University of Massachusetts Amherst
Human Research Protection Office

Student Handbook: A Guide to Conducting Human Subject Research

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This handbook is an adaptation of “Student Handbook: Making Sense of Human Subjects Research” developed by the University of Southern California Office for the Protection of Research Subjects (OPRS)
# Table of Contents

Introduction to Human Subject Research Protections.........................................................ii

I. Human Subject Research at a Glance........................................................................1

II. Ethical and Regulatory Framework........................................................................3

III. Institutional Review Board......................................................................................8

IV. What is/isn’t Human Subject Research?.................................................................9

V. Types of IRB Review................................................................................................20

VI. Tips for Expedited and Exempt Research............................................................25

VII. Student Investigators and the IRB Review Process.............................................26

VIII. Investigator Reporting Responsibilities after IRB Approval...............................33

Appendix A: Determination Form..................................................................................37

Appendix B: IRB Submission Process..........................................................................43

Appendix C: What do the Reviewers Want? Things to Consider When Submitting a Protocol.................................................................44

Appendix D: Tips for Better IRB Submissions............................................................51

Appendix E: Helpful Links............................................................................................54

Appendix F: Glossary of Common IRB Terminology..................................................55

Appendix G: e-Protocol User Guide.............................................................................65
Introduction to Human Subject Research Protections

Conducting research with human subjects is a privilege not a right.

Whether research is classified as social, behavioral, educational, or biomedical, all human subject research must be conducted responsibly and in such a way as to ensure the protection of the rights, welfare and safety of participants.

The purpose of this Handbook is to assist student investigators in meeting these obligations by summarizing important components of the federal regulations, introducing the commonly cited ethical principles that serve as the foundation for the ethical conduct of human subject research, and providing guidance on UMass Amherst human subject research policies and Institutional Review Board (IRB) processes.

Comments or questions about information in this Handbook may be addressed to the UMass Amherst Human Research Protection Office (HRPO) by emailing humansubjects@ora.umass.edu or by calling 413-545-3428.

Additional information and educational materials may be found on the UMass Amherst HRPO website (http://www.umass.edu/research/human-research-protection-office-hrpo) contains.
I. Human Subject Research at a Glance

Research involving human subjects conducted by personnel affiliated with UMass Amherst must be reviewed and approved by the UMass Amherst Institutional Review Board (IRB) prior to research activities being initiated. The UMass Amherst HRPO manages the submission and review process for the IRB as well as other administrative needs of the IRB.

All investigators, whether staff, students, or faculty are required to adhere to federal and state regulations, university policies, and ethical principles when conducting human subject research.

Student investigators must follow the study procedures approved by the IRB. If deviations from the IRB approved protocol or violations occur, they must be reported promptly to the IRB.

Revisions (changes) to an IRB-approved research study must be reviewed and approved by the IRB prior to implementation, unless subjects are at immediate risk of harm. These changes are submitted as revisions in e-protocol, the online system for managing IRB submissions. For instructions on how to submit a revision see the e-Protocol guidance in this document.

The informed consent process is a central element of the ethical treatment of human research subjects. During this process the investigator informs the potential participant about the research as well as any possible risks or benefits associated with it. The goal is to ensure prospective participants have all of the information they need in order to make an informed decision about whether or not they would like to participate in the study. Investigators must be forthright and realistic when describing the benefits and risks of research participation and when answering questions posed by subjects. For sample consent documents, please visit UMass Amherst’s Informed Consent Guidance and Templates page.

Reporting Adverse Events and Unanticipated Problems Involving Risk to Subjects or Others

Although not specifically defined in the regulations, an adverse event is generally defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events may encompass both physical and psychological harms.
They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

Unanticipated Problems are unexpected events related or possibly related to the research that places subjects or others at a greater risk of physical or psychological harm. These unanticipated events must be reported promptly in accordance with IRB policy using the e-Protocol system for reportable events. For more information on reportable events please see Chapter VIII of this document.

**Approval Period and Continuing Review of Research by the IRB**

Research studies that are considered minimal risk are generally approved by the IRB for a period of 12 months. The IRB approval letter for a research project will contain an expiration date not to exceed 12 months from the date of approval and therefore ongoing research studies must undergo continuing review by the IRB at a minimum of every 12 months. Requests for renewal (continuing review) are made submitting a renewal application in e-protocol. In the event renewal is not approved prior to the expiration date, all research activities associated with the research must stop until renewal is approved (this includes recruiting additional subjects, analyzing data, etc.)

