human subjects exercises the following responsibilities:

1. The Principal Investigator shall submit an application for Approval of Research with Human Subjects to the Board. The application includes all criteria for submission.

2. The Principal Investigator and personnel named in the application or who will have access to data, shall complete the required training.

3. The Principal Investigator shall begin the research project ONLY after receiving written approval from the IRB.

4. The Principal Investigator shall make no alterations to the approved protocol without the prior approval of such alterations by the IRB.

5. The Principal Investigator shall report at once to the IRB any unanticipated harm to human subjects.

6. The Principal Investigator shall submit a status report to the IRB on the conduct of the research and shall seek approval for continuation of the research at least annually, and more frequently if the IRB so requires.

7. The Principal Investigator shall cooperate fully with the Protection of Human Subjects Review Board in monitoring the progress of the research.

F. IRB Membership

The IRB is responsible not only for reviewing, regulating, and monitoring human subject research but also for educating the University community in the protection of human subjects.

1. The IRB shall have no fewer than five voting members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

2. A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, *etc*., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, *e.g.*, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to US DHHS's OHRP.

3. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. At least one member's area of expertise shall include children. At least one member shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. The IRB may NOT have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available to the IRB; such individuals may not vote with the IRB.

4. Members are appointed for one to three-year terms and may be reappointed to additional terms.

5. All IRB members are formally confirmed by the President (or designee) of the University; any designation must be specific and in writing.

6. The Chair of the IRB should be a tenured faculty member with experience in conducting human subject research. Appointment is confirmed officially by the President or designee and is for two years; may be reappointed to additional terms. A Vice Chair may be appointed, if desired, using the same confirmation procedure.

G. IRB Functions and Operations

The IRB shall:

1. Follow written procedures in the same detail as described in 45 CFR 46.103(b)(4), and to the extent required by 45 CFR 46.103(b)(5).

2. Except when an expedited review procedure is used (see section I.), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting

H. IRB Review of Research

1. All research shall be reviewed by the IRB. The IRB shall make the final decision on whether research is exempt from further review or meets the requirements for an expedited review. The IRB shall review protocol applications and has the authority to approve, require modifications, or disapprove research activities with human subjects.

2. Ensures that legally effective informed consent of human research subjects will be obtained in a manner and method that meets the requirements of federal, state, and local rules and laws and in accordance with section K.

3. The IRB shall require documentation of informed consent or may waive documentation in accordance with section L.

4. The IRB shall notify investigators and the Institutional Official in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5. The IRB shall monitor the research it has approved by any means it deems appropriate, including observation of the consent process and the research activities and appointment of a third party to undertake such observations.

6. The IRB shall conduct continuing review of approved research activities at intervals appropriate to the degree of risk, but not less than once per year, except as described in 7 below

7. Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

   i) Research eligible for expedited review in accordance with 46.110.
   ii) Research reviewed by the IRB in accordance with the limited IRB review described in 46.111
   iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

      (a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
      (b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

8. An IRB shall have authority to observe or have a third party observe the consent process and the research.

I. Expedited Review Procedures

1. Following is a list of categories of research that may be reviewed by the IRB through an expedited review procedure. Investigators may request an expedited review when proposed research activities meet one or more of these categories. Ten business days are required for an expedited review. (Note: projects falling into one of the exemption categories – section C. -- will routinely be expedited.)

2. Applicability

   a. Research activities that (i) present no more than minimal risk to human subjects, and (ii) involve only procedures listed in one or more of the categories detailed below, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. 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 subjects.

   b. The categories in this list apply regardless of the age of subjects, except as noted.

c. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, 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.

d. The expedited review procedure may not be used for classified research involving human subjects.

e. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

f. Research categories 3.a. through 3.g. below pertain to both initial and continuing IRB review.

3. Research Categories

a. Clinical studies of drugs and medical devices only when condition 1) or 2) is met.

1) Research on drugs for which an investigational new drug application (21 CFR part 312) is not required. (Note: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

2) Research on medical devices for which (i) an investigational device exemption application (21 CFR part 812) is not required; or (ii) the medical device is cleared/approved for marketing, and the medical device is being used in accordance with its cleared/approved labeling.

b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

2) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

c. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition

assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. [45 CFR 46.101(b)(4)]. This listing refers only to research that is not exempt.)

f. Collection of data from voice, video, digital, or image recordings made for research purposes.

g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. [45 CFR 46.101(b)(2) and (b)(3)]. This listing refers only to research that is not exempt.)

h. Continuing review of research previously approved by the convened IRB as follows:

    1) where(i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    2) where no subjects have been enrolled and no additional risks have been identified; or

    3) where the remaining research activities are limited to data analysis.

i. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where research categories 3.b. through 3.h. do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

4. The IRB may use the expedited review procedure to review either or both of the following:

   a. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk;

   b. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

   Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

5. The IRB shall keep all members advised of research proposals that have been approved under the expedited review procedure by including a list of those proposals on the monthly agenda and subsequent minutes.

6. The department or agency heads[1] may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

J. Criteria for IRB Approval of Research

The IRB approves research only when it has determined that all of the following requirements are satisfied:

1. Risks to subjects are minimized. Procedures used are consistent with sound research design and do not unnecessarily expose subjects to risk. Whenever appropriate, the research uses procedures already being performed on the subjects for other purposes, such as diagnosis or treatment.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB considers only those risks and benefits that may result from the research. The IRB does not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

[1] "Department or Agency heads" refers specifically to the heads of various federal departments or agencies, and not state government officials or campus department heads.

3. The selection of subjects is equitable, taking into account the purpose of the research and the setting in which the research will be conducted.

4. Informed consent is sought from each prospective subject or the subject's legally authorized representative. The IRB conforms to federal regulations of informed consent procedures and may impose additional requirements.

5. Informed consent is appropriately documented or appropriately waived, in accordance with, and to the extent required by, federal regulations. The IRB may also impose documentation requirements in addition to those required by federal regulations.

6. When appropriate, the research protocol makes adequate provision for monitoring the data collected to insure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included in the protocol to protect the rights and welfare of these subjects.

K. General Requirements for Informed Consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

1. Basic elements of informed consent. Except as provided in paragraph 3. or 4. of this section, in seeking informed consent the following information shall be provided to each subject:

    a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

b. A description of any reasonably foreseeable risks or discomforts to the subject;

c. A description of any benefits to the subject or to others which may reasonably be expected from the research;

d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

h. A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. 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) that are currently unforeseeable;

b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c. Any additional costs to the subject that may result from participation in the research;

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and

f. The approximate number of subjects involved in the study.

3. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; **and**

b. The research could not practicably be carried out without the waiver or alteration.

4. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

a. The research involves no more than minimal risk to the subjects; **and**

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**

c. The research could not practicably be carried out without the waiver or alteration; **and**

d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

5. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws that require additional

information to be disclosed in order for informed consent to be legally effective.

6. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

L. Documentation of Informed Consent

1. Except as provided in paragraph 3. of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

2. Except as provided in paragraph 3. of this section, the consent form may be either of the following:

   a. A written consent document that embodies the elements of informed consent required by section K. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

   b. A short written consent document stating that the elements of informed consent required by section K. have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

3. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

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

b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

M. Assurance of Compliance

The University of Maine conducts federally funded non-exempt human subject research; as such, it has a legally binding agreement with US DHHS -- a Federal Wide Assurance. This Federal Wide Assurance is administered by US DHHS's OHRP and governs all human subject research receiving, or eligible to receive federal (US DHHS) funds. This agreement is guided by the ethical principles of the *Belmont Report* and requires, at a minimum, compliance with 45 CFR 46 (The Common Rule). The University of Maine's Federal Wide Assurance number is: FWA00000479.

N. Review by Institution

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

O. Suspension or Termination of IRB Approval of Research

The IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. When the IRB exercises this authority, it promptly communicates its action and the reasons for the action in writing to the Principal Investigator, Institutional Official or other appropriate campus official, and the extramural sponsor of the research, if any.

P. Cooperative Research

Cooperative research projects are those projects covered by this policy, or the Common Rule, involving more than one institution, whether within UMaine System campuses or other institutions outside the System. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. A campus participating in a cooperative project may enter into a joint review arrangement with another campus IRB, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Q. IRB Records

1. The IRB shall prepare and maintain adequate documentation of its activities, including the following:

    a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

    b. Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; votes on actions including the number of members voting for, against, and abstaining; basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

    c. Records of continuing review activities.

    d. Copies of all correspondence between the IRB and the investigator.

    e. A list of all IRB members in the same detail as described in section F.

    f. Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

    g. Statements of significant new findings provided to subjects, as required by §46.103(b)(5).

2. The records required by this policy shall be retained for at least 3 years; and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspections and copying by authorized representatives of US DHHS OHRP at reasonable times and in a reasonable manner.

R. Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects

Certain types of research proposals may not have fully defined plans set forth in the application or proposal. Such proposals may include institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by the IRB before an application for award can

be filed, nor before an award may be made. However, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB.

S. Research Undertaken without the Intention of Involving Human Subjects

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by the IRB.

T. Use of Federal Funds

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

U. Early Termination of Research Support: Evaluation of Applications and Proposals

1. The IRB, senior administrator responsible for the IRB, or the UMaine System may terminate or suspend an approved project if an investigator has failed to comply with the terms of this policy.

2. The IRB, senior administrator responsible for the IRB, or the UMaine System may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph 1. of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have in their judgment materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

V. Conditions

With respect to any research project or any class of research projects, the senior administrator responsible for the IRB or the UMaine System may impose additional conditions necessary for the protection of human subjects.

II. Research Involving Children

A. Applicability

1. The regulations in this section are applicable to **all** biomedical and behavioral research involving children conducted by any member of the University of Maine.

2. All research involving children as subjects must comply with any state or local laws limiting such research.

3. The requirements of this section are in addition to those imposed under the other sections of the University of Maine Policies and Procedures for the Protection of Human Subjects of Research.

4. Note that the exemptions described in section C. of Administrative Procedures for Human Subjects Research and at 45 CFR 46.101(b)(1) and (b)(3) through (b)(6) are applicable to this section. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this section. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this section, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

B. Definitions

As used in this section:

1. 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.

2. Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

3. Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

4. Parent means a child's biological or adoptive parent.

5. Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

C. Special IRB Duties

In addition to other responsibilities assigned to the IRB in this section, the IRB shall review research covered by this section and approve only research that satisfies the conditions of all applicable parts of this section.

D. Research not Involving Greater than Minimal Risk (45 CFR 46.404)

Research in which the IRB finds no greater than minimal risk to children to be present may be approved only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth below.

E. Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subject (45 CFR 46.405)

If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, the proposed research may be approved only if the IRB finds that:

1. The risk is justified by the anticipated benefit to the subjects;

2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in H. in this section. [§46.408]

F. Research Involving Greater than Minimal Risk and no Prospect of Direct Benefit to the Individual Subject, but likely to Yield Generalizable Knowledge about the Subject's Disorder or Condition (45 CFR 46.406)

If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, the proposed research may be approved only if the IRB finds that:

1. The risk represents a minor increase over minimal risk;

2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

3. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

4. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians as set forth in H. in this section. [§46.408]

G. Research not Otherwise Approvable that Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children (45 CFR 46.407)

If the IRB does not think the proposed research meets the requirements of the three immediately preceding conditions, research may only be approved if:

1. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

2. The Secretary of US DHHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

   a. The research in fact satisfies the conditions in D., E., or F. in this section [§46.404, §46.405, or §46.406], as applicable, or
   b. the following:

      1) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

      2) the research will be conducted in accordance with sound ethical principles;

      3) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in H. in this section.

H. Requirements for Permission by Parents or Guardians and for Assent by Children (45 CFR 46.408)

1. In addition to the determinations required under other applicable sections of this section, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB

the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with section K. of the Administrative Procedures for Human Subject Research. (45 CFR 46.116)

2. In addition to the determinations required under other applicable parts of this section, the IRB shall determine, in accordance with and to the extent that consent is required by K. of the Administrative Procedures for Human Subject Research (§46.116), that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under D. and E. in this section [§46.404 or §46.405]. Where research is covered by F. and G. in this section [§46.406 and §46.407] and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

3. In addition to the provisions for waiver contained in L. [§46.116] of the Administrative Procedures for Human Subject Research, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in A. in this section and paragraph 2. above provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

4. Permission by parents or guardians shall be documented in accordance with and to the extent required by L. [§46.117] of the Administrative Procedures for Human Subject Research.

5. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

I. Wards

1. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under F. and G. in this section (§46.406 or §46.407) only if such research is:

   a. Related to their status as wards; or

   b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

2. If the research is approved under paragraph 1. above, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in *loco parentis*. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

III. Research Involving Prisoners

A. Applicability

1. The regulations in this section are applicable to **all** biomedical and behavioral research involving prisoners conducted by any member of the University of Maine.

2. All research involving prisoners as subjects must comply with any state or local laws limiting such research.

3. The requirements of this section are in addition to those imposed under the other sections of the University of Maine Policies and Procedures for the Protection of Human Subjects of Research.

B. Purpose

Inasmuch as prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this section to provide additional safeguards for the protection of prisoners involved in activities to which this section is applicable.

C. Definitions

As used in this section:

1. Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. The University of Maine extends the term “prisoner” to include persons on pre-trial supervised release, on community supervision or on probation, or who is in any court-ordered deferred prosecution or diversion program.

2. Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

D. Composition of IRB where Prisoners are Involved

In addition to satisfying the requirements in section F. of the Administrative Procedures for Human Subject Research, the IRB shall also meet the following specific requirements:

1. A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.

2. At least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB only one Board need satisfy this requirement.

A prisoner representative with appropriate background may include an attorney with experience in criminal defense or prisoners' rights, a member of a prisoners' rights advocacy organization, a chaplain or a counselor or other similar professional who deals, or has dealt with, prisoners.

E. Additional Duties of the IRB where Prisoners are involved

1. In addition to all other responsibilities prescribed for the IRB under this part, the IRB shall review research covered by this subpart and approve such research only if it finds that:

    a. The research under review represents one of the categories of research permissible under 306(a)(2);

    b. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

    c. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

    d. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the

group of available prisoners who meet the characteristics needed for that particular research project;

e. The information is presented in language which is understandable to the subject population;

f. Adequate assurance exists that parole boards, community release supervisors, and/or probation officers will not take into account a prisoner's participation in the research in making decisions regarding parole, community supervision, or probation, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole, community supervision, or probation; and

g. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

2. The IRB shall carry out such other duties as may be assigned by the Secretary of the US DHHS.

3. The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the IRB under this section have been fulfilled.

F. Permitted Research Involving Prisoners

1. Biomedical or behavioral research not conducted or supported by DHHS may involve prisoners as subjects only if all of the conditions outlined above for general human subject research, and the special conditions for research with prisoners, are met.

2. Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

a. The institution responsible for the conduct of the research has certified to the Secretary that the IRB has approved the research under 45 CFR 46.305; and

b. In the judgment of the Secretary, the proposed research involves solely the following:

1) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

2) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere; and research on social and psychological problems, such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the *FEDERAL REGISTER*, of his intent to approve such research; or

4) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the *FEDERAL REGISTER*, of the intent to approve such research.

3. Except as provided in paragraph F.2. of this section, biomedical or behavioral research conducted or supported by US DHHS shall not involve prisoners as subjects.

IV. Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

This subpart applies to all research involving pregnant women, human fetuses, neonates, and neonates of uncertain viability or nonviability.

The exemptions noted in section C. of Administrative Procedures for Human Subject Research are applicable to this subpart.

This policy does not alter any present or future state or local laws or regulations that may otherwise be applicable and which may provide additional protections for human subjects. This subpart is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

This policy does not alter any present or future foreign laws or regulations that may otherwise be applicable and which may provide additional protections for human subjects.

A. Definitions

1. Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she test positive on a pregnancy test or exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative, or until delivery.

2. Fetus means the product of conception from implantation until delivery.

3. Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

4. Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

5. Neonate means a newborn.

6. Viable, as it pertains to a neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

7. Nonviable neonate means a neonate after delivery that, although living, is not viable.

B. Research Involving Pregnant Women or Fetuses

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical studies (including studies on pregnant animals) and clinical studies (including studies on nonpregnant women) have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

2. The risk to the fetus is caused solely by interventions or procedures that have the prospect of direct benefit for the woman or the fetus; or, if there is no prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

3. Any risk is the least possible for achieving the objectives of the research.

4. If the research has the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions.

5. If the research has the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father must be obtained in accord with the informed consent provisions, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

6. Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

7. For children who are pregnant, assent and permission are obtained in accord with the informed consent provisions for children.

8. No inducements, monetary or otherwise, can be offered to terminate a pregnancy.

9. Individuals engaged in the research can have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

10. Individuals engage in the research can have no part in determining the viability of a neonate.

C. Research Involving Neonates

1. A neonate, after delivery, that has been determined to be viable may be included in research by and in accord with the requirements described in sections Administrative Procedures for Human Subject Research and Additional Protections for Children Involved as Subjects in Research.

2. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

    a. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

    b. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

    c. Individuals engaged in the research will have no part in determining the viability of a neonate.

    d. Requirements outlined in 3. and 4. below have been met as applicable.

3. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the following additional conditions have been met:

    a. IRB determines that:

        1) The research has the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

        2) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research.

    b. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the section on

Administrative Procedures for Human Subject Research, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

4. After delivery, nonviable neonates may not be involved in research unless all of the following conditions are met:

   a. Vital functions of the neonate will not be artificially maintained.

   b. The research will not terminate the heartbeat or respiration of the neonate.

   c. There will be no added risk to the neonate resulting from the research.

   d. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

   e. The legally effective informed consent of both parents of the neonate is obtained. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.