**Study Completion and Final Reports**

When the research study is complete, student investigators are expected to notify the IRB of study completion and closure. This can be done by submitting a Final Report in e-protocol. For more information on the e-Protocol system see Chapter VIII.
II. Ethical and Regulatory Framework

The current ethical and regulatory framework for the conduct of human subject research dates back to the 1940’s Nuremberg Code. In this section we provide a brief summary of the major ethical and legal regulations that pertain to human subject research.

**Nuremberg Code**

Following the atrocities committed by the Nazi regime during World War II, the Nuremberg Code was developed and outlined 10 key points to govern the ethical conduct of human subject research. The Nuremberg Military Tribunal convened to bring to trial, Nazi physicians who conducted inhumane medical experiments on prisoners without their consent. The Code provided many of the basic principles that still govern the ethical conduct of human subject research today. For example, it asserts that “the voluntary consent of the human subject is absolutely essential” to conducting medical research.

The Nuremberg Code further explains that this requirement for subjects includes:

- capacity of participants to consent
- voluntary participation
- freedom from coercion
- no penalty for withdrawal
- full knowledge of the risks and benefits of participation

The Nuremberg Code can be found at: http://www.hhs.gov/ohrp/archive/nurcode.html

**Declaration of Helsinki**

In 1964, the World Medical Association adopted the Declaration of Helsinki as guidance for medical doctors undertaking biomedical research involving human subjects. The Declaration addresses international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki has undergone numerous revisions, the most recent occurring in 2008.
The Declaration of Helsinki states:

- Research involving medical interventions with humans should be based on results from laboratory and animal experimentation
- Human research protocols should be reviewed by an independent committee prior to initiation
- Informed consent of research participants is necessary
- Research should be conducted by medically/scientifically qualified individuals
- Risks should not exceed benefits


Belmont Report

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the U.S. Congress. The Commission was established in response to public outrage over the Tuskegee syphilis study conducted by the U.S. Public Health service in the 1940’s. The research involved using disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available. As a result, the Commission produced "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research."

The Belmont Report identifies three basic ethical principles for conducting research involving human subjects: respect for persons, beneficence, and justice. These three principles provide the framework for the regulations governing human subject research in the U.S. These terms have specific meaning when applied to human subject research as noted below:

1) Respect for persons

Respect for persons requires that individuals be treated as autonomous beings, that is, as having the capacity to make their own choices. It also provides that persons with diminished autonomy be protected. In other words, a person must be capable of making an informed decision whether or not to participate in a human subject research project and safeguards must be in place for those who cannot make an informed decision on their own. Gaining the informed consent of human research subjects is one of the most fundamental and important principles of ethical research and is derived from the principle of respect for persons.
2) Beneficence

Beneficence is demonstrated when subjects are protected from harm, specifically, by maximizing possible benefits and minimizing possible harms from their participation in a research study.

The “risk-to-benefit” ratio for participants in a study must be acceptable to the IRB in order for the research to be approved.

3) Justice

Justice refers to equitable selection of subjects for a research study without undue burden of risks or exclusion from likely benefits of a particular population. For example, exclusive enrollment of a subset of the population for a condition that is not unique to that subset is not just. Additionally, enrollment of a population unlikely to benefit from the results of the research is also unjust.

The Belmont report can be found at: http://www.hhs.gov/ohrp/policy/belmont.html

Federal Policy for the Protection of Human Subjects (Common Rule)

In 1991, the U.S. Department of Health and Human Services codified into regulation the Policy for the Protection of Human Subjects (Title 45, Part 46). These regulations, called the “Common Rule” (Subpart A), provide the basic foundation for the human subject protection program in use today. This Federal Policy has been codified by most federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title “Common Rule.” The Policy in Subparts B, C, D, provides additional protections to what are considered “vulnerable populations”.

Vulnerable populations requiring special protections when involved in human subject research are:

- pregnant women, fetuses, and neonates (Subpart B),
- prisoners (Subpart C), and
- children (Subpart D).