D. Research Involving After Delivery, the Placenta, Dead Fetus, or Fetal Material

1. Research involving after delivery, the placenta, dead fetus, macerated fetal material; or cells, tissues, or organs excised from a dead fetus, must be conducted in accord with applicable federal, state, or local laws and regulations regarding such activities.

2. If information associated with 1. of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are considered research subjects.

WHAT ARE THE MAJOR CHANGES IN THE REVISED COMMON RULE?

Changes to definitions:

- The definition of research now excludes journalistic endeavors, oral histories and data collection for professional non-research purposes (examples, criminal justice activities and data collection for national security purposes).
- The human subject definition is changed to include identifiable biological specimens.

Changes to Continuing Review Regulations:

- As part of the new regulations, annual continuing reviews are eliminated for all new expedited studies approved on or after January 21, 2019, **unless the IRB determines that a continuing review should be required for a specific study**.
- Continuing review is also not required if the research was initially approved by a convened meeting and has progressed to the point that it involves only one or both of the following activities:
    - Data analysis (including analysis of identifiable information or identifiable biospecimens)
    - Access to follow-up clinical data from procedures that subjects would undergo as part of clinical care
- Full board studies will still need annual continuing review approval.
- Please note that even if a continuing review is not required modifications and reportable events (adverse events and/or unanticipated problems) must be submitted to the IRB for review.

Changes to Consent Forms:

Long consent forms and/or consent forms for federally funded studies will **require a concise summary**:

- The concise summary is meant to be brief. The purpose of the summary is for the participant to decide why he/she may want to participate but should also include information on why he/she may not want to participate in the study (for example a huge time commitment or other risks). The summary should not include all foreseeable risks but the risks that would be most likely or most severe to the participant.
- The summary should include the following 5 elements:
  1) A statement that the project is research and that it is voluntary.
  2) A summary of the research (purpose, overview of procedures etc.)
  3) Any foreseeable risks or discomforts
  4) Any expected benefits to participants (if applicable)
  5) If applicable, alternative procedures to course of treatment

You will find concise summary examples on the Forms and Samples page.

Changes to the Exempt categories:

Exempt 1 – Normal educational practices - Revised

- The following restriction was added “not likely to adversely impact student’s opportunity to learn required educational content, or assessment of educators who provide instruction”.

Exempt 3 Benign Behavioral Intervention – New category

- The former exempt category 3 was eliminated and replaced with a category granting exemption to studies involving only “benign behavioral interventions” with adult subjects. The data must be anonymous or non-sensitive, or have sufficient protections in place to ensure data security.
- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
- Benign behavioral interventions are defined as: “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.”

  Examples that would fit under Category 3:
  1. having subjects play an online game
  2. having subjects solve puzzles under various noise conditions
  3. playing economic games

- If a study involves deception, it can be exempt under category 3 if the participants are told during the recruitment/consent process that there is an element of deception in the study, and they agree to participate knowing this.

Exempt 7 – Not implemented at the University of Maine at this time

- Allows for the storage of data and/or specimens in a repository, with identifiers maintained, that were collected under an approved IRB protocol with Broad Consent* for future secondary use research.

Exempt 8 - Not implemented at the University of Maine at this time

- Allows for secondary research use/analysis of identifiable data/biospecimens that were collected under an approved IRB protocol with Broad Consent*

* Broad consent is an alternative consent process for use only for the storage, maintenance and secondary use of identifiable private information or biospecimens for future research (yet to be determined). See HHS Recommendations for Broad Consent Guidance for more information on broad consent.

At this time the University of Maine (similar to many other institutions) will not use broad consent.

Changes to review of cooperative research:

- Research conducted by investigators at multiple research sites must rely on a single IRB of record (sIRB). However, implementation for this is January 20, 2020.

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Anonymous vs. Confidential

When collecting data (most often from surveys), researcher will say that the data are anonymous or confidential.

The two words mean different things, and it is important for the participant, their protection, and their willingness to participate that the correct term is used.

Anonymous

1. The researcher is not collecting any unique identifiers from individual subjects (for example, name, email, phone number).
2. The researcher is not collecting identifiers that, if combined, would be likely to identify a participant (for example, age, race, occupation, years in that occupation in a relatively small sample of participants).

In short, anonymous data can never be linked to an individual.

Confidential

1. Confidential data means that the researchers will be able to identify the participants. But it also means that the data will never be reported in a way that allows a participant's identity to be known (e.g., responses are combined with those of other participants and reported in aggregate form).

In short, an activity is confidential if participants provide identifying information but the connection
between participant and results is not shared.

Data cannot be both anonymous and confidential.

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Continuing Review Instructions

In accordance with Federal Regulations, all Full Board and some expedited projects (determined by the IRB) must undergo a continuing review. Investigators must submit a protocol summary, a status report on the progress of the research, and current/new consent forms. Although investigators will receive a request from the IRB Office for review information, it is their responsibility to submit review information in sufficient time to allow for IRB review (at least three weeks prior to the approval expiration).

Where continuing review is not required, the IRB requires submission of a progress report at periodic intervals. At the time of initial approval, the IRB will specify the interval for submission in the approval notice. The IRB may set the interval for reporting at one, two, or three years. Future reporting requirements will be assessed during each review and may be changed at any time. The IRB office will send the PI a reminder for when the progress report is due.

Regardless of the requirement set by the IRB for reporting study progress (continuing review or progress report), investigators still must inform the IRB of any changes to the protocol and inform the IRB of reportable events.

Please respond to the following questions: (Please type your responses on a **separate sheet** of paper.)

1. Include a brief protocol summary. (This should be no more than one or two pages.)
2. Status Report Includes:
    1. Indicate the number of subjects accrued during this reporting period and, for ongoing studies, the total number accrued.
    2. Report all changes in personnel involved with the study.
    3. Include a description of any: adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research.

or complaints about the research.

4. Include a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, and any other relevant information, especially information about risks associated with the research.

3. Attach a copy of the current, IRB-approved informed consent document (stamped copy). Also include a "clean" copy for approval and stamping.

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Data Encryption

To ensure confidentiality of identifiable, electronic data, the Institutional Review Board (IRB) requires that the electronic key linking participants' identities to their data be encrypted. This is accomplished by the use encryption software. The IRB contacted Information Technologies for advice on encryption software, and below is their response:

The Information Security Office requires as a standard, AES 128 or AES 256 encryption for data at rest. By far the most popular encryption software employed in the UMS is BitLocker for Windows and FileVault for Macs. There isn't a cross-platform solution that we are aware of.

- Windows: BitLocker is included with Windows 8 and 8.1 and Windows 7 Enterprise and Ultimate versions (it is not known what the cost is for other versions of Windows 7). An open source alternative is Diskcrytor.
- Macs: FileVault2 is included with OS X version 10.7 and higher (the only supported versions of OS X).
- Linux: The most apparent encryption to us is Linux Unified Key Setup (LUKS).

There are many alternatives, including some that are not intended for full disk encryption, but suitable for file encryption. If there is a particular alternative that would someone would like to discuss, contact Information Technologies.

Remember!

- This is for ELECTRONICALLY COLLECTED/STORED IDENTIFIABLE DATA.
- If data are collected without identifiers (i.e., anonymous data), encryption is not required.
- Most often, the only data that must be encrypted is the computer file that is the key linking participants' names to collected data – generally a small file. If data are

linking participants' names to collected data – generally a small file. If data are coded, but the key is in paper format (i.e., handwritten), there is nothing to encrypt (obviously!).

- If electronic, identifiable data are not coded, the entire dataset must be encrypted. This might occur if: a) the dataset includes participants' names (usually not done), or b) the data could be identifiable because of the type of data collected (e.g., some demographics can identify people).

Contact the IRB Office with questions about the requirement, but contact Information Technologies for assistance in selecting/using an encryption program.

Institutional Review Board

Guidance for Researchers

Depression and Suicidality in Human Research

Overview

University of Maine research studies often include measures that screen for depression (e.g., Beck Depression Inventory (BDI), Children's Depression Inventory (CDI), Structured Clinical Interview). The Institutional Review Board for the Protection of Human Subjects (IRB) has developed this guidance to assist researchers as they develop and write their human subjects application proposing to use such measures. The IRB's goal is to be sure that applications for studies assessing depression and/or suicidality consistently contain information on the use of such measures, as well as plans for follow-up with participants whose responses raise concerns regarding level of depressive symptoms and/or intent to harm him/herself.

Adult Participants:

1. Information to be included in an IRB application where adult participants are anonymous:

If research is proposed where data collection will be anonymous (e.g., on-line surveys, paper/pencil surveys):

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide item, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks).

- The consent form must include referrals for mental health services (following the referral template found on the IRB website). In addition to the consent form, referrals should repeated at the end of the survey.

2. Information to be included in an IRB application where adult participants' identities are known:

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide item, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks).

- The risk section must, in addition to stating that referrals for mental health services will be provided, describe the researcher's plan for follow-up in situations where a participant's responses/score indicate a high level of depressive symptoms and/or intent to harm him/herself.

- The consent form (risk section) must, in addition to listing referrals in case they become upset (following the referral template found on the IRB website), inform the potential participant that the researcher will follow-up with them if their responses to the questionnaires cause the researcher to be concerned for their well-being.

Instructions for follow-up:

- **In the case of follow-up for depressive symptoms**, the researcher should follow-up as soon as possible after the measures are completed. For studies done in the lab, if the instruments could be scored quickly, a discussion could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):

    - "I am [investigator/faculty supervisor] of the research study that you recently completed. From your answers to the questionnaires, you seemed to be feeling quite down. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider." Repeat the Counseling Center information for UMaine students and the community resources that were originally given community participants.

    - Researchers will need to be sure contact information is obtained at the start of the study (especially critical for community participants). This could be a sentence at the end of the consent form asking for preferred method of contact.

- **In the case of follow-up for responses indicating suicidality or imminent harm:** (regardless of the participant's total score), the researcher must follow-up the same day the measure is taken. For studies done in the lab, if the instruments could be scored quickly, a discussion could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):

    - "I am [investigator/faculty supervisor] of the research study that you recently completed. From your answers to the questionnaires, I am concerned that you may harm yourself. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider." Repeat the Counseling Center information for UMaine students and the community resources that were originally given community participants. If the researcher feels immediate intervention is required, contact the Counseling Center (UMaine Students only) or Community Health & Counseling Services has a mobile crisis team that will respond on-site.

- Researchers will need to be sure contact information is obtained at the start of the study (especially critical for community participants). This could be a sentence at the end of the consent form asking for preferred method of contact.

Minor Participants:

1. <u>Information to be included in an IRB application where minor participants are anonymous:</u>

If research is proposed where data collection will be anonymous (e.g., on-line surveys, paper/pencil surveys):

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide item, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks, school district will not allow question to be used, etc.).

- Referrals for mental health services must be provided in the consent form to parent/guardian (following the referral template found on the IRB website).

2. <u>Information to be included in an IRB application where minor participants' identities are known:</u>

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide question, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks, school district will not allow question to be used, etc.).

- The risk section must, in addition to stating referrals for mental health services will be provided, describe the researcher's plan for follow-up in situations where a minor's responses/score indicate a high level of depressive symptoms or intent to harm him/herself. (If the study is conducted at a school, it may be the case that parents/guardians are informed that the guidance counselor will be informed and he/she will follow up with them.)

- The parental consent form (risk section) must, in addition to listing referrals in case their son/daughter become upset (following the referral template found on the IRB website), inform the parent/guardian that the researcher will follow-up with them if their child's responses to the questionnaires cause the researcher to be concerned for his/her well-being. (If study is conducted at a school, it may be the case that

parents/guardians are informed that the guidance counselor will be informed and he/she will follow up with them.) The assent script should tell children that if the researcher is concerned about how they are feeling, they will talk with their parent (or guidance counselor).

Instructions for Follow-up:

- **In the case of follow-up for depressive symptoms**. The parent/guardian is most often the one who will be contacted with concerns. When research is conducted in schools, it is often the case that the guidance counselor is the first point of contact. Researchers need to check with schools to design follow-up procedures. For studies done in the lab, if the instruments could be scored quickly, a discussion with the parent/guardian could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):

    - "I am [investigator/faculty supervisor] of the research study that your son/daughter recently completed. From his/her answers to the questionnaires, he/she seemed to be feeling quite down. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider." Repeat the community resources that were originally given community participants.

    - Researchers will need to be sure contact information is obtained at the start of the study. This could be a sentence at the end of the consent form asking for preferred method of contact.

- **In the case of follow-up for responses indicating suicidality or imminent harm**. The parent/guardian is most often the one who will be contacted with concerns. When research is conducted in schools, it is often the case that the guidance counselor is the first point of contact. Researchers need to check with schools to design follow-up procedures. For studies done in the lab, if the instruments could be scored quickly, a discussion with the parent/guardian could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):

    - "I am [investigator/faculty supervisor] of the research study that your son/daughter recently completed. From his/her answers to the questionnaires, I am concerned that he/she may have thoughts about harming him/herself. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider." Repeat the community resources that were originally given community participants.

- Researchers will need to be sure contact information is obtained at the start of the study. This could be a sentence at the end of the consent form asking for preferred method of contact.

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Exemption Categories

It is important to remember that the investigator may not determine on his/her own that the proposed research is exempt from further review. An application must be submitted to the IRB.

Research Activities that may be Exempt from Further Review

Research involving children*, fetuses, prisoners, mentally disabled persons, or other adult subjects of diminished autonomy is subject to special restrictions. For adult subjects of undiminished autonomy, capable of making a truly voluntary and uncoerced decision whether or not to participate as subjects in research, the categories of research exempt from further review requirements are:

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 subjects can be identified, directly or through identifiers linked to the subjects; and
   - any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation.

3. Research involving Benign Behavioral Interventions through verbal, written

3. Research involving benign behavioral interventions through verbal, written responses, (including data entry or audiovisual recording) from *adult* subjects who prospectively agrees and ONE of the following met:
    - Recorded information cannot readily identify the subject (directly or indirectly/linked);
    - Any disclosure of responses outside of research would NOT reasonably place subject at risk (criminal, liability, financial, employability, educational advancement, reputation); OR
    - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily ascertained, directly or indirectly through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required.

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 subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are 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.

When the human subjects are children, only five of the above categories apply. Exemption 2 (for research involving survey or interview procedures or observations of public behavior), does not apply to research with children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

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FERPA Guidance

Considerations When Collecting Student Records

When collecting education records from students (K-12 and higher education) The Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupils Rights Amendment (PPRA) are two laws that must be taken into consideration.

FERPA (34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. **It is the investigator's responsibility to be aware of when these laws would affect their research and to be aware of his/her obligations with the school.**

PPRA (20 U.S. Code § 1232h) is a federal law that affords certain rights to parents of minor students with regard to surveys that ask questions of a personal nature.

FERPA

Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record.

Exceptions to FERPA

1. FERPA allows schools to disclose those records, without consent, to the following parties or under the
following conditions:

- School officials with legitimate educational interest;
- Other schools to which a student is transferring;

- Specified officials for audit or evaluation purposes;
- Appropriate parties in connection with financial aid to a student;
- Accrediting organizations;
- To comply with a judicial order or lawfully issued subpoena;
- Appropriate officials in cases of health and safety emergencies; and
- State and local authorities, within a juvenile justice system, pursuant to specific State law
- Organizations conducting certain studies for or on behalf of the school.

2. Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them.

Researchers should contact each educational institution from which he/she proposes to access student records and follow that institution's FERPA policy and procedures when accessing and proposing to disclose any directory information.

3. Schools may disclose information from student education records without prior consent if all personally identifiable information has been removed from the records, provided that the institution has made a reasonable determination that a student's identity would not be personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information.

Note that it is the educational institution that holds the student records that has to make this determination.

PPRA

The PPRA applies to the programs and activities of a State educational agency (SEA), local educational agency (LEA), or other recipient of funds under any program funded by the U.S. Department of Education. It governs the administration to students of a survey, analysis, or evaluation that concerns one or more of the following eight protected areas:

- political affiliations or beliefs of the student or the student's parent;
- mental or psychological problems of the student or the student's family;
- sex behavior or attitudes;
- illegal, anti-social, self-incriminating, or demeaning behavior;
- critical appraisals of other individuals with whom respondents have close family relationships;
- legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and
  ministers;
- religious practices, affiliations, or beliefs of the student or student's parent; or,
- income (other than that required by law to determine eligibility for participation in a program or
  for receiving financial assistance under such program).

Researchers whose research is subject to the PPRA should review the policies of the local educational
agency early in the study design process.

References

1) Things to consider when collecting student records (Yale University IRB)

1) Things to consider when collecting student records (Yale University IRB)
2) University of Pittsburgh Department of Education Policies and Procedures
3) FERPA: Federal Education Rights and Privacy Act (Lehigh University)

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Guidelines for Class Projects Involving Human Subjects

These guidelines are intended to assist instructors in determining when class projects meet the definition of research with human subjects and require review by the University of Maine's Institutional Review Board for the Protection of Human Subjects (i.e., IRB).

For questions or additional guidance, contact the IRB Office.

For clarification, the following are NOT class projects; if they involve human subjects, they are considered research and must be reviewed and approved by the IRB:

- Senior research projects conducted within the framework of the senior capstone experience
- Honors theses
- Master's theses
- Doctoral dissertations

—

- Instructors should meet with students as soon as possible and go over these guidelines to determine if the proposed class project could be considered research.
- If there is even a remote possibility that a class project may fall under the definition of research, instructors are advised to submit a human subjects review application with the student to the IRB. **Remember, class projects that involve protected populations, collection of sensitive information, or entities covered by another IRB, e.g., EMMC, Penobscot Nation (as defined at the end of this document) require IRB review and approval.**

If the class project meets the definition of research:

The instructor should meet with the student to prepare the human subjects review application.

- If the project goes before the Full Board at its monthly meeting, the instructor must attend the IRB meeting with the student.

If the class project <u>does not meet</u> the definition of research

Review Procedures

- Class projects that involve systematic collection of data and for which the design or objective is to develop or contribute to generalizable knowledge are considered research. In other words, if the student (or instructor) plans to use the data outside of the class, **the project is considered research and requires IRB review.**
- Marketing studies – if students collect data for a company or entity (e.g., restaurant) as part of a class marketing project, IRB review would NOT be required as long as these three conditions are met:
    - Students are simply giving the collected data to the company, and the data are for the company's internal use only (e.g., the data will not be presented in a public forum).
    - Students have no plans to use the data for an honors thesis, research presentation at conferences, master's thesis, or dissertation.
    - The project does NOT involve protected populations, collection of sensitive information, or involve entities covered by another IRB, e.g., EMMC, Penobscot Nation (as defined at the end of this document).
- Class projects that are designed solely with the objective of providing students with training about and experience with research methods are not considered research. In cases in which data will not be used outside of the classroom context and data will be destroyed upon completion of the project, **these projects are not considered research and do not require IRB review. HOWEVER, if the instructor allows a student to design a class project that involves protected populations, collection of sensitive information, or entities covered by another IRB, e.g., EMMC, Penobscot Nation (as defined at the end of this document), IRB review and approval are required.**

Training Requirements

Instructors assigning class projects **are required** to complete the IRB training tutorial.

- Instructors should require students to complete the IRB training tutorial as part of the learning experience, even in cases when the student's project does not have to obtain IRB approval.

Instructors' Responsibilities

- Instructors should meet with students as soon as possible and go over these guidelines to determine if the proposed class project could be considered research.
- If there is even a remote possibility that a class project may fall under the definition of research, instructors are advised to submit a human subjects review application with the student to the IRB. **Remember, class projects that involve protected populations, collection of sensitive information, or entities covered by another IRB, e.g., EMMC, Penobscot Nation (as defined at the end of this document)**

require IRB review and approval.

If the class project meets the definition of research:

The instructor should meet with the student to prepare the human subjects review application.

- If the project goes before the Full Board at its monthly meeting, the instructor must attend the IRB meeting with the student.

If the class project does not meet the definition of research

- It is the responsibility of the instructor to ensure that the student project does not meet the definition of research.
- It is the responsibility of the instructor to ensure that the class project is conducted according to the ethical standards of the relevant discipline.
- Remember that from the participant's viewpoint, giving out personal information does not differ for a class assignment or a research project. Personal information is personal information. Instructors should advise students to identify the project to participants as a class assignment and be sensitive to the personal nature of the obtained information. Labeling the class project as "research" is inaccurate and misleading to participants.
- Students should inform participants that data will be destroyed after their assignment or class project is completed (end of the semester).
- Instructors are advised to tell students that data from human subjects should not contain any personal, identifying information whenever possible.
- All class projects must include informed consent language that closely follows the guidelines. Information on what to include in a consent form/script is described below. For an on-line survey, this would be the first page of the survey or in the email post.
- The IRB is available to give feedback on any proposed class project not meeting the definition of research, even though the IRB would not officially act on the project.

Any class project that meets the definition of research or involves protected populations, collection of sensitive information, or involves entities covered by another IRB, e.g., EMMC, Penobsoct Nation must be reviewed and approved by the IRB (contact the IRB Office). **Approval cannot be granted retroactively under any circumstances for any research project.**

We would like to acknowledge the use of IRB guidelines on class-related projects from both Pennsylvania State University and Duke University.

Information to Include in Email Postings or Verbal Scripts for Informed Consent

When information is collected for a class project that does not meet the definition of research (as defined by the federal regulations) and does not require approval by the IRB, it is still important to "inform" the participants about the class project, whether posted as an email message or presented verbally in person. Make sure the participant is told:

- The identity of the student (introduce yourself!). (This may not always be necessary, as many students enlist the help of friends or family to collect data for a class project.)
- They must be at least 18 years of age to participate.
- It is a class project. (Give a little information, e.g., This is for my business class, I am trying to see if there is a relationship between X and Y.)

- What they will be asked to do ("I would like to ask you some questions about why you chose to attend the University of Maine. If there are any questions you don't want to answer, it is fine to skip them.").
- How long the interview, survey, etc., may take to complete.
- What will happen to the information collected ("The information will be used to write my paper for the class, and I will give a presentation in class. All of my notes, surveys, etc., will be destroyed when the semester is over.")
- If they will be identified: examples: "I will not write your name on my notes"; "Do not write your name on the survey;" "I will not use your name in my paper."
- The student's and instructor's contact information if they have any questions (provide phone number/email).

Here is an example of a posting for a survey: NOTE: If you use Qualtrics, SurveyMonkey, etc., the consent information should also be the first page of the survey.

This survey is for a class research project in (Course #/Name.) Our names are XXXXX. We are conducting a survey about XXX for a report and a class presentation.

Participation: You need to be at least 18 to participate. Participation is voluntary. You can stop the survey at any time or skip questions. The survey should take only about 10 minutes to complete.

Risks: Risks for participating are minor—just your time.

Confidentiality: We are not collecting any names, so the survey is anonymous.

Presentation: We are going to use the information for a class presentation and then destroy survey data.

Contact Information: Please contact us if you have any questions: names/emails

Instructor: name and contact information)

Protected Populations/Sensitive Information/Other Exceptions

*Protected Populations – Examples include, but are not limited to:

- Children/Minors (under the age of 18) (**Exception** – projects conducted in established or commonly accepted educational settings involving normal educational practices. Contact IRB office for guidance.)
- Prisoners (now includes non-publicly available secondary data)
- Pregnant women
- Fetuses and products of labor and delivery
- People with diminished capacity to give consent
- Mentally or physically challenged individuals

*Sensitive Information – Examples include, but are not limited to:

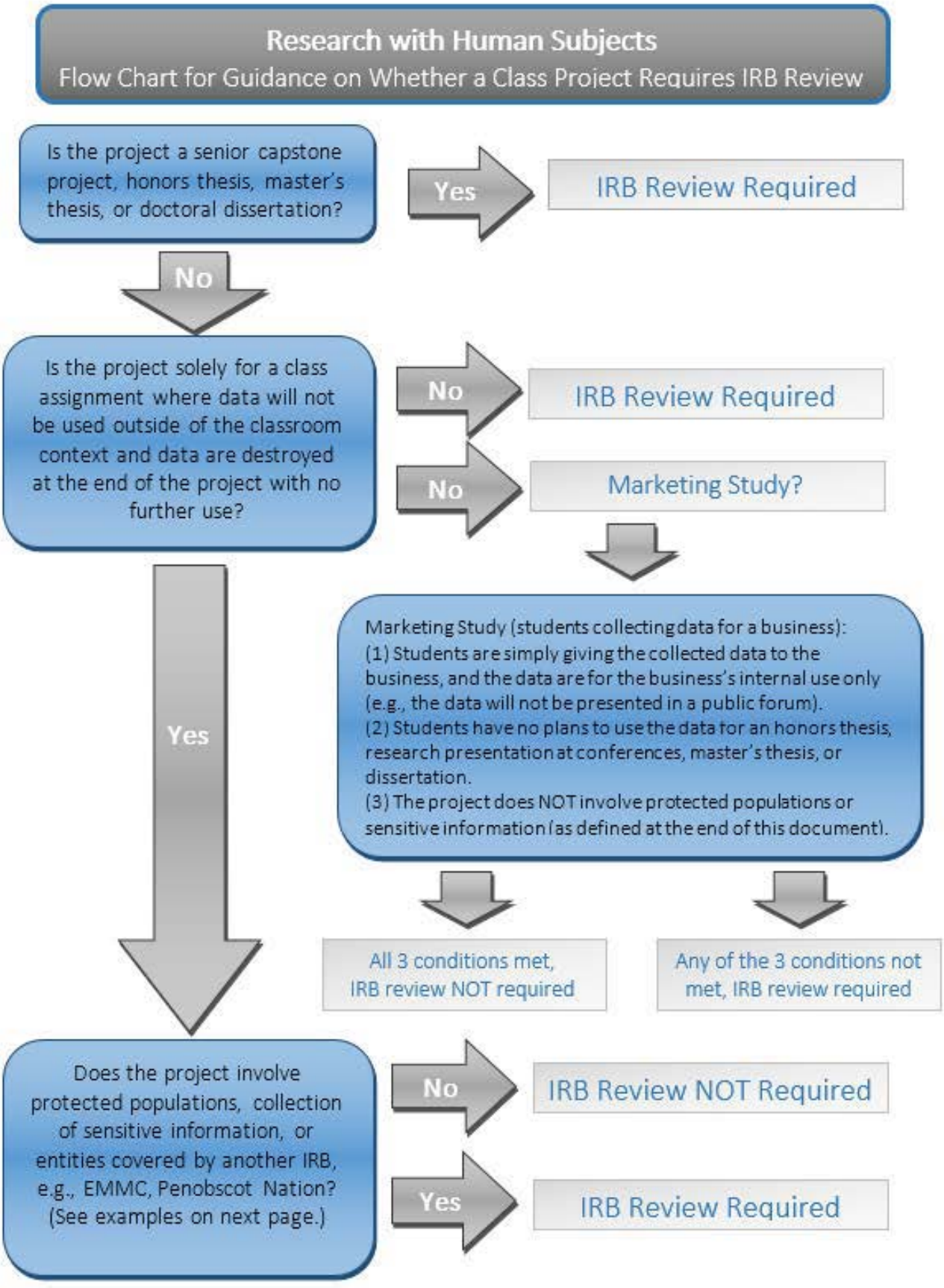
- Information relating to an individual's psychological well being or mental health
- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol or drugs
- Information relating to illegal behavior
- Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation
- Information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to discrimination, stigmatization, etc.

*Other:

- Be aware that there could be instances where a class project could fall under the authority of another IRB such that these guidelines would not apply, e.g., studies proposed to involve Eastern Maine Medical Center (EMMC) staff or patients, members/citizens of the Penobscot Nation (specifically targeted).

*Instructors/students who are unsure of whether a proposed project involves a protected population or sensitive information should contact the IRB Office.

Flow Chart for Guidance on Whether a Class Project Requires IRB Review (PDF)


Research with Human Subjects
Flow Chart for Guidance on Whether a Class Project Requires IRB Review
Is the project a senior capstone project, honors thesis, master's thesis, or doctoral dissertation?
Yes
IRB Review Required
No
Is the project solely for a class assignment where data will not be used outside of the classroom context and data are destroyed at the end of the project with no further use?
No
IRB Review Required
No
Marketing Study?
Yes
Marketing Study (students collecting data for a business):
(1) Students are simply giving the collected data to the business, and the data are for the business's internal use only (e.g., the data will not be presented in a public forum).
(2) Students have no plans to use the data for an honors thesis, research presentation at conferences, master's thesis, or dissertation.
(3) The project does NOT involve protected populations or sensitive information (as defined at the end of this document).
All 3 conditions met, IRB review NOT required
Any of the 3 conditions not met, IRB review required
Does the project involve protected populations, collection of sensitive information, or entities covered by another IRB, e.g., EMMC, Penobscot Nation? (See examples on next page.)
No
IRB Review NOT Required
Yes
IRB Review Required

Examples of Protected Populations/Sensitive Areas/Other Exceptions

Protected Populations – Examples include, but are not limited to:

- Children/Minors (under the age of 18) (Exception – projects conducted in established or commonly accepted educational settings involving normal educational practices. Contact IRB office for guidance.)
- Prisoners (now includes non-publicly available secondary data)
- Pregnant women
- Fetuses and products of labor and delivery
- People with diminished capacity to give consent
- Mentally or physically challenged individuals

Sensitive Information – Examples include, but are not limited to:

- Information relating to an individual's psychological well-being or mental health
- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol or drugs
- Information relating to illegal behavior
- Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation
- Information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to discrimination, stigmatization, etc.

Other –

- Be aware that there could be instances where a class project could fall under the authority of another IRB such that these guidelines would not apply – e.g., studies proposed to involve Eastern Maine Medical Center (EMMC) staff or patients, members/citizens of the Penobscot Nation (specifically targeted).

Instructors/students who are unsure of whether a proposed project meets the guidelines for class projects should contact the IRB Office at 1-2657, email: umric@maine.edu. Remember, the IRB will not conduct retroactive reviews, so ask questions early and plan early! Conducting research with human subjects without IRB approval is a violation of the University's Policy on the Protection of Human Subjects.

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CIE 424 URBAN TRANSPORTATION PLANNING SPRING 2010

Instructor: Per Gårder, contact me by First Class or e-mail Garder@Maine.edu or, if important, cell phone 852-8268. Open door office policy

Text: Urban Transportation Planning, Second Edition by Michael D. Meyer & Eric J. Miller. Publisher: McGraw-Hill, Inc. ©: 2001

Objectives: To teach students basic concepts and practices in the field of transportation planning, including the process and policy surrounding urban transportation planning.

Catalog Description: Basic concepts and practices in the field of transportation planning, including the process and policy surrounding urban transportation planning, characteristics of urban travel, air quality, noise, energy, land use, the elements of decision making, data management and diagnosis, demand and supply analysis, project evaluation and implementation. A transportation demand management study constitutes a major part of the course. (2.0 ED/1.0 ES) Lec. 3. Prerequisites & Notes: CIE 225. Credits: 3

Expected Course-Specific Outcomes:

The student will:

1. understand basic terminology used by transportation planners
2. have a basic understanding of some of the history behind today's transportation planning
3. understand how automobile traffic influences safety, mobility, environment, and financing
4. understand how trips are generated, distributed and assigned to modes and routes
5. acquire an understanding of professional and ethical responsibility
6. acquire a knowledge of contemporary transportation-planning issues
7. acquire an understanding of the impact of engineering solutions in a global and societal context
8. acquire an ability to identify, formulate, and solve transportation planning problems
9. acquire an ability to design and conduct experiments, as well as to analyze and interpret data
10. acquire an ability to design a system, component, or process to meet desired needs, such as maximum allowed noise levels.

General Information:

1. Good attendance is encouraged since the tests will include questions not only on the textbook but also additional material covered during the lectures. Quizzes may appear without any notice!

2 A project will be completed. The project will be worked on in groups of 2 - 4 students. The objective of the project will be decided on together with the students. It is recommended that this year, the projects should deal with issues relating to the City of Bangor's next comprehensive plan (due during 2010). Should Bangor's transportation systems be 'nudged' in a specific direction or should market-forces rule? What about bicycling? Public transportation? Connections to other regions, etc. But the project could also be to do a Travel Demand Management Study for a smaller urbanized area; or to look at noise concerns in…. or…. The work should typically include detailed structuring and scheduling of the study, formulation of hypotheses to be tested, observational field studies, making up and administering interviews and questionnaires, the writing of a report, and presentations of the findings to the class and possibly to invited professionals. ***Survey forms must be discussed in class before they are administered.*** If a project includes a survey, or other direct interaction with people, make sure that:

a) You approach people over the age of 18 only
b) You identify the project to participants as a class assignment, not as university research
c) You inform participants that data will be destroyed after their assignment or class project is completed

d) The data does not contain any personal, identifying information whenever possible

e) The project includes informed consent language. For an on-line survey, this would be the first page of the survey or in the email post. Make sure the participant is told:
   - about the identity of the investigating student(s) (introduce yourself)
   - that this is a class project. (Give a little information, e.g., This is for my … class, I am trying to study…)
   - what they will be asked to do ("I would like to ask you some questions about why you …. If there are any questions you don't want to answer, it is fine to skip them.")
   - how long the interview, survey, etc., may take to complete
   - what will happen to the information collected ("The information will be used to write my paper for the class, and I may give a presentation in class. All of my notes, surveys, etc., will be destroyed …")
   - if they will be identified. Examples: "I will not write your name on my notes"; "Do not write your name on the survey;" "I will not use your name in my paper."
   - the student's and instructor's contact information if they have any questions (provide phone number/email).

f) Protected Populations. Do not approach these groups. Examples include, but are not limited to: Children/Minors (under the age of 18), prisoners (now includes non-publicly available secondary data), pregnant women, fetuses and products of labor and delivery, people with diminished capacity to give consent, mentally or physically challenged individuals.

g) Sensitive Information that you cannot include – Examples include, but are not limited to: Information relating to an individual's psychological well being or mental health; information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol or drugs; information relating to illegal behavior, information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation; information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to discrimination, stigmatization, etc.

3. Homework problems will be assigned but not collected or graded. Test questions will sometimes be similar to assigned homework.

4. Students are expected to be present during times assigned to the project and for all tests. Make-up tests will be given only for authorized medical reasons.

5. All computations and steps should be shown for all exams, whenever requested. Some tests may be of multiple-choice type.

6. Civil Engineering students must adhere to the University of Maine Conduct Code. Each student is expected to work independently on all exams, including take home exams. Students may neither give nor receive assistance on examinations. All written material, including term papers, reports, etc., must be the student's original work. The bounds of original work and the degree of collaboration that will be allowed in this class will be established by the professor. The work(s) of others may only be used with proper reference or acknowledgement. Failure to adhere to this policy can result in the receipt of a failing grade, suspension or dismissal from the University. Group interaction is generally necessary for laboratory data gathering and is encouraged but not necessary for data reduction.

7 Accommodations for students with disabilities: If you have a disability for which you may be requesting an accommodation, please contact either me or Ann Smith, Coordinator of Services for Students with Disabilities (Onward Building, 581-2319), as early as possible in the term.