The Code of Federal Regulations (Title 45 Part 46) can be found at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. These regulations apply to most research conducted by UMass Amherst students, staff, and faculty.
United States Food and Drug Administration (FDA) Regulations on Protection of Human Subjects and Institutional Review Boards (21 CFR 56)

FDA regulations are not usually applicable to the type of research conducted at UMass Amherst. They mainly apply to clinical research. Nevertheless, if you’re working with drugs, devices or biologics (for example, vaccines, blood and blood products, allergenic extracts, human cells and tissues, etc.), you should familiarize yourself with the following regulations:

1. **21 CFR 50** contains the federal definition of human subjects, federal requirements for informed consent and the required safeguards for clinical investigations.
2. **21 CFR 56** contains specific regulations regarding the composition, organization, and functions of Institutional Review Boards.

Health Insurance Portability and Accountability Act (HIPAA) / (Privacy Rule)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal privacy law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities and clinics) from using or disclosing patients’ "protected health information" (PHI) without written authorization. Although UMass Amherst is not a HIPAA-covered entity, HIPAA regulations may come into play if an investigator is intending to utilize PHI. Informed consent is not sufficient documentation to allow the disclosure and use of PHI. Disclosure and use of PHI must be effected by a HIPAA Authorization form signed by the individual to whom the private information applies.

When a student investigator intends to obtain PHI in connection with their research, he/she must indicate so in the IRB application and include the HIPAA Authorization form that will allow the disclosure and use of such information by the research participant.

Protected Health Information (PHI) is health information transmitted or maintained in any form or medium that includes ALL of the three following conditions:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

The Privacy Rule governing PHI can be found at the HIPAA privacy website of the Office for Civil Rights (OCR): [http://www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa).
Additional information can be found on the UMass Amherst HRPO website at [www.umass.edu/research/hipaa](http://www.umass.edu/research/hipaa).
III. Institutional Review Board (IRB)

What is the Institutional Review Board?

The IRB is an independent board established at institutions or organizations where human subject research is conducted or supported.

The IRB is charged with reviewing research projects involving human subjects for compliance with institutional policies and state, local, and federal regulations. The IRB will also assess whether the risks posed to research subjects are proportional to the benefits that may be derived.

The IRB is comprised of at least five members from relevant academic disciplines including at least one who is not affiliated with the institution. The membership includes faculty, staff, and members from the local community. IRBs must also be diverse in terms of race, gender, and cultural backgrounds.

IRB members must have the necessary experience and expertise to evaluate proposed research projects.

The IRB functions as a surrogate “human subject advocate” whose role is to protect subjects participating in research by reviewing research projects before research is allowed to begin.

IRB functions and duties are described in the 1991 Federal Policy for the Protection of Human Subjects (Common Rule - Title 45 CFR 46).

What does the IRB do?

The IRB is responsible for reviewing and approving proposed or continuing human subject research. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, obtaining fully informed consent, minimizing risks, maximizing possible benefits, and assuring the maintenance of privacy and confidentiality of persons and their personal information (data). Human subject research projects cannot be conducted without the approval of the IRB.

The IRB has the authority to approve, require changes to study procedures, or disapprove proposed research projects. Institutional officials can disapprove an IRB approved project but cannot approve a project that has been disapproved, suspended, or terminated by the IRB.
IV. What is/isn’t Human Subject Research?

The first question an investigator should consider with respect to an IRB application is whether the project fits the definition of human subject research. In order to do so, the project must meet the federal regulatory definitions of both research and human subjects in order to require IRB approval.

Research

Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102 (d)).

"Generalizable knowledge" is information where the intended use of the research findings can be applied to populations or situations beyond that studied.

As described in the Belmont Report, “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

Human subject research generally does not include journalism, political polls, or public health surveillance. However, some of these activities may include or constitute human subject research in circumstances where there is a clear intent to contribute to generalizable knowledge – and the study collects data about the subjects themselves. If this is the case then the entire project must reviewed and approved by the IRB.

Human Subjects

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

The following list contains brief explanations of the terms found in the definition of human subjects.

- The term living individual refers to the state of the subject. The
specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from non-living subjects are not subject to the human subject protection regulations.

- “About whom” indicates that the data received from the living individual is about the person. A human subject research project requires that the data received from the living individual is about the person. Some interactions with people for the purpose of collecting information do not collect any information about that person. For example, a researcher may contact a non-governmental organization to ask about its sources of funding. A researcher might also contact individuals in order to collect information about a product or a service. In both cases, the data being collected is not about the individual. Therefore, in these cases the individuals would not be considered human subjects.

- **Intervention** includes physical procedures, manipulations of the subject, or manipulations of the subject’s environment for research purposes.

- **Interaction** includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

- **Identifiable private information**\(^1\) includes information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record) and information about behavior that occurs in a context in which an individual can reasonably expect that no recorded observation is taking place (such as a locker room or public restroom).

- **Identifiable** means the information contains one or more data elements that can be used alone or combined with other reasonably available information to identify an individual (e.g. social security number, birthdate, home address). Please note that studies based on data collected for non-research purposes may not constitute human subjects research if individuals are not identifiable (e.g. data such as service statistics, school attendance data, crime statistics, or election returns).

**NOTE:** Observational studies of public behavior (including watching television or observing conversation in internet chat rooms) are not human subject research if they do not involve intervention or interaction with the subjects and if the behavior is not private.

\(^1\) Disclosure of private information may place subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation. Researchers must use caution with collections of identifiable data of a sensitive nature.

In light of the potential regulatory consequences of not obtaining IRB review and approval, the investigator should err on the side of caution and consult the IRB when he/she is uncertain if a project is human subject research.
Determining if a Study is Human Subject Research

Determining whether a project requires review by the IRB is sometimes difficult and for this reason it is always best to consult with the Human Research Protection Office (HRPO) for guidance. The flowchart on the next page is designed to assist in making this determination.

The HRPO makes the determination whether or not a project meets the definition of human subject research. Federal regulations require that proposed research involving human subjects be reviewed and approved by the Institutional Review Board prior to project initiation.

If you are unsure if your project meets the definition of research or if you require documentation that your project does not require IRB review, complete and submit the Determination of Human Subject Research form found in Appendix A of this document.

The determination of whether or not a project or activity is defined as human subject research rests on the answers to the following three questions:

1. **Is it research?** The federal regulation defines research as a systematic investigation, including research development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge. Research is usually described in a protocol, a formal document that describes the research question or hypothesis and how it is to be tested (methodology) to establish facts and reach conclusions.

2. **Is the intent to produce generalizable knowledge?** The *intent* to develop or contribute to generalizable knowledge makes an activity research. Generalizable knowledge is knowledge that is expressed in theories, principles, or statements of relationships that can be generally applied to our experiences. Activities designed to contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. The information is collected to share with others in a discipline and is created to make a broad statement (conclusion) about a group of people, procedures, programs, etc.

   *If the activity is not a systematic investigation designed to contribute to generalizable knowledge, the activity does not meet the regulatory definition of research.*

Generalizable knowledge includes one or more of the following concepts: (1) The information contributes to a theoretical framework or an established body of knowledge; (2) The primary beneficiaries of the study are other researchers, scholars, and practitioners in the field of study; (3) Publication, presentation or other distribution of the results is intended to inform the field of study; and, (4) The results are intended to be replicated in other settings.
Flowchart to Determine if an Activity is Considered Human Subject Research and Requires IRB Approval

Is the activity a **systematic inquiry** to develop or contribute to **public knowledge and understanding**?

- **Yes**
- **No**

Activity is research. Does the research involve obtaining information about **living individuals**?

- **Yes**
- **No**

Does the research **involve intervention or interaction** with the individuals? (Interaction includes observation)

- **Yes**
- **No**

Is **private information** being collected? (Private means information was provided for specific purposes by an individual, which they can reasonably expect will not be made public, or is about behavior occurring in a context that an individual can reasonably expect will not be recorded or observed)

- **Yes**
- **No**

This activity is **research involving human subjects** and must go through the UMass—Amherst IRB.

You do not need to file with the UMass-Amherst IRB, but other Federal, State, or Local laws and/or regulations may apply.

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Is the information **individually identifiable**? Can the researcher link information to specific individuals either directly or indirectly through coding systems?

- **Yes**
- **No**

The research may meet criteria for **EXEMPT review**, but this review and determination must be carried out by the UMass Amherst IRB.
3. **Does it involve human subjects?** Although a seemingly straight-forward question, whether or not an activity involves human subjects can be somewhat confusing, especially when using coded private information or specimens. Human subjects are defined as “living individuals about whom an investigator conducting research obtains:

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

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

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

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

For purposes of this document, *coded* means that:

- Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Determinations of what does or does not involve human subject research must be made by the IRB or individuals designated by the IRB Chair who have sufficient training and expertise in making such determinations.