8. No tuition refund will be allowed if course dropped later than second week of classes-unless very extraordinarily extenuating circumstances exist.

9. Examinations:

Test 1	15%	Quizzes	2% each	Main Project	20%
Test 2	15%	Mini-project 1/2	5%	Final exam	20%
Test 3	15%	Newspaper	3%		

10. Grades:

90% and above	A	70-74.99%	C
87.5-89.99%	A-	67.5-69.99%	C-
85-87.49%	B+	65-67.49%	D+
80-84.99%	B	60-64.99%	D
77.5-79.99%	B-	Below 60%	E
75-77.49%	C+		

11. SCHEDULE CIE 424: Tuesdays and Thursdays 8:00-9:15 in 130 Barrows Hall

Jan. 12 Introduction and consensus exercise
14 Rethinking Urban Sprawl. Andres Duane, video.
19 Chapter 1 & notes. Mini-project: Travel Diary Mini-project 1 and 2 assigned
21 Continued Chapter 1 and notes
26 Transportation Planning and Decision-Making, Question 7 (page 83) assigned + Mini-project assignment: Review BDN for two weeks 'environment' and 'transportation'
28 Transportation Systems, Chapter 3. Project. Finalizing overall objectives and group belongings.

Feb 2 Air Quality
4 Noise (Chapters 3, 7). Assignment
9 Energy-Land use (Chapters 3, 7)
11 Characteristics of Urban Travel
16 Safety, Travel costs, Chapter 3
18 Test 1
23 Data Management and Use, Chapter 4. Question 4 (page 239) assigned
25 Demand Analysis, Chapter 5 and Project-presentation of group objectives, draft outlines and discussion on surveying techniques

Mar 16 Trend analysis, Elasticity models Homework. Chapter 5.
18 Minimum path—equilibrium Assignment.
23 Gravity model, Chapter 5, Modified Question 6 (page 322) take-home quiz assignment
25 Logit model, Chapter 5. Questions 8 & 9 (page 324) assigned
30 Test 2

Apr 1 Urban Activity Systems. Chapter 6. Question 5 (page 377) assigned
6 continued Chapter 6
8 Supply Analysis (fundamental eq.), Chapter 7 Time-distance diagrams, queuing theory. Questions 1, 2, and 3 (page 474) assigned Transit/walking, Question 5 (page 476) assigned
13 Cost models, Chapter 7
15 Transportation System and Project Evaluation, Chapter 8. Question 4 & 6 (page 558) assigned
20 Program and Project Implementation, Chapter 9
22 Test 3
27 Project presentations
29 Traffic calming or SL. Class evaluation

May 3-7 Final Exam (open book)

Note: The above schedule and procedures in this course are subject to change in the event of extenuating circumstances. In the event of disruption of normal classroom activities due to an H1N1 swine flu outbreak, the format for this course may be modified to enable completion of the course. In that event, you will be provided an addendum to this syllabus that will supersede this version.

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Human Subject Payment Guidelines

1. University of Maine researchers may provide cash (or cash equivalents [incentives], including gift cards, meal money, apparel, etc.) to human subjects if the protocol has been approved by the Institutional Review Board (IRB).

2. It is the responsibility of the researcher (not the IRB, Office of Research Administration, or the Office of the Vice President for Research and Dean of the Graduate School) to make appropriate funding arrangements.

3. If the approved IRB protocol assures the confidentiality of human subjects, researchers will maintain the following data*, as specified in the IRB-approved protocol, in a secure project file:

- Subject name
- Subject address
- Date the payment was provided
- Value or amount of the payment
- Form of the payment
- Name of researcher providing the payment
- Peoplesoft chartfield combination
- UMS employee status of the subject (UMS employee or non-employee).

4. If the University of Maine is subject to an audit, researchers may be required to provide auditors access to confidential data.

5. If the value of a **one-time payment exceeds $75.00**, subject data must be reported to other offices within the University of Maine and University of Maine System, as follows:

- If the human subject is an employee of the University of Maine, the researcher must report any such payments to the Department of Human Resources. The Department

report any such payments to the Department of Human Resources. The Department of Human Resources will determine whether the value of the reported incentive needs to be added to the employee's gross wages, and whether the payment will be subject to taxation and withholding.

- If the human subject is not an employee of the University of Maine, the researcher shall report any such payments to Michael Noblet in the Department of Purchasing. The researcher will work with the Department of Purchasing to comply with IRS regulations that require the University of Maine System to issue a Form 1099 when cumulative payments to a non-employee reach $600 in a calendar year.

*If the subjects are minors, contact the IRB office for further guidance.

Guidelines last revised 09/29/2015.

University of Maine | Orono, ME 04469 | 207.581.1865

Office of Research Compliance

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Information About Oral History Activities

Recently, representatives from the Office of Human Research Protection (OHRP) and the Oral History Association engaged in a dialog about whether oral history interviewing activities meet the OHRP's definition of research. According to OHRP, oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and do not meet the definition of research offered by the Department of Health and Human Services. The University of Maine's IRB recognizes this and concurs that the majority of oral history interviewing projects probably do not constitute research.

However, some oral history interviewing projects may meet the definition of research. Thus, it would be difficult and misleading to adopt a policy for any type of activities by any department, group, or individuals under a particular heading (e.g., oral history interviewing projects) that unequivocally states that the activity does not meet the definition of research and does not require review by the IRB. The IRB realizes that individuals may construe our position on this issue as ambiguous. The IRB, however, needs to make decisions about projects on a case by case basis. Thus, we cannot adopt a policy that directly states that all oral history interviewing activities are not considered research. We offer the following information that might be helpful in determining when a project is considered to be or not to be research.

To assist individuals in determining when/if oral history activities require human subjects review, we have provided the following information from Michael Carome (OHRP). (This information represents a response to Northern Illinois University's request for clarification regarding oral history projects.)

The University of Maine's IRB found this information to be helpful. As University of Maine employees, students, and agents read this and see statements such as, "Unless such research is exempt under HHS regulations at 45 CFR 46.101(b)..." remember that it is

UMaine policy (as it is at most institutions) that someone OTHER than the investigator must determine if a project fits one of the six categories judged exempt from further review. "Exempt" does not mean a review is NOT required.

More formal guidance is expected from OHRP, so we will post additional information when/if it is available.

Listed below are the examples provided to assist in determining when a review might be required.

"As you are aware, representatives of oral history organizations earlier this year asked OHRP to review a policy statement that they had drafted regarding the relationship between research (as defined by the Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d)) and oral history activities. They also asked whether OHRP agreed with the content of their draft policy.

OHRP responded to the oral historians with a letter stating OHRP's concurrence with the draft policy statement that oral history activities in general do not involve research as defined by the HHS regulations and providing some suggested edits. I have attached a pdf file containing a copy of OHRP's letter below. Please note that the inclusion of the words "in general" in OHRP's response means that certain human subjects research activities may include oral history activities, and such research activities should be reviewed by an institutional review board (IRB) unless the research is exempt under HHS regulations at 45 CFR 46.101(b). I

Indeed, in its September 22 letter, OHRP noted that on occasion, investigators conducting human subjects research as defined by the HHS regulations may use oral history interviewing procedures. Unless such research is exempt under HHS regulations at 45 CFR 46.101(b), IRB review would be required if the research is conducted or supported by HHS or conducted under an applicable OHRP-approved assurance.

History

Issues regarding oral history and human subjects research date back to the National Commission and most recently emerged with NBAC, NHRPAC, and a letter from oral historians to OHRP.

The Regulatory Definition of Research

A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution's FWA and HHS regulations for the protection of human research subjects (45 CFR 46) is based on the prospective intent of the investigator and the definition of "research" under HHS regulations at 45 CFR 46.102(d): "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Specifically, for the purposes of our discussion, the evaluation of such activities hinges upon whether the person is engaged in the creation of "generalizable knowledge" that is, whether the activity represents a systematic investigation in which the person engaged in such activities intends to develop or contribute to generalizable knowledge. However, 45 CFR 46 does not provide a definition of "generalizable knowledge". Oral history activities, as described to OHRP by the oral history representatives, in general are designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge.

General principles for evaluating Oral History type activities

1. Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would NOT constitute "research" as defined by HHS regulations 45 CFR part 46.
    - Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.
2. Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute "research" as defined by HHS regulations at 45 CFR part 46.
    - Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.
3. Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive WOULD constitute research under 45 CFR part 46.
    - Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

An institution should perform an initial two step evaluation prior to deciding whether an activity constitutes human subject research:

- determine whether the activity constitutes "research" as defined by 45 CFR 46.102(d); and
- determine whether the "research" includes human subjects as defined by 45 CFR 46.102(f).

In summary, the August 26, 2003 Policy Statement attached to OHRP's September 22, 2003 letter was not drafted by OHRP, does not constitute OHRP guidance, and the characterizations of oral history activities in the third paragraph of the Policy Statement alone do not provide sufficient basis for OHRP's determination that oral history activities in general do not involve research as defined by HHS regulations at 45 CFR part 46. Other activities involving open-ended interview that have similar characteristics can involve research as defined by the HHS regulations when the activities are part of a systematic investigation designed to develop or contribute to generalizable knowledge."

We hope that the above information may be helpful to individuals who engage in oral history interviewing activities. If an individual has any question as to whether his or her project could be considered research, please contact the IRB office.

University of Maine | Orono, ME 04469 | 207.581.1865

7/2020

Informed Consent

Except where specifically waived or altered by the IRB under Section I.K.3-4 of the University of Maine's *Policies and Procedures for the Protection of Human Subjects of Research*, all human subjects research will require written informed consent. For projects exempt from further review, documentation (signature) of informed consent is not required, but the same basic elements of an informed consent should be applied. The following two paragraphs were taken from the Office for Human Research Protections (NIH) website on the protection of human subjects of research.

"Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process."

"Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. **Think of the document primarily as a teaching tool not as a legal instrument**."

NOTE: For studies requiring continuing review, approval information (with expiration date) will be added to the approved informed consent document; that version will be provided to the researcher and **must be used in obtaining consent**. This procedure helps ensure that only the current, IRB-approved informed consent document is presented to subjects and serves as a reminder to the investigator of the need for continuing review.

Informed Consent Checklist

Include these items in the form: **(NOTE: The form should be written at no higher than an eighth grade reading level. FOLLOW THE SAMPLES [INCLUDING HEADINGS] found on the IRB website.)**

1) With the Revised Common Rule that went in effect in January 2019 studies with longer consent forms (more than 1 page) or Federally funded studies a concise summary is required.
The concise summary is meant to be brief. The purpose of the summary is for the participant to decide why he/she may want to participate but should also include information on why he/she may not want to participate in the study (for example a huge time commitment or other risks). The summary should not include all foreseeable risks but the risks that would be most likely or most severe to the participant.

   The summary should include the following 5 elements:
   1) A statement that the project is research and that it is voluntary.
   2) A summary of the research (purpose, overview of procedures etc.)
   3) Any foreseeable risks or discomforts
   4) Any expected benefits to participants (if applicable)
   5) If applicable, alternative procedures to course of treatment

2) A statement that the potential subject is being asked to participate in a **research** project. Include the name of the person who is conducting the research and his/her title/department. If the principal investigator is a student, the faculty sponsor should also be identified with his/her affiliation.

3) An explanation of the purpose of the research.

4) A description of the procedures to be followed. Include sample questions from any instruments that may be used (not required for mail/internet surveys where the questionnaire is enclosed/follows the consent).

5) An estimate of the amount of time it may take to participate.

6) A risk statement (reasonably foreseeable risks or discomforts). Examples: in some studies, answering questions may cause people to become uncomfortable; for studies involving standard blood draws, the possibility of bruising exists. For studies that have no foreseeable risks, examples include, “There is no more risk to you in participating than in everyday living,” or “Except for your time and inconvenience, there are no risks to you from participating in this study.” Do not state that there are no risks – all studies have risks even if only time and inconvenience! Do not state “You could become uncomfortable answering questions and except for your time and inconvenience, there are no risks to you from participating.” If someone could

become uncomfortable answering questions, the risk is more than time and inconvenience – it's one or the other.

7) A description of any potential benefits to the subject or to others that may *reasonably* be expected from the research. It is possible that a study will have no direct benefit to the participant! (e.g., "While this study will have no direct benefit to you, this research will help us learn more about…"). **There should be two statements** – benefit of the research to the participant and benefit of the research in general.

8) A description of compensation, if applicable. List any compensation for participation (money, course credit, etc.). Also indicate how compensation will be handled if a participant withdraws from the study. Do not include if there is no compensation.

NOTE: If the compensation exceeds $75 in value, the following language should be added to the Compensation Section (See Human Subjects Payment Guidelines for additional information.).

Basic information (your name and address, date of payment, value of payment, my name as researcher) will be given to a University office for tax reasons:

- *Employee of UMaine (including student employee): Information will be sent to the Human Resources Department. The value of the compensation may be added as wages and subject to taxation.*
- *Non Employee: Information will be sent to the Purchasing Department. If you receive $600+ during a calendar year (January 1 – December 31) from participating in UMaine research projects, Form 1099 will be generated and mailed to you. If you do not receive that much money, information will be destroyed at the end of the calendar year (i.e., December 31st).*

9) For treatment studies only, include a description of appropriate alternative procedures or courses of treatment that might be advantageous to the subjects.

10) A description of confidentiality. Will names be associated with the data? Will the data be coded and linked to a master list of names (key)? Who will have access to the data? Where will the data be stored (e.g., locked office, password protected computer)? If you are keeping the key electronically, you need to encrypt it (see guidelines on encryption. Explain the retention of the data (including any audio, video, or film recordings): a) if coded, when will the key be destroyed? and b) How long will the data be kept (e.g., destroyed by *date*, kept indefinitely, etc.)? Is the study anonymous? Don't confuse anonymity and confidentiality. If names are connected to data (even if you have coded the data), you can't tell participants that their identity will remain anonymous! You can only guarantee anonymity if no one, including you as the researcher, can identify participants. If participants will be involved in a group interview, you can assure them that you will keep their

responses confidential and will ask other participants to do the same, but you cannot absolutely guarantee that other group members will keep their responses confidential. Use dates (month/year) for destroying keys, data, etc., if applicable. Do not simply say "upon completion" or "when all data have been collected." Participants don't know when that will be!

11) A statement that participation is voluntary. If subjects choose to participate, they may stop at any time or skip any questions they do not wish to answer. If the study involves compensation such as payment or course credit, make sure it is clear what happens if they drop out (e.g., do they have to complete the entire study to receive the compensation, is there partial compensation for completing part of the study, or do they receive the compensation regardless of the length of participation (e.g., "you may stop at any time without loss of research credit").

    For an anonymous mail survey, include the statement, "return of the questionnaire implies consent to participate" (if electronic, use "submission").

12) An explanation of who to contact for answers to questions about the research (include name, phone, e-mail). If a student is the principal investigator, also include the same information for the faculty sponsor. Also include a statement directing people to the Office of Research Compliance, University of Maine, 207-581-2657, umric@maine.edu, if they have questions about their rights as a research participant.

13) A statement that their signature (if not exempt) indicates they have read and understand the information and agree to participate. Indicate that they will receive a copy of the form. The investigator should NOT sign the consent form – doing so gives the appearance of a contract, which is not accurate.

Other suggestions:

- Use familiar words, e.g., "cholesterol" instead of "blood lipids."
- Avoid using scientific, medical, or legal terms – if you must use them, define them.
- Avoid abbreviations or acronyms.
- Use bullets if procedures are lengthy.
- For ease of reading, have "white space" on the form.
- Know your target population. For example, if you are studying the elderly, use a larger font size.
- Have someone else outside your discipline read the informed consent for readability/comprehension.

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How to Request a Modification to a Previously Approved Study

Follow these simple steps to modify an existing study:

1. Using a different color font (or track changes), edit **all** applicable sections of the previously approved application (make sure you are using the final approved copy). Make sure new recruitment materials (emails/flyers), new measures, new consent forms, etc., are included, as applicable. Note that changes in the procedure often need to be reflected in the consent (e.g., adding measures may increase the time needed to complete the study). This edited application should be **ONE document (Word only; no PDF)**.
2. Please note that if you have already collected data but now want to change methods/measures going forward, you need to retain all of your original approved materials in the application and then add the modification describing what you want to do differently in the future.
   You should clearly designate the original procedures vs. the new procedures. The application needs to reflect the **entirety** of the project.
3. Send an email to umric@maine.edu requesting the modification. The email should reference the title and number of the approved application, and briefly describe the modification. Attach the updated application and send.

When is a modification really a new study?

If the proposed modification includes changes to two or more of the following criteria, the IRB would consider this to be a new study and the investigator would need to submit a new study application.

1. Study population

2. Study procedures
3. Study purpose

Change in Personnel

If you simply need to update personnel on an approved study, you do not need to edit the approved application. An email referencing the study title and number along with name of person(s) to be added, years of human subjects research experience, role on the project, and email is sufficient. If the CITI training was not completed through UMaine please also provide the training certificate.

Some personnel changes may also require a change to other sections of the application such as the consent document, and recruitment materials. In such cases, the application should be modified to include these changes and submitted as a modification for review.

Please contact the IRB office with any questions.

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Internal Institutional Data Collections

Internal institutional data collections are typically not considered research* and, therefore, review by the Institutional Review Board for the Protection of Human Subjects (IRB) is not required. Internal data collections are most often used to change/improve a campus service. Examples include:

1. Surveys of dining preferences
2. Evaluations of student satisfaction for accreditation reports
3. Exit surveys for graduates or employees
4. Surveys to determine residence hall programming needs

If an internal institutional data collection follows the examples and purpose stated above (i.e., to change/improve a campus service), IRB review is not required. If you have any questions on whether a proposed internal institutional data collection requires IRB review, please contact the IRB Office.