In analyzing a particular activity under this question, it is important to focus on what is being obtained by the investigators. If the investigators are not obtaining either data through intervention or interaction with living individuals, or identifiable private information, then the research activity does not involve human subjects.

**What about Research Involving Coded Private Information or Biological Specimens?**
Whether or not an activity is classified as “not involving human subjects” or qualifies for exemption under 45 CFR 46.101(b)(4) is determined by the following:

- the source of the data (primary or secondary data)
- the ability or inability of the investigator to link data or specimens to specific individuals either directly or indirectly through coding systems

Research involving only coded private information or specimens is not considered human subject research if both of the following conditions are met:

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals (i.e. it is pre-existing data); and
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
   a. The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
   b. There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
   c. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

The exemption under 45 CFR 46.101(b)(4) applies to research involving private information and specimens when:

1. Data is already existing at the time the research is proposed and is available publicly, or
2. The information is recorded by the investigator(s) in such a manner that subjects cannot be identified, directly or through identifiers linked to subjects.

This exemption would not apply if the investigators, having obtained identifiable private information or specimens from existing records or specimens, record the data or information in a coded manner, since the code would enable subjects to be identified through identifiers linked to the subjects.

NOTE: If it is determined that the research does NOT require IRB approval, the investigator, will receive a letter to confirm the decision was made by the IRB.
Identifying Studies that Are Human Subject Research

Certain studies may have the characteristics of research but do not meet the regulatory definition of human subjects research. Federal Regulations state that the definition of human subjects and research must both be met in order for a study to be considered human subject research.

Examples of activities that are Human Subject Research:

1. Utilizing test subjects for new devices, products, drugs, or materials. Examples of this type of research may include testing the effectiveness of a new drug treatment or testing the effectiveness of a newly developed exercise machine.

2. Collecting data through intervention or interaction with individuals. Examples of this type of research include drug trials, internet surveys, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors that contribute to generalizable knowledge.

3. Using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question. An example of this type of research would be an investigator performing a chart review of patient health records as part of data collection.

4. Using bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if one did not collect these materials for the study. However, such research may be considered exempt or not human subjects research if the materials/data are coded and the investigator does not have access to the key. Guidance on research involving coded private information or biological specimens may be found at http://www.hhs.gov/ohrp/policy/cdebiol.html. An example of this type of research would be collection of saliva samples from participants in order to measure changes in cortisol levels during a specific task.

5. Producing generalizable knowledge about categories or classes of subjects from individually identifiable information. Much research falls into this category. One example would be collecting data regarding the eating habits of freshmen college students in hopes of generalizing the findings to
freshmen college students in the U.S. Another example would be data collection from individuals undergoing a particular cancer treatment in order to make generalizations about the treatment and how it will work for others diagnosed with cancer.

7. Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living, working space or test chamber.

Identifying Studies that Are Not Human Subject Research (Do Not Need IRB Review):

Examples of activities that are Not Human Subject Research (NHSR):

1. **Data collection** for internal departmental, school, or other university administrative purposes. *Examples: teaching evaluations, customer service surveys.*

2. **Service surveys** issued or completed by university personnel for the intent and purposes of improving services and programs of the university or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary. This would include surveys by professional societies or university consortia. *Example: A university-issued survey regarding employee use of and satisfaction with Parking Services.*

   **Note:** If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.

3. **Information-gathering interviews** where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. *Example: canvassing librarians about inter-library loan policies or rising journal costs.*

4. **Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are not intended for use outside of the classroom. *Example: instruction on research methods and techniques. For more detailed information on course-related activities/class projects, please see the end of this chapter.*

   **Note:** The IRB is only required to review studies that meet the Federal
definitions of “research” and “human subject”².

5. **Biography or oral history** research involving a living individual that is not generalizable beyond that individual. *Example: Interviewing an individual about their experience during a past event, such as the September 11th terrorist attacks.*

6. **Independent contract for procedures** carried out for an external agency. *Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.*

7. **Research involving cadavers**, autopsy material or bio-specimens from now deceased individuals. *Example: Obtaining organs from deceased individuals for use in biology research.*

   **Note:** Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the HRPO for further information.

8. **Innovative therapies** except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.) *Example: Based on a growing recognition that “a moist wound healing environment predisposes surgical incisions to a faster healing and better patient outcome” a surgeon uses an advanced wound care technology on a patient who underwent a radical mastectomy to improve patient outcomes.*

9. **Quality improvement** projects are generally **not** considered research unless there is a clear intent to contribute to generalizable knowledge **and** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. *Example: Institutional research conducts a campus wide survey of students regarding their assessment of food services in the campus dining facilities.*

   **Note:** Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the HRPO for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

10. **Case histories (medical)** which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a

description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.