*Research is defined as: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)] Generalizable knowledge is information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

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Reactivating a Closed Study

Re-opening a closed study is handled on a case by case basis by the IRB. You can request reactivating a closed study up to 12 months after the study was closed. After this time, a new application submission will be required.

To re-open the study the PI must submit the following:

1. The reason why the study was closed and the reason why it needs to be re-opened.
2. Confirmation that no participants were enrolled and no data collection occurred while the study was closed and that this is the continuation of the same study.
3. If applicable, a modification with any requested changed to the application, personnel, etc. since the application was last approved.
4. An updated continuing review (if applicable) will need to be submitted.
5. If participants need to be notified of the re-opening, the PI must explain how this will be accomplished.

ATTENTION RESEARCHERS:
This is a template for a handout to be used for studies on sensitive topics where referrals are required. Edit as necessary and delete this row containing these instructions. Be sure to provide names of organizations (with contact information and hours of operation) that are relevant to your specific study. All contact information must be accurate and up-to-date. National directories may be appropriate for online studies where the locations of subjects are unknown.

Counseling Services

ON-CAMPUS RESOURCES Available for UMaine Faculty, Staff, and Students		
Counseling Center **Cutler Health Building (Gannet Hall side)** **(FREE to UMaine students)**	**207-581-1392** **http://www.umaine.edu/counseling/**	Weekdays 8:00 am-4:30 pm After business hours, call UMaine Police, 581-4040 or 911
Psychological Services Center **330 Corbett Hall** (Sliding fee scale; costs are your responsibility)	**207-581-2034** **https://umaine.edu/psychology/psychological-services-center/**	Weekdays 8:00 am – 4:30 pm

COMMUNITY RESOURCES Available to Anyone		
Community Health & Counseling Services **42 Cedar Street** **Bangor, ME 04401** (Any costs are your responsibility)	**207-947-0366** http://www.chcs-me.org/	Weekdays 8:00 am-5:00 pm
Maine Crisis Hotline (Any costs are your responsibility)	**1-888-568-1112** **https://heretohelpmaine.com/**	7 days/week 24 hours
Psychological Services Center **330 Corbett Hall** (Sliding fee scale; costs are your responsibility)	**207-581-2034** **https://umaine.edu/psychology/psychological-services-center/**	Weekdays 8:00 am – 4:30 pm
Contact Your Primary Care Provider (Any costs are your responsibility)		

NATIONAL RESOURCES
Behavioral Health Services Locator https://findtreatment.samhsa.gov/
National Suicide Prevention Lifeline, Toll-Free, 24-hour Hotline, 1-800-273-TALK (1-800-273-8255)

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Considerations When Assessing Sex and Gender in Research

The IRB at the University of Maine encourages researchers to be sensitive to and inclusive of differences when collecting data about identities of participants.

Definitions

Gender/Gender Identity is a person's internal held sense of their gender, regardless of biology.

Sex refers to biological differences between males and females, such as the genitalia and genetic differences. Sex is assigned at birth.

Sexual Orientation is a term used to describe one's pattern of emotional, romantic and/or sexual attraction.

Sample Questions

Below are sample questions and response options for gender identity, sex, and sexual orientation.

1. What is your current gender identity? (Check all that apply.)

- Male
- Female
- Transgender female / trans woman (or Male-to-Female (MTF) transgender, transsexual, or on the trans female spectrum)
- Transgender male / trans man (or Female-to-Male (FTM) transgender, transsexual, or

on the trans male spectrum)
- Non-binary, genderqueer, or genderfluid
- Gender identity not listed:
- Prefer not to reply

2. What is your sex assigned at birth?

- Male
- Female
- Intersex
- Not Listed:
- Prefer not to reply

3. What is your sexual orientation?

- Heterosexual/Straight
- Gay/lesbian
- Bisexual
- Pansexual
- Not listed:
- Prefer not to reply

4. [If investigators will refer to participants directly it is respectful to ask which pronouns they should use]:

> What pronouns would you like study staff to use when referring to you? (The PIs may want to consider introducing themselves by name and pronouns to demonstrate what this looks like and to indicate that this is an inclusive space).
>
> - He/him/his
> - She/her/hers
> - They/them/theirs
> - Other (please specify):

Tips for Researchers

- Use the term sex when reporting biological factors and gender when reporting gender identity, psychosocial or cultural factors.
- Consider if it is relevant to the study to include questions regarding sexual health history and/or sexual orientation.
- Sex, gender identity, and sexual orientation are both sensitive and personal characteristics. Therefore, it is important to protect this information, especially when recorded as identifiable. Investigators must ensure that research subjects provide this information in a location where they are comfortable and that ensures their privacy.
- All study documents (*including surveys*) should use gender-neutral language, avoiding gendered terms (e.g., mailman, chairman) and gendered pronouns (he, she, he/she). Gendered terms should be replaced with non-gendered versions (e.g., mail carrier instead of mailman or chairperson instead of chairman). Sentences using gendered pronouns should either use gender-neutral pronouns (e.g., singular they as in "Each subject will receive their gift card upon completing the study.") or be reworded entirely to avoid such pronoun use (e.g., "Subjects will receive their gift card upon completing the study.").
  Avoid presuming roles whenever possible. For example say "spouse/partner" instead of "husband/wife".

Incorporate gender neutral diagrams in research materials.

- Do not assume pronouns when interacting with a subject until they identify a preference.
- Train your research team members to increase their comfort level in asking and answering sensitive questions about gender and sexual orientation from subjects. The Fenway Institute is a good source for training materials.

References and Resources

Reporting Sex, Gender, or Both in Clinical Research

Guidelines and tips for collecting patient data on sexual orientation and gender identity

Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use

Canadian Institutes of Health Research Online Training Module

Reviewer Guidance to Evaluate Sex as a Biological Variable (NIH)

Inclusion of sex and gender in biomedical research: Survey of clinical research proposed at the University of Pennsylvania

UHSRC Guidance: Use of Gender Inclusive Language

Sex and Gender Research Considerations (Tufts)

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What is GDPR?

The General Data Protection Regulation (GDPR) is a European law that went into effect May 2, 2018 and establishes protections for privacy and security of "personal data" about individuals in the European Economic Area (EEA).

Please note that GDPR considers "coded date" to be "personal data" even where one lacks access to the key-code/coding system required to link data to an individual data subject. This is in contrast to US regulation protecting human subjects.

What countries are part of the EEA?

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the UK.

Please note that the participant does not need to be an EEA resident for the GDPR to apply.

Under GDPR what is considered "Personal Data"?

Information that relates to an identified person. Examples are: name, email, IP address or cookie number, personal characteristics (this also includes photographs).

Additional protections are given to sensitive personal information such as race, political opinions, religious beliefs, genetic data etc.

Tips on how to comply with GDPR?

If the study can be completed using de-identified data that would be the best option. If you need to collect personal data collect the minimum amount of demographic/personal data necessary.

Be aware that online survey sites often collect IP addresses by default so make sure you set up your survey to collect only the information you need for the study.

If you are collecting identifiable data you need to have a plan on how you will remove the data if the participant requests this.

How to ensure consent process complies with GDPR?

The consent process needs to be active so for example, in an electronic survey the participant should click to consent to proceed with the survey. It must be an affirmative action.

You must maintain consent records for the participants. For example, if the participant is giving verbal consent you must maintain a log with the subject name or ID and the date and time consent was provided.

Consent forms must contain the following information:

- Who is collecting the information? (must include contact information of person(s) collecting the information)
- What information is being collected?
- How is the information collected?
- How will the information be used?
- How will information be stored and for how long?
- Who will data be shared with?
- How does a participant withdraw from the study? (The participant needs to be informed of their rights to request access, erasure, and/or object to the processing of the data.)

Additional information about GDPR

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Zoom Guidance for IRB Studies

When using Zoom technology, at a minimum, please follow the guidelines outlined below:

1. Participants should be reminded to protect their privacy by completing activities in a private and quiet space, to ensure conversations are not overheard and ensure that there are minimal interruptions.

2. Researcher should establish ground rules with participants; this could include not taking screen shots, not recording the session etc.

3. Passwords should be used for Zoom meetings with research participants.

4. Participants should be told how and where Zoom recordings are saved.

To disable Cloud Recordings (this is the preferred setting for recordings) follow these steps:

- In the "Meeting Settings" select the "Recording" tab.
- Turn ON the "Record on the local computer" option.
- Turn OFF the "Cloud Recording" option.
- This enables you to save both audio and video files of Zoom recordings to your computer.

If using Cloud Recordings: In some cases, it may be necessary for you to use Cloud Recordings in order to utilize Zoom's "Audio Transcript" feature. If you would like to create Cloud Recordings, participants must provide their consent. You must include the following information in the "Confidentiality" section of the consent form:

- Tell participants that recordings will be stored on the Zoom Cloud and tell

them when those recordings will be deleted (recordings should be deleted as soon as possible from the Zoom Cloud).
- Tell participants that the recordings are subject to Zoom's privacy policy.

You have flexibility on how to present Zoom information to participants. Reminders can be part of consent form or recruitment script, or at the beginning of the Zoom session.

NOTE: The free and regular paid versions of Zoom are not HIPAA compliant and should not be used for any study involving the collection or use of protected health information (PHI).

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Federal and State Regulations & Guidance Materials

OHRP – Office for Human Research Protections

- 45 CFR 46 – Federal Regulations for the Protection of Human Subject – applies to ALL human subjects studies

NIH – National Institutes of Health

- Education Requirement – FAQs regarding the NIH Education Requirement
- Special Topics:
  - Certificates of Confidentiality
  - Data Sharing
  - Inclusion Policies for Research Involving Human Subjects
  - Single IRB

NSF – National Science Foundation

- Human Subjects – NSF Policy for human subjects research (HSR)
- Behavioral and Social Science Research – NSF interpretation of Common Rule and Behavioral and Social Science Research

FDA – Food and Drug Administration

Studies using investigational drugs, devices or biologics

- 21 CFR 50 – FDA Regulations for Protection of Human Subjects
- 21 CFR 56 – FDA Regulations for Institutional Review Boards
- Guidance for interpreting 21 CFR 50 and 56

- Comparison of FDA and HHS Human Subject Regulations

VHA – Veterans Health Administration

- ORO – Office of Research Oversight

HIPPA Regulations

- 45 CFR 160, 162 and 164

DoD – Department of Defense

- DoD Directives
- DoD Instruction

General

- The Belmont Report
- The Nuremberg Code
- Declaration of Helsinki ("The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects.")
- The Common Rule – Federal Policy for the Protection of Human Subjects

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Required Training for the Protection of Human Subjects

ALL personnel named in an existing or new "Application for Approval of Research with Human Subjects" must complete the Collaborative Institutional Training Initiative (CITI) web-based training on the protection of human subjects (this includes faculty sponsors on student studies).

Instructions for CITI Training (PDF)

The CITI training is valid for four years from the date of completion. After four years, the "refresher" modules will need to be completed (you will receive a reminder from CITI).

It is estimated that the training will take 1 hour. Passing score for quizzes is 80%. The components of the CITI training include:

- Basic Courses in the Protection of Human Research Subjects. While there are four choices when enrolling, the one that should be taken for the majority of UMaine faculty, staff, and students is Social and Behavioral Research Investigators. The Biomedical Research Investigators course can be selected for researchers that are conducting mostly biomedical research.

- Electives: These electives do not appear until you have completed the main course. Select the area(s) pertaining to your research. You might need to take more than one, but you are required to take at least one. If none of the electives seems relevant to your research, we suggest Conflicts of Interest in Research Involving Human Subjects or Internet Research.
    - Conflicts of Interest in Research Involving Human Subjects
    - International Research
    - Internet Research

- Research with Children
- Research with Prisoners
- Research in Public Elementary and Secondary Schools (we recognize the heading states "Public," but please take this module if your research is conducted in private elementary/secondary schools)

Instructions to Access CITI Training

Office of Research Compliance (ORC), University of Maine

The Office of Research Compliance (ORC) delivers a variety of research training through the University of Maine System (UMS) subscription service to the Collaborative Institutional Training Initiative (CITI). These instructions guide you through the institution-specific CITI registration and enrollment processes. Further information about Research Compliance at the University of Maine and training requirements can be found on the ORC website.

IMPORTANT NOTE: You are only required to complete the training(s) for your specific area(s) of research compliance.

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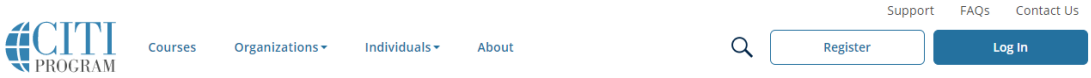
I. Establish a CITI Account

a. Please note: if you have previously set up a CITI account, please do NOT create another one. See Section II (Log into CITI as an Existing User) of this document for guidance.

b. Go to [CITI Program (https://about.citiprogram.org/)](https://about.citiprogram.org/) and click on the white "Register" button located in the upper right hand corner of the homepage.



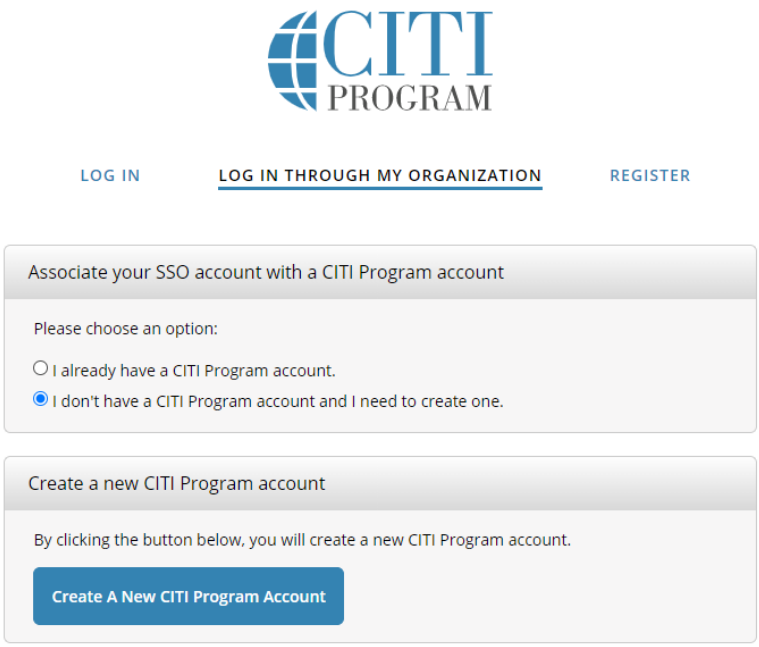
c. Search for 'University of Maine System' in the section titled 'Select your Organizational Affiliation' and click on it.

   i. Click the check boxes to agree to the CITI Terms of Service and Privacy Policy, and to agree that you are an affiliate of the University of Maine System.

   ii. Click the "Continue to SSO Login/Instructions"

   iii. Note: No action is needed in the bottom section titled "Independent Learner Registration."

d. Under “Associate your SSO account with a CITI Program account” click “I don’t have a CITI Program account and I need to create one.”
    i. Click the button that appears below labeled “Create A New CITI Program Account.”



    ii. This will automatically create an account for you using your UMaine SSO (Single Sign-On), the same login information used to log into the UMaine Portal, etc. You should also receive a confirmation email via your maine.edu email address with this information.

II. Log into CITI as an Existing User

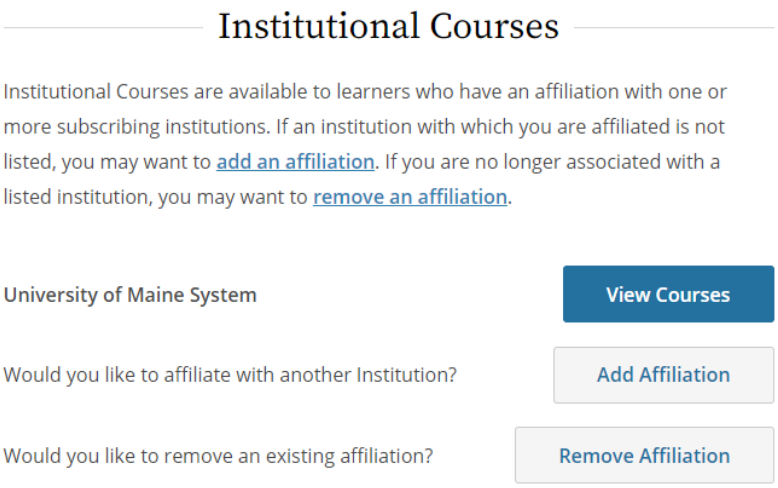
a. To log into CITI once you have established your CITI account, go to [CITI Program (https://about.citiprogram.org/)](https://about.citiprogram.org/) and click the blue “Log In” button located in the upper right hand corner of the homepage.

b. On the login page, click the center option labeled “Log In Through My Organization.”
c. On the list of organizations that appears, click on “University of Maine System” and you will be logged in using your UMaine SSO.
d. NOTE: if you already had an account set up with CITI from another institution, you can affiliate that existing account with UMaine. See [instructions from CITI on how to add/change your affiliated institution.]

III. Enroll in CITI Courses

a. New Users

i. After you enroll, you will be brought to your "My Courses" page. Under "Institutional Courses," click the button next to University of Maine System labeled "View Courses."



ii. You will be brought to the "Select Curriculum" page. Select any desired course(s) from the list**. See section IV (Required Trainings) of this document for details on which specific trainings are required for each area of research.**

iii. Once you have made your selection(s), hit the "Submit" button at the bottom of the page (Note: you are able to sign up for additional courses later, after you have made this initial selection – see section III.b [Returning Users] of this documentfor instructions).

b. Returning Users

i. After logging into CITI as a returning user, you will be brought to the "My Courses" page. Click on the "View Courses" button next to the University of Maine System (as shown above under New Users).

ii. On this page, you will see a list of all courses you are currently enrolled in and have previously completed.

iii. To enroll in another course, scroll to the very bottom of the page to the section labeled "Learner Tools for University of Maine System." Click the link for "Add a Course."

iv. You will be brought to the "Select Curriculum" page. Select any desired course(s) from the list**. See section IV (Required Trainings) of this document for details on which specific trainings are required for each area of research compliance.**

IV. Required Trainings

PLEASE NOTE: You are only required to take the trainings for your specific area(s) of research compliance.

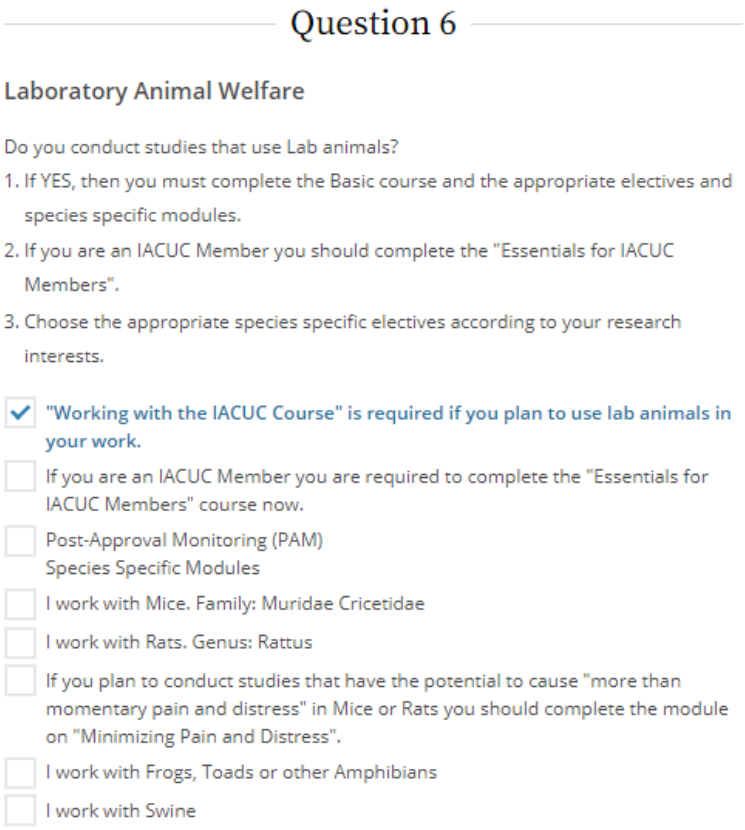
If you are unsure of which trainings may be required for your research, please explore the resources available on the ORC website and reach out to the ORC for additional guidance as needed.

Once you know which trainings are required for your research, find the relevant compliance area below and follow the instructions to sign up. See section III (Enroll in CITI Courses) of this document for instructions on how to enroll as a new or existing CITI users.

a. Animal Care

i. Visit Animal Care on the ORC website for guidance on when and for whom this training is required.

ii. To enroll, on Question 6, select the required course "Working with the IACUC" (as shown below). In addition to the required "Working with the IACUC" course, we strongly recommend you take modules from these sections that apply to your research.



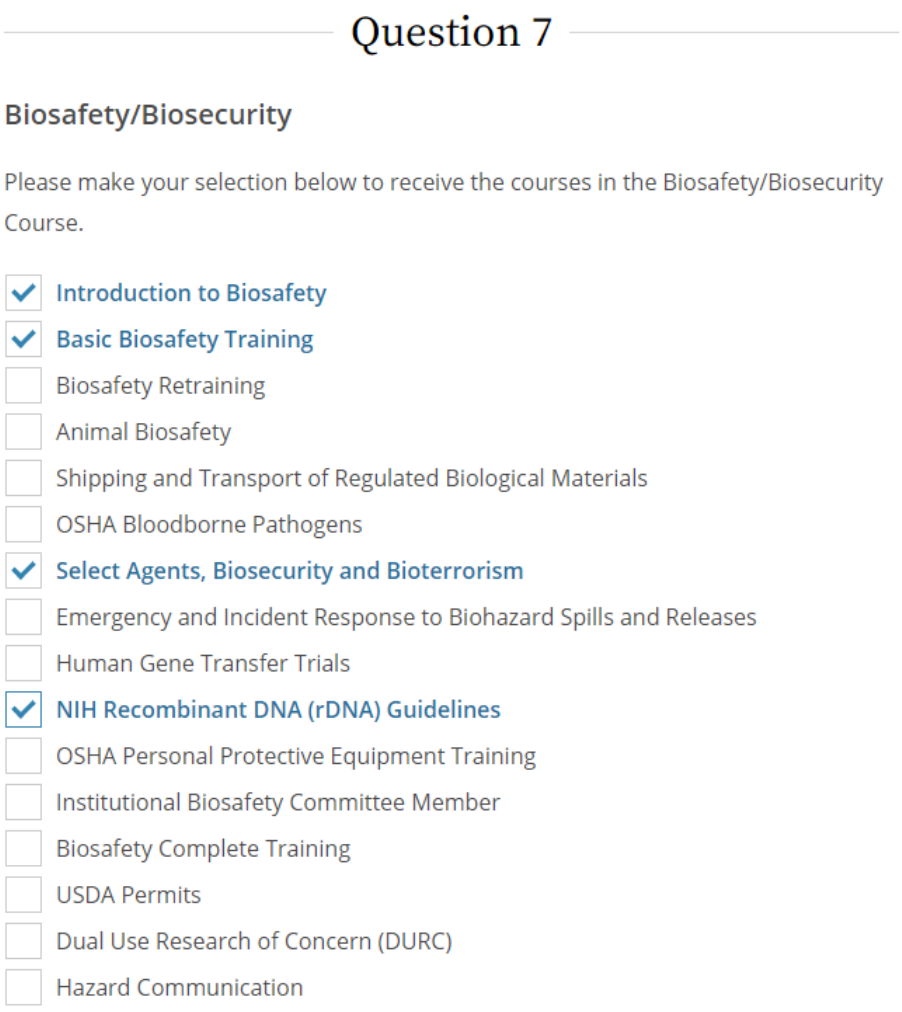
List continues – see the CITI enrollment page for the full list of available modules. In addition to the required "Working with the IACUC" course, we strongly recommend you take modules from these sections that apply to your research.

b. Biosafety

i. Visit Biosafety on the ORC website for guidance on when and for whom this training is required.

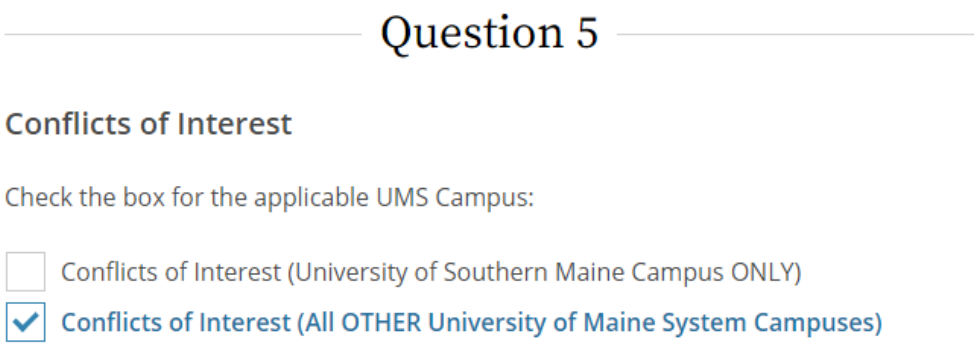
ii. To enroll, on Question 7, select the following 4 courses:

1. Introduction to Biosafety
2. Basic Biosafety Training (Note: after enrollment, on My Courses page, the title will appear as "Training for Investigators, Staff and Students Handling Biohazards.")
3. Select Agents, Biosecurity and Bioterrorism
4. NIH Recombinant DNA (rDNA Guidelines)



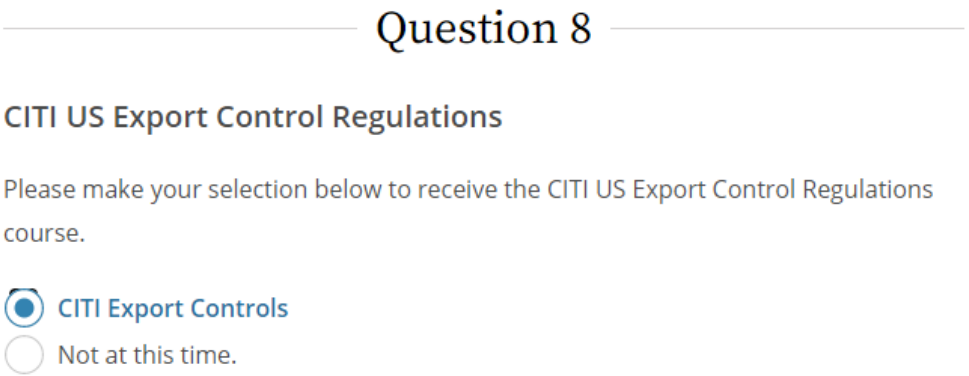
c. Conflict of Interest

i. Visit Conflict of Interest on the ORC website for guidance on when and for whom this training is required.
ii. To enroll, on Question 5, select "Conflicts of Interest (All OTHER University of Maine System Campuses)."



d. Export Control

i. Visit Export Control on the ORC website for guidance on when and for whom this training is required.
ii. To enroll, on Question 8, select "CITI Export Controls." (Note: after enrollment, on My Courses page, the title will appear as "CITI Export Controls Course.")

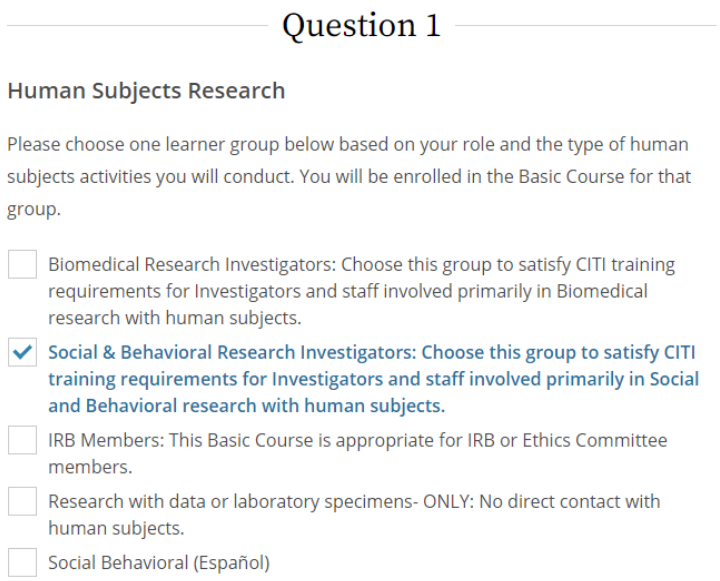


e. Human Subjects

i. Visit Human Subjects on the ORC website for guidance on when and for whom this training is required.

ii. On Question 1, select one learner group based on your role and the research you will be conducting. You will be able to go back and add another learner group later on, if needed.

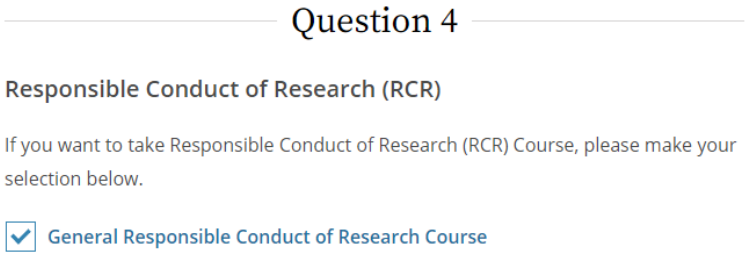
1. The most common selection is "Social & Behavioral Research Investigators," shown below. (Note: after enrollment, on My Courses page, the title will appear as "Social & Behavioral Research - Basic/Refresher.")
2. The Biomedical Research Investigators course can be selected for researchers that are conducting mostly biomedical research.



f. Responsible Conduct of Research

i. Visit Responsible Conduct of Research on the ORC website for guidance on when and for whom this training is required.

ii. On Question 4, select "General Responsible Conduct of Research Course." (Note: after enrollment, on My Courses page, the title will appear as "General RCR.")



As a reminder, please note that you are only required to take the trainings for your specific area(s) of research compliance. If you are unsure of which trainings may be required for your research, please explore the resources available on the ORC website and reach out to the ORC for additional guidance as needed.

V. Access CITI User Records and Reports

a. Users can access training records and Completion Reports through the "My Records" link in the menu bar at the top of the CITI page.
b. CITI will automatically alert ORC when you complete training, however there is a slight delay. ORC is also able to view in CITI when your training is complete. Please do not need to send copies of completion reports to ORC.
    i. If you require immediate assistance (i.e. you've just completed Financial Conflicts of Interest training and need access to PARS), please contact sponsored@maine.edu.
    ii. For all other CITI training inquiries, please contact umric@maine.edu.

APPLICATION COVER PAGE

- ***KEEP THIS PAGE AS ONE PAGE – DO NOT CHANGE MARGINS/FONTS!!!!!!!!!***
- ***PLEASE SUBMIT THIS PAGE AS WORD DOCUMENT***

APPLICATION FOR APPROVAL OF RESEARCH WITH HUMAN SUBJECTS
Protection of Human Subjects Review Board, 311 Alumni Hall

(Type inside gray areas)
PRINCIPAL INVESTIGATOR: **EMAIL:**
CO-INVESTIGATOR: **EMAIL:**
CO-INVESTIGATOR: **EMAIL:**
FACULTY SPONSOR: **EMAIL:**
(Required if PI is a student):
TITLE OF PROJECT:
START DATE: **PI DEPARTMENT:**

STATUS OF PI: FACULTY/STAFF/GRADUATE/UNDERGRADUATE (F,S,G,U)

If PI is a student, is this research to be performed:

☐ **for an honors thesis/senior thesis/capstone?** ☐ **for a master's thesis?**
☐ **for a doctoral dissertation?** ☐ **for a course project?**
☐ **other (specify)**

Submitting the application indicates the principal investigator's agreement to abide by the responsibilities outlined in Section I.E. of the Policies and Procedures for the Protection of Human Subjects.

Faculty Sponsors are responsible for oversight of research conducted by their students. The Faculty Sponsor ensures that he/she has read the application and that the conduct of such research will be in accordance with the University of Maine's Policies and Procedures for the Protection of Human Subjects of Research. REMINDER: if the principal investigator is an undergraduate student, the Faculty Sponsor MUST submit the application to the IRB.

Email this cover page and complete application to umric@maine.edu.

****

FOR IRB USE ONLY **Application #** **Review (F/E):** **Expedited Category:**
ACTION TAKEN:

☐ **Judged Exempt; category** **Modifications required?** **Accepted (date)**
☐ **Approved as submitted. Date of next review: by** **Degree of Risk:**
☐ **Approved pending modifications. Date of next review: by** **Degree of Risk:**
Modifications accepted (date):
☐ **Not approved (see attached statement)**
☐ **Judged not research with human subjects**

FINAL APPROVAL TO BEGIN

Date

August 2020

IRB APPLICATION FORM INSTRUCTIONS
DO NOT SUBMIT WITH APPLICATION

Things to remember when completing the application cover page:

- **The principal investigator must have a UMaine affiliation.**
- **Faculty sponsor required if the principal investigator is a student.**
- **The title should describe the specific subject matter to be researched. If the study is funded, the title must match the grant/proposal.**
- **The start date refers to when the research with human subjects proposes to begin, and should not be earlier than ten days from the date the application is submitted.**
- **Submit as WORD DOCUMENT (not a PDF).**

Please note:

- **Please read and follow instructions; incomplete applications will be returned.**
- **FACULTY SPONSORS: you are responsible for the quality of the application; do not approve an application that is incomplete or does not follow the instructions – it will be returned to you.**
- **For undergraduate students, the application MUST BE SUBMITTED (EMAILED) BY THE FACULTY SPONSOR.**
- Type responses to points below; please include the nine major headings detailed below (e.g., Funding, Summary, Personnel, Participant Recruitment), but do not include the application instructions.
- Page number **entire** document. PLEASE SUBMIT AS ONE DOCUMENT. The Cover page should be submitted separately (and kept as Word document), but the narrative of the application (items 1-9 below), with appendices (measures, recruitment materials, consent forms, etc.) should be one document.
- Please submit the document as ONLY a Word document (not a PDF).

Application Narrative:

1. **Funding: if the proposed study has been submitted for funding or is funded, please list funding agency and grant/proposal number, if known. Note that the title of the IRB application should match the title of the grant. If the study is not funded, state N/A**

2. **Summary:**
   Describe the rationale of the study in concise, non-technical language.
   - Although the IRB does not wish to receive grant/dissertation proposals, this section should include a description of the scientific significance and goals of the study, including background information and citations, to justify conducting the study. The background information should also explain the rationale for the choice of the particular participant population, as well as the use of specific measures and procedures.

- Include a methods section (with "Methods" heading). This section need not be long, but the IRB wants to understand early on how the study will be conducted. Some can be as brief as: "This study will involve face-to-face interviews at a location of the participant's choosing. The interviews may take 45-60 minutes and will be recorded." This section would be longer if there are many components of your study.
- Include a reference page for the citations (we expect to see citations!).
- Include questionnaires, interview questions, measures, etc., as appendices.

2. Personnel:

- Identify the person(s) named on the cover page (including the faculty sponsor, if applicable), as well as others who will have contact with the participants and/or with identifiable data. (NOTE: Make sure principal investigator is named; do not state: "I will be the principal investigator." Be sure to define the roles that the named personnel will have in the research project.
- Specify the affiliation/qualifications of everyone listed, e.g., "Jane Doe, Graduate student in the Department of Psychology, College of Liberal Arts and Sciences." Briefly explain each person's experience with research with human participants. Include the years of human subjects research experience for all personnel listed.
- Everyone named in this section is required to have completed the human subjects training.

3. Participant recruitment:

- Describe the characteristics of the participant population. Describe the expected number of participants or the expected response rate (e.g., plan to send out 500 surveys and expect 20% response rate). Include the age range of the participants and whether particular demographics and characteristics (e.g., state of health) are sought. If you are recruiting only one gender, explain why. (NOTE: if you are specifically recruiting members/citizens of the Penobscot Nation, please be sure to state they are your targeted population.)
- Describe how the proposed number of participants was determined.
- Describe participant identification and recruitment procedures, e.g., email (explain how are email addresses obtained), post flyers, etc. If you plan to recruit participants from another institution, please be aware that you may need to get permission from that institution to access participants and, if applicable, get approval from that institution's review board. Please note that if you are seeking participants with a specific physical or mental health condition, you CANNOT ask a professional services provider to give you a list of names of individuals who fit your criteria. However, these service providers may share your recruitment materials with those who appear to be eligible for your study, and interested individuals can contact you directly. Include (as appendices) recruitment letters, phone/email scripts, flyers, advertisements, postings, etc., that may be used to recruit participants (see samples on the IRB website). Reference the appendix number/letter.

Please note: The IRB requires special measures of protection for participants of diminished autonomy. (See Sections II, III, and/or IV from Policy.) Vulnerable populations must be treated with special sensitivity to their restricted ability to protect

themselves. The risks imposed by a proposed study involving such populations must be recognized and the benefits to be derived from participation must justify the risks. In certain instances, advocates must be appointed to protect the participants. Such populations include fetuses (and by extension pregnant women), patients, prisoners or parolees, minors (less than 18 years old), and mentally or physically challenged people. In addition, the IRB may require special measures to preserve the rights of participants whose circumstances may make them vulnerable to undue influence to participate in research. These may include, for example, students and employees of the University. State which, if any, of the above groups may be represented in your participant population, and justify their inclusion.

4. Informed consent (See Sections I.K. and I.L. of Policy):

- Describe the type of consent (oral or written) to be used and the means of obtaining it. Describe how and when potential participants will get the consent form.
- If the participants are minors or mentally incompetent, describe the means of obtaining both the participants' assent (if feasible) and the consent of parents or legal guardians.
- Include a copy (**in an appendix at the end of the application)** of the consent form(s) and assent scripts (if applicable). Consent forms should be written no higher than an 8th grade reading level.
- **Review the informed consent checklist and FOLLOW THE SAMPLE(s) FOUND on the IRB website Please note:** The **documentation** (signature) of informed consent is not necessary for a project in one of the exemption categories. THE SAMPLE FORMAT, WITH HEADINGS, MUST BE FOLLOWED OR THE APPLICATION WILL BE RETURNED.

5. Confidentiality:

- Describe the precautions that will be taken to ensure privacy of the participants and the confidentiality of the data, both in your possession and in reports and publications (e.g., are responses anonymous, are responses coded with identification numbers and a key used to link names to identification numbers).
- If data collection will occur on-line, state the program that will be used (e.g., Qualtrics, Skype, etc.). If applicable, state whether IP addresses will be collected (preferable that they are not collected!). State whether data will be downloaded off program to researcher's computer, as well as the expected date data will be deleted off the program site.
- State the location where data will be stored. Describe the disposition of the research data, including any audio, video, or film recordings, when the research is completed (define as expected date to be destroyed or kept indefinitely). If not keeping indefinitely, don't say "kept until study completed," or "when analysis completed," etc. State an approximate date (month/year) of those occurrences, e.g., January 2024. **If you are not keeping data indefinitely, be sure to be generous with a destruction date, so you don't end up in a situation where you are not ready to destroy the data, but must because that is what you told the participant – NOTE: if you say you will keep the data indefinitely, you can destroy it at any time—but if you give an actual date, you must adhere to it!**

- If recording, state whether a transcription service will be used or if named investigator(s) will transcribe.
- If applicable, state whether the key is paper or electronic and where and how long the key will be kept (key should be kept separate from data). Keys are typically kept for a lesser amount of time than data are kept. Use a date for destroying the key, but give yourself plenty of leeway with the timing in case your project gets delayed. If you wish to keep the key indefinitely, please explain why, as it impacts participant confidentiality. If the key will be stored electronically, it must be encrypted. Please see information on encrypting electronic, identifiable data (the key linking names to data or entire dataset).
- Assurance must be provided that all identifiable data will be secured under conditions that limit their access to the investigator(s) only.
- If focus groups are used to collect data, the researcher should acknowledge that he/she cannot guarantee confidentiality of participants' responses, but will encourage participants to not discuss responses outside of the focus group.
- If the data are published, care must be taken to remove identifying references in order to preserve privacy.
- The IRB recognizes that some studies, such as oral histories, do not require confidentiality of data. The regulations and the IRB are flexible – explain what will happen with the data. If applicable, explain why data will not be confidential.

6. Risks to participants:

- Describe in detail any possible physical, psychological, social, legal, economic, or other risks (including a risk of identification) to the participants, either immediate or long range. **Do not state that there are no risks**. All studies have risks (e.g., time and inconvenience).
- If the participants will be exposed to greater than minimal risk, justify the use of the procedures and state reasons for not using a procedure that would entail a lesser risk.
- Describe procedures used to minimize risk (e.g., assuring participants that they may skip questions they prefer not to answer). If applicable, include referrals to relevant resources from which participants could seek support. Use the Referral Handout Template and edit as necessary.
- Describe what procedures will be followed if research procedures reveal that participants are at elevated risk (e.g., high blood pressure, clinical levels of depressive symptoms). See Guidance for Researchers – Depression and Suicidality in Human Research.

7. Benefits:

- The description is two parts. (1) Describe the benefits of the research to the participants, if any (if no direct benefit to the participants, so state). **NOTE**: Money, course credit, gifts, etc., are not benefits; they are compensation. (2) Describe the overall potential benefit of the research.

8. Compensation:

- If applicable, list any compensation for participation (money, course extra credit, raffle, etc.). Also indicate how compensation will be handled if a participant

withdraws from the study (e.g., no compensation, prorated compensation, or full compensation; must reach end of survey to enter raffle; must complete survey, except for the occasional skipped question, to enter the raffle, etc.). Regarding extra credit: if extra credit is offered, the course instructor must offer other methods of earning extra credit such that participating in the research is not the only way a student can earn extra credit. If a study involves several classes with different instructors, all must agree to grant extra credit and all must offer other methods of earning extra credit. Compensation shouldn't just be for some of the participants.

- For raffle/compensation for on-line studies (where the link to the raffle/compensation takes the participant to a new page to enter their contact information), include the text of that page as part of your application. It need not be long – thanking them for taking the survey, reminding them that their contact information is not linked to their survey responses, along with place for name/email/phone, etc.
- If the value of a one-time payment **exceeds $75.00**, subject data must be reported to other offices within the University of Maine and University of Maine System, as follows:

    - If the human subject is an employee of the University of Maine, the researcher must report any such payments to the Department of Human Resources. The Department of Human Resources will determine whether the value of the reported incentive needs to be added to the employee's gross wages, and whether the payment will be subject to taxation and withholding.

    - If the human subject is not an employee of the University of Maine, the researcher shall report any such payments to the Department of Purchasing. The researcher will work with the Department of Purchasing to comply with IRS regulations that require the University of Maine System to issue a Form 1099 when cumulative payments to a non-employee reach $600 in a calendar year.

SEE Consent Guidelines for the wording to be used in the consent form.
SEE Human Subjects Payment Guidelines for additional information.

Submission Instructions:

- **Email complete application and cover page to umric@maine.edu).**

- **REMEMBER – If an undergraduate is the principal investigator, the faculty sponsor must submit the application.**

- **The submission email should have two attachments:**
  1) The completed cover page as Word document.
  2) The narrative of the application (items 1-9 above) along with the appendices -- consent form(s), recruitment materials, measures, etc. as ONE document – PAGINATED.

- Please note that the IRB expedites many applications (reviews outside of a full board meeting). The IRB will expedite applications when possible, typically within ten business days. The IRB will make the final determination of whether your study is eligible for expedited review.

- If your study involves sensitive topics, protected populations, and/or more than minimal risk, the application may require full board review. In those cases, the application is **due by the first Friday of the month** for inclusion on the agenda for that month.

Please contact the IRB if you have questions – 207-581-2657 or e-mail umric@maine.edu.

Request for Student Data for Use in Research Project

All requests must be in accordance with FERPA regulations and have Institution Review Board for Protection of Human Subjects (IRB) approval. If this is a project that a student is conducting, there must be a faculty advisor that approves the data request.

Storage of this data, either electronic or paper, must be in a secure location and not shared with a third party.

Requestor's Information

Name: _____

Department: _____ Phone: _____

Faculty Advisor (if applicable): _____

Signature: _____ Date: _____

Project Information

Purpose of Project: _____

Data Requested: _____

_____

_____

How will the data be stored (electronic & paper): _____

At the end of the Project, what will happen to the data: _____

Approval

Documentation of IRB Approval Attached? _____

Faculty Approval: _____

Office of Student Records Approval: _____

The student and the faculty member will be notified of the approval status of their request.

SAMPLE ASSENT SCRIPT

For studies involving children, an assent script is required. Children with permission to participate in a research study also have the right to be informed about the study and choose whether they wish to participate. Create a script that describes the study, what they'll be asked to do, confidentiality issues, etc. Use age-appropriate language! Children do not sign any documents.

Below is a very basic sample script, one that could be used with most young children. For middle school children, you may include more information and increase the reading level slightly. We suggest you test your assent script on children you may know to see if they understand what you are asking. For high school students under 18, it is acceptable to use the parent/guardian consent form you created and modify it to reflect that it is an assent script directed at them and not their parent.

Hi, my name is _____, and I'm from the University of Maine. I am here today because I am doing a project to learn about _____.

I would like to ask you to _____ (*explain in very simple language the activities the child will be asked to do).* If you say "yes," you can still stop at any time by just telling me you want to stop. No one will be upset if you don't want to do this, or if you want to stop after you have started. If I ask you a question and you don't want to answer it, that's ok. Your parents have said it is ok for you to be in the project if you want to.

Your answers will be private and only used for my project.

Would you like to be in my project?

NOTE: Depending on the type of study, additional information may be required, e.g., "some questions could make you sad" (risk statement).

SAMPLE CONCISE SUMMARY

With the Revised Common Rule that went in effect in January 2019 studies with longer consent forms or Federally funded studies a concise summary is required.

The concise summary is meant to be brief. The purpose of the summary is for the participant to decide why he/she may want to participate but should also include information on why he/she may not want to participate in the study (for example a huge time commitment or other risks). The summary should not include all foreseeable risks but the risks that would be most likely or most severe to the participant.

The summary should include the following 5 elements:

1) A statement that the project is research and that it is voluntary.

2) A summary of the research (purpose, overview of procedures etc.)

3) Any foreseeable risks or discomforts

4) Any expected benefits to participants (if applicable)

5) If applicable, alternative procedures to course of treatment

CONCISE SUMMARY EXAMPLE – Biomedical (non-drug/device study)

You are being asked to join a research study. The research is to help…….

Before you consider the research you should be aware of the following information:

- Research is voluntary. You do not have to be in this study.
- The study will require 2 visits to the lab for 2 hours (total time of 4 hours).
- We will ask you questions about your health.
- The study involves a blood draw to collect biomarker information and exercise testing.
- If you think you want to be in the study, you should read the rest of this document. The document explains what will happen to people in the study

CONCISE SUMMARY EXAMPLE – Social and behavioral

You are being asked to join a research study. The research is to help…….

Before you consider the research you should be aware of the following information:

- Research is voluntary. You do not have to be in this study.
- You will complete pre-screening surveys about your mental and physical health.
- You will have your blood pressure and heart rate measured.
- If after the screening you qualify for the study, you will return to the lab to complete some challenging mental stress tests. This part will be videotaped.
- The pre-screening will take 1 hour in the lab and the study will take 2 hours in the lab.
- If you think you want to be in the study, you should read the rest of this document. The document explains what will happen to people in the study

SAMPLE CONSENT FORM FOR ANONYMOUS ELECTRONIC SURVEY

You are invited to participate in a research project being conducted by (*name*), a (*faculty member, staff member, graduate student, undergraduate student*) in the Department of (*name*) at the University of Maine. *If the principal investigator is a student, also name the faculty sponsor and his/her department.* The purpose of the research is _____. You must be at least 18 years of age to participate. *The age statement is not always required. An example of when it is required is if the study involves the UMaine undergraduate student population. If there is a chance that someone in the population you are studying could be under 18, include the statement.*

What Will You Be Asked to Do?

If you decide to participate, you will be asked to take an anonymous survey. It should take you about X minutes to complete.

Risks:
Note that there is always some risk, at minimum the participant's time and inconvenience. Listed below are examples.

- Except for your time and inconvenience, there are no risks to you from participating in this study.

OR

- There is the possibility that you may become uncomfortable answering the questions. You may skip any questions that make you uncomfortable. *Provide referral resources if questions very sensitive, e.g., depression, suicide, etc. Referral resources may include UMaine Counseling Center* (*if UMaine students*)*, National Hotlines, etc. Either mention the resources within the consent, or link to resource information (see referral handout).*.

Benefits (***Two*** *benefit statements are required – benefit to participant (if any) and potential benefit of the research*)

(*Most surveys do not have a benefit to participants*)

- While this study will have no direct benefit to you, this research may help us learn more about…

Compensation: *Listed below are examples; if you are not offering compensation, leave this section out.* ***NOTE: See Item #7 on checklist for additional guidance if compensation exceeds $75****.*

- You will receive $X for participating in this study.
- You may enter a raffle to win *one of two $25 Amazon gift cards*.
- You will receive *1 hour* of research credit *(or other wording for extra credit)* for participating in this study.

Confidentiality

This study is anonymous. Please do not write your name on the survey. There will be no records linking you to the data. Data will be kept on a password-protected computer indefinitely. Information for the raffle/compensation/extra credit is not connected to survey responses.

Voluntary

Participation is voluntary. If you choose to take part in this study, you may stop at any time. *Explain whether stopping will alter compensation to be received, e.g., "… stop at any time, but you must reach the end of the survey to enter the raffle; "While you may skip the occasional question, you must complete the survey to be eligible for compensation."* You may skip any questions you do not wish to answer.

Submission of the survey implies consent to participate.

Contact Information

If you have any questions about this study, please contact me at (*phone, e-mail*). You may also reach the faculty advisor on this study at (*phone, e-mail*). If you have any questions about your rights as a research participant, please contact the Office of Research Compliance, University of Maine, 207-581-2657 (or e-mail umric@maine.edu).

SAMPLE CONSENT FORM

(Use in conjunction with the checklist!)

You are invited to participate in a research project being conducted by (*name*), a (*faculty member, staff member, graduate student, undergraduate student*) in the Department of (*name*) at the University of Maine. *If the principal investigator is a student, also name the faculty sponsor and his/her department.* The purpose of the research is _____. You must be at least 18 years of age to participate. *The age statement is not always required. An example of when it is required is if the study involves the UMaine undergraduate student population. If there is a chance that someone in the population you are studying could be under 18, include the statement. There may need to other inclusion criteria listed, such as "You must be between 50-75 and have suffered a stroke in the last two years."*

What Will You Be Asked to Do?

If you decide to participate, you will be asked to (*describe procedures, give examples of sample questions if applicable*). *If the study involves a focus group, indicate how many people will be in the group. If an interview or focus group will be recorded, state that in this section.* It may take approximately (*amount of time*) to participate. *If the procedures are numerous, we suggest you use bullets to make the form easier to read.*

Risks:

Note that there is always some risk, at minimum the participant's time and inconvenience. Listed below are examples.

- Except for your time and inconvenience, there are no risks to you from participating in this study.

OR

- There is the possibility that you may become uncomfortable answering the questions. You may skip any questions that make you uncomfortable. *Provide referral resources if questions very sensitive, e.g., depression, suicide, etc. Referral resources may include UMaine Counseling Center* (*if UMaine students*)*, National Hotlines, etc. Either mention the resources within the consent, or reference an attachment with resource information.*

Benefits *(**Two** benefit statements are required – benefit to participant* (*if any*) *and potential benefit of the research*)

- While this study will have no direct benefit to you, this research may help us learn more about…

- You may learn how your energy level changes your mood. In addition, this research may help us learn more about…

- You will have a cholesterol screening at no charge. In addition, this research may help us learn more about…

Compensation: *Listed below are examples; if you are not offering compensation, leave this section out.* ***NOTE: See Item #7 on checklist for additional guidance if compensation exceeds $75****.*

- You will receive $X for participating in this study.
- You will receive $X for completing the first part of this study and $X for the remaining part.
- You will receive *1 hour* of research credit for participating in this study.
- You will be able to enter a raffle for a $X gift card to _____.

Confidentiality

Sample for when data are confidential, i.e., names are connected to data, typically by use of a code/key. NOTE: this is a sample; it may not fit your study. The important aspect is to tell people how the data will be kept to ensure confidentiality and how long it will be kept – or to inform that that it won't be kept confidential, as in the case with some studies (*e.g., oral histories*)*.*

Your name will not be on any of the data. A code number will be used to protect your identity. A key linking your name to the data will be kept separate from the data *in a locked office* (*if paper*) and destroyed by XXXX (*date*). *If a key will be kept electronically, explain that it will be stored on a password-protected computer using software that provides additional security.* Data will be kept on a password protected computer and kept (*indefinitely or destroyed by date*). *Specifically address the retention of any audio, video, or film recordings. List others who may have access to data, such as faculty advisor and/or others working on the project. If a transcription service will be used* (*instead of named researchers*)*, include that information.* Your name or other identifying information will not be reported in any publications (*statement not needed for anonymous studies*).

For Focus Groups, also include this statement: Due to the group format, I cannot guarantee that others will keep responses confidential.

Voluntary

Participation is voluntary. If you choose to take part in this study, you may stop at any time (*explain whether stopping will alter the benefit or compensation to be received*). You may skip any questions you do not wish to answer.

Contact Information

If you have any questions about this study, please contact me at (*phone, e-mail*). You may also reach the faculty advisor on this study at (*phone, e-mail*). If you have any questions about your rights as a research participant, please contact the Office of Research Compliance, University of Maine, 207-581-2657 (or e-mail umric@maine.edu).

*If the study is **not** exempt from further review, continue with the following statement.*

Your signature below indicates that you have read the above information and agree to participate. You will receive a copy of this form.

_____ _____

Signature Date

***NOTE:** If your study involves children (<18 years old), the consent letter is written to Dear Parent/Guardian, and reference to "your child" or "your son/daughter" is used.*

EMAIL RECRUITMENT TEMPLATE ELECTRONIC SURVEY

Greetings,

You are invited to participate in a research study. The research is being conducted by (*name, title, Department at the University of Maine*). *Say how the participant's contact information was obtained for example*: John Doe suggested I contact you *or* I found your contact information on "Z" website. *NOT needed if posting an email on listserve, Facebook, etc.*). *State the purpose of the research. Insert age requirement, for example*: you must be at least 18 years old to participate *(not needed if you know your targeted population is at least 18) or* you must be between ages ____ to participate. *Include any other applicable inclusion/exclusion criteria.*

If you agree to participate, you will be asked to take an anonymous/confidential (*state one or the other!)* survey. The survey will take approximately (*state how much time it will take*). *If there is compensation you should add that information in the recruitment email.*

Please click on the link below to learn more about the study and to take the survey (*insert survey link – FYI the first page of the survey will be the consent form*).

If you have any questions, please feel free to contact me at (*insert email and phone number*).

General Email Posting (listserves, Facebook, University folders, etc.):

You are invited to participate in a research study. The research is being conducted by (*name, title, Department at the University of Maine*). *Insert age requirement for example*: you must be at least 18 years old to participate *(not needed if you know your targeted population is at least 18*) *or* you must be between ages ____ to participate. *Include any other applicable inclusion/exclusion criteria.*

I am conducting a research study about (*insert purpose of research*). If you agree, you will be asked to (*briefly describe procedures, including time commitment, location, any recording – audio/video*).

If you would be interested in participating in this study, please contact me (*provide contact information*).

Thank you.

Phone Script (interview over the phone/in-person):

Hello, my name is (*name*) and I am a researcher at the University of Maine. *Say how participant's phone number was obtained*. I am conducting a research study about (*insert purpose of research*). I am calling to ask if you would be willing to let me interview you. The interview can be conducted over the phone or at a location of your choosing. The interview should take (*insert time interview will take*). *Say if the interview will be recorded*. *Insert age requirement*, *for example*: you must be at least 18 years old to participate *(not needed if you know your targeted population is at least 18) or* you must be between ages ____ to participate. *List any other applicable inclusion/exclusion criteria.*

If you would be interested in participating in this interview, we can set up a time now or you can let me know when a good time would be to schedule it.

If interested, investigator will set up date and time and will provide participant with investigator contact information. For example: I have scheduled you for an interview on (*date and time*). If you have any questions, I can be reached at (*insert phone number and email*). Thank you for your help.

If participant is not interested, investigator will end the call. Thank you for your time.

Email/letter recruitment:

My name is (*name*) and am a researcher at the University of Maine. *Say how participant's contact information was obtained*.) I am conducting a research study about (*insert purpose of research*).

I am contacting you to ask if you would be willing to participate. Participation would involve (*briefly explain what they will be asked to do and where it takes place*). *Insert age requirement for example*: you must be at least 18 years old to participate *(not needed if you know your targeted population is at least 18) or* you must be between ages ____ to participate. *List any other applicable inclusion/exclusion criteria*.

If you would be interested in participating, please reply to this email/contact me (*provide contact information*).

Thank you for your time.

INVITATION TO PARTICIPATE IN A UNIVERSITY OF MAINE RESEARCH STUDY

You are invited to participate in a research study about (*add research topic*).

Give name of PI(s), Title, and Department at the University of Maine.

We are looking for individuals (*add age requirement here*) who would want to participate in an (*recorded, if applicable*) interview. *If in person, give a location or say over the phone*. The interview may last between (*give time it will take*). *If there is compensation and/or refreshments it should be listed in the announcement*.

All information shared in the interviews will remain confidential.

If you would like to participate and/or have questions about this study, please contact (*add name, phone and email*).

SAMPLE SONA RECRUITMENT SCRIPT

Study Name: Recruitment Messages and Course Selection
Type: Online
Credits: 1 credit

Description:
We are working to understand how college admissions view books are related to the desire to take courses or participate in a certain major. You will be randomly assigned to view either captions or photos from a certain major. We will ask you a series of questions concerning your beliefs, interests, and other personal factors. You must be 18 years of age or older to participate in this research survey.

Office of Research Compliance

Human Subjects

- IRB Overview
- Guidance & Policy
- Regulations
- Training
- Forms and Samples
- Application Deadlines
- Resources
- IRB FAQs

Deadlines for Submission of Applications for Approval

For submission of applications, the Protection of Human Subjects Review Board (IRB) has a standard deadline date of the first Friday of every month. An application submitted on the first Friday of the month will be reviewed at that month's meeting (the IRB typically meets during the 3rd week of the month).

An investigator may request an expedited review of his/her application if the proposed research activity is within one of the categories eligible for expedited review. Applications requesting expedited review may be submitted at any time. The IRB aims to review and send comments back to investigators within ten working days.

Please contact the IRB office if you have questions.

Institutional Review Board Membership List

Office of Research Compliance

Human Subjects

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- IRB FAQs

Resources

- Deadlines: The deadline for submitting applications for approval is the first Friday of the month.
- IRB Membership List
- What is HIPAA?

Useful Links

- Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations (PDF)
- Federal and State Regulations & Guidance Materials
- Human Subject Regulations Decision Charts
- Public Responsibility in Medicine and Research (PRIM&R). (Mission: Since its founding in 1974, Public Responsibility in Medicine and Research (PRIM&R) has been committed to the advancement of strong research programs and to the consistent application of ethical precepts in both medicine and research. Through national conferences and published reports thereon, it has addressed a broad range of issues in biomedical and behavioral research, clinical practice, ethics, and the law.

IRB FAQs

Definitions:

Q. What is the IRB?

IRB is the acronym for the Institutional Review Board for the Protection of Human Subjects. The IRB reviews all research conducted by faculty, staff and students that involves human subjects. The purpose of the IRB is to ensure that research with human subjects is conducted ethically. The IRB ensures that the risks to participants are minimized, that selection of participants is equitable and that participants are informed about what participation in the study will entail.

Q. What is considered research by the IRB?

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Q. What is the difference between consent and assent?

Consent: Can only be given by a competent individual who is of legal age and has been given sufficient information about the purpose of the study, the benefits and risks of the study.

Assent: Agreement of a minor to participate in a research study. Assent MUST be accompanied by informed consent of the minor's parent or legal guardian.

Q. What is the difference between compensation and benefits?

Compensation: Is a payment or reimbursement of the participant's time or expense. This can even be class credit.

Benefits: Is something that can be related to or resulting from research efforts. Could be a benefit to the subject or to society.

Q. What is the difference between anonymous and confidential data?

Anonymous means that you are not collecting any identifying data from the subjects and that you will have no means to contact or follow-up with the subjects.

When data is confidential, identifiable data will be collected and the researcher can identify the subject. In this case the subject could be contacted for follow-up procedures.

COVID and IRB Applications:

Q. Where can I find information about research and current COVID restrictions?

See official information about the University of Maine policies on restrictions on research.

Q. What modifications should I make to my application?

The researcher should first review the University of Maine COVID-19 guidance for researchers. You should modify any in-person research visit that does not have to be conducted on-site to a remote visit. These changes will require a modification submission.

Q. Are there COVID changes that do not require a modification?

The IRB has determined that these activities are not considered a 'change to the research' and therefore do not need to be submitted as modifications to research protocols:

- General communications with subjects about COVID-19. These are not study-specific communications, but rather are providing information that is publicly available, e.g., on the University of Maine website or CDC recommendations.
- Screening procedures for COVID-19 infection consistent with procedures on the University of Maine COVID-19 guidance for researchers. These are not study-specific procedures.

Initial Submissions:

Q. What documents do I need to submit with my initial submission?

This will vary depending on your study but in general you will need to submit a cover page and an application that includes the narrative, measures you will administer, recruitment script(s), consent form(s) and assent script (for studies with participants under 18 years old).

Initial submissions should be as complete as possible but we understand that submissions aren't perfect from the start (especially if it is your first submission). Prepare what you believe is needed, and the IRB Office will let you know of any changes or additional documents that are needed for your IRB review.

Q. My study is Quality Improvement; do I need to submit an application?

If your project involves human subjects or their data, the best practice is to check with the IRB to confirm if IRB oversight is required, even if you think your project is Quality Improvement or Quality Assurance. You may simply provide a brief explanation of your study along with some sample measures to umric@maine.edu and the IRB will let you know if an application is required.

Q. Which consent template should I use?

We have several consent form templates on the IRB website to choose from. Select the template you believe is appropriate, and the IRB Office will let you know if something different is needed once they start their review.

Q. Does my project need IRB review?

The project must be **research** and involve **human subjects** to need IRB review. Please do not attempt to determine for yourself that your project is not research involving human subjects. **You should have the IRB make this determination**.

The Common Rule defines "**research**" as a *systematic* investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*.

Systematic is an activity that follows a written plan and adheres to scientifically accepted principles for research design to answer a question. Examples of some activities are surveys, interviews, review of medical charts.

Generalizable knowledge is defined as knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. The results are expected to be generalized to a larger population beyond the site of data collection; the results are intended to be replicated in other settings.

The Common Rule defines a **human subject** as a living individual about whom an investigator conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or 45 CFR 46.102(e) (2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Q. When should I submit my application?

If your study is exempt or can be expedited you should submit your application at least 30 days before you intend to start your research. This allows the IRB time to review it and it will you give time to make any changes requested by the IRB in a timely manner and still meet you start date. For Full Board review, your proposal should be submitted by the submission deadline listed on the IRB website.

Q. What should be my consideration if I am using Zoom for my study?

You should create a private meeting with a unique meeting ID and password. To protect the privacy of the participants, consider using only audio and not video recording. Learn more about Zoom guidance for IRB studies.

Q. What information should be included in the recruitment materials?

The recruitment scripts must have sufficient information so potential participants can make an informed decision about participation. The following items must be included:

- The name and contact information of the Principal Investigator.
- The purpose of the research.
- The time commitment required of subjects.
- The location of the research.
- A clear statement that it is a research project.
- A clear statement that it is voluntary.

IRB Approvals:

Q. My research will be done in another country. Do I need IRB approval from the

University of Maine?

Yes, you must get approval from the IRB at the University of Maine. You should also be aware that you many need approval from an IRB or ethics committee from the country where you will be conducting the study, so please plan accordingly.

Q. Do I need approval from the IRB even if my study if not funded?

Yes, you must obtain IRB approval from the University of Maine regardless of funding.

Q. May I begin recruitment of subjects while IRB approval is pending?

No, you need IRB approval BEFORE recruitment or study enrollment begins.

Q. Do I need to submit an IRB application if I am not collecting any identifying information in my research project?
Q. Can the IRB approve a research study retroactively?

No, there is not provision in the Federal regulations that allows the IRB to approve a study that has already been conducted. This is why it is so important to check with the IRB if approval is needed before you start a research study.

Q. What if I am not sure if my activity needs IRB review?

Email a brief summary of the activity to umric@maine.edu and the IRB will respond with a determination.

Q. If I submit a grant proposal do I have to submit an IRB application at the same time?

You can submit the IRB application at the same time as the proposal. Depending on the sponsor you may also submit the IRB application at the time of award. We strongly encourage you to check with the sponsor on their requirements.

Principal Investigator and Study Team Management:

Q. I am leaving the University; what happens to my IRB study?

The PI should close out the applications or notify the Office of Research Compliance in writing that the study will be transferred to another qualified PI at the University of Maine.

Changes in the PI should be submitted to the IRB prior to the new PI assuming oversight of the study. The change must be submitted at least 14 business days prior to the departure of the former PI. If the former PI is leaving the institution but will remain a study team member, please contact the IRB office. See "How do I submit a change in PI?" below.

If the study is funded the PI should also notify the Office of Research Administration.

Q. How do I submit a change in PI?

The change in PI should be submitted as a modification. The request will be reviewed at a Full Board meeting unless the original study was expedited and continues to meet criteria for review under expedited procedures.

The research team should consider whether study documents are affected by the change in PI, such as the consent forms and recruitment materials. If participants are still enrolled in the research study, the IRB recommends that the research team provides a written update to the participants, such as an information sheet or letter, to inform them of the change in PI and to update them regarding changes in relevant contact information

of the change in PI and to update them regarding changes in relevant contact information (e.g., for study-related questions).

Q. What is the faculty sponsor's role for student projects?

The main expectation is that the sponsor assists students during the IRB process. The sponsor must review the application before submission to ensure that the application is thorough and accurate. The faculty sponsor must also monitor the students during the study to ensure that the student is following the procedures described in the application and that if any unexpected or adverse events occur they are promptly reported to the IRB. If the Faculty Sponsor is leaving the institution and the study is still active another qualified Faculty Sponsor must be appointed; see "How do I submit a change in PI?" above.

Q. How do I add study personnel to my approved IRB study?

If you simply need to update personnel on an approved study, you do not need to edit the approved application. An email to umric@maine.edu referencing the study title and number along with name of person(s) to be added, years of human subjects research experience, role on the project, and email is sufficient. If the CITI training was not completed through UMaine please also provide the CITI training certificate.

Some personnel changes may also require a change to other sections of the application such as the consent document, and recruitment materials. In such cases, the application should be modified to include these changes and submitted as a modification for review.

Q. Who should be listed as study staff on the application?

All study staff members who are reasonably engaged in the design, conduct or analysis of the study should be listed in the application. If the staff or students will have direct contact with subjects or access to subject identifiable data, they must be listed in the application. The person must also have completed all the required IRB training.

Q. Do all personnel have to be listed on the consent form?

No. The PI must be listed on the consent form. Beyond that, we suggest no more than 3 people the research participant is most likely to encounter during the conduct of the study.

Co-Investigators are not required to be listed on the consent form.

Ongoing Study Management:

Q. How do I submit a continuing review?

You will need to submit the continuing review form that was emailed to you along with the status report and consent forms to umric@maine.edu. If you are also requesting a modification, you will also need to submit the edited application and follow the modification instructions on the IRB website. Do not wait until the Study Expiration date to submit your continuing review, as the study will very likely enter lapse state.

Q. I did not submit my continuing my review and my study has lapsed, what does this mean?

The IRB Office sent you reminders for a continuing review and you did not respond to the IRB. Please submit the continuing review documents or study closure immediately.

Research activities must stop while the study is lapsed. This includes recruitment, consent, interactions with participants, and collection of data. Advertisements currently

running in the media must be pulled. Data collected during a lapse in IRB approval cannot be used. Continuation of research activities without IRB approval is a violation of federal regulations.

Q. When should I close my IRB application?

When all research activities are complete. We recommend you keep your study open until journal manuscripts have been submitted and accepted, just in case further data analysis is needed.

Q. Do I need to report to the IRB when a study is completed?

Yes, the regulations require "prompt reporting to the IRB of changes in research activity." Completion of a study is a change in activity and should be reported to the IRB.

Q. Can I reactivate a previously closed study?

Yes. See Reactivating a Closed Study for guidance.

Working with Outside IRBs:

Q. Will the University of Maine rely on a foreign IRB?

We will not rely on an IRB that is outside of the United States.

Q. What is the difference between Single, Reviewing and Relying IRB?

Single IRB: One IRB of record (also called Reviewing IRB), selected on a study-by-study basis, that provides the regulatory and ethical review for all sites participating in a multisite study.

Reviewing IRB: The IRB providing regulatory oversight (IRB of Record) for any participating sites that have waived oversight to this IRB.

Relying IRB: The IRB of a participating site that has waived regulatory oversight to another IRB (the Reviewing IRB).

IRB Required Training:

Q. Federal regulations require that all researchers receive ethics training. How do I meet this requirement?

All staff, students and faculty who submit an application for IRB review must complete the online CITI training.

Q. What if not all personnel have completed CITI training but I really need to get started on my research?

That is okay. You can submit the application with just those people that have completed the training and get approved to start your research. Once additional personnel complete the training, you can submit an email to umric@maine.edu requesting to add those individuals, following the instructions to request a modification to a previously approved study.

Q. I completed the CITI Responsible Conduct in Research (RCR) course. Does this meet the IRB training requirement?

No. All personnel must complete the Social/Behavioral or Biomedical IRB course. See instructions for selecting the correct IRB training.

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