   **Note:** Investigators should contact the HRPO if they are uncertain as to whether the data qualifies as “publicly available”.

12. Coded private information or biological specimens that were not collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects’ names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator.

   **Note:** Investigators are not allowed to make this determination. These projects require verification from the IRB.

**Class Projects**

Class projects are designed to provide students an opportunity to practice various research methods such as interview, observation, and survey techniques, as well as data analysis. They do not require IRB review. Research conducted by students (graduate or undergraduate) as part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to nor will it likely lead to generalizable results. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures including research methods (interviewing, observation and survey techniques) as well as data analysis.

Class projects that meet ALL of the conditions stated below may be conducted under the supervision of the faculty member without submitting a protocol to the IRB. Projects that do not meet all of these conditions must be submitted to the IRB for review.

The class project must meet the definition of classroom research. This is defined as a project which:

- is a normal part of the student’s coursework
- is supervised by a faculty member
- has as its primary purpose the development of the student’s research skills
• does not present more than minimal risk to participants or to the student investigator

• does not include as research subjects any vulnerable populations as classified in Subparts B,C, or D of 45 CFR 46 such as pregnant women, fetuses, neonates, prisoners, and individuals under the age of 18.

• Is not “genuine research” that is expected to result in generalizable data or expected to result in publication or some other form of public dissemination.

The above refers to student class projects only. Independent research projects conducted by students such as honors projects, theses, dissertations, and independent study projects that collect data through interactions with living people or access private information DO fall under the jurisdiction of the IRB. These projects will require that a protocol be submitted to the IRB for review.

PLEASE NOTE: Even if it is not the intent of a class project to produce generalizable knowledge, if the project involves more than minimal risk to participants or involves a sensitive topic area, it WILL require IRB review and approval. Categories of sensitive topics include information:

• relating to sexual attitudes, preferences or practices

• relating to the use of alcohol, drugs or other addictive products

• pertaining to illegal conduct

• that if released could reasonably damage an individual’s financial standing, employability, or reputation within the community

• that would normally be recorded in a patient’s medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination

• pertaining to an individual’s psychological well-being or mental health

• genetic information.
V. Types of IRB Review

Federal regulations provide for three types of IRB review: exempt, expedited, and full-board\(^3\). The following chapter provides an explanation of each type of review and examples of studies that represent each type. The IRB conducts reviews using the criteria contained in the Federal Policy for the Protection of Human Subjects (CFR 45; Part 46, Section 46.111).

Exempt Review

Exempt research is research with human subjects that is “exempt” from the provisions of the Code of Federal Regulations (45 CFR 46). An exempt research project does not require annual continuing review unless the project is revised in such a way that it no longer meets the criteria under which it was determined to be exempt.

The IRB staff – not the researcher – must determine when a research project falls under one of the six exempt categories. There are six exempt categories listed in the federal regulations (45 CFR 46.101(b)).

Exempt Review Categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or comparison of 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: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (b) 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.\(^4\)

\(^3\) A unique category, Not Human Subjects Research, is used when the research does not meet the federal definition of human subjects and/or research and thus will not require IRB review. This term may also be used for coded data/specimens when use of such collections meets certain conditions.

\(^4\) Studies involving children can be exempt if the PI only plans to observe and not interact with the children. Student investigators are advised to contact the HRPO for further information regarding subjects under the age of 18 and other categories of vulnerable subjects.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g, or for the National Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.

4. Research involving the collection or study of existing data, documents, records, pathological 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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) 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 (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level found to be safe, an agricultural chemical or environmental contaminant at or below the level found safe by the Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**Expedited Review**

Expedited review applies to those research projects that do not fit an exempt category but do not present more than minimal risk to subjects. These projects must meet one of the nine categories for expedited review. Expedited review requires the same approval criteria as a full board study, but because these studies entail less risk, they are reviewed by the IRB Chair or a Designated Reviewer, rather than the convened IRB. During this process, designated reviewers exercise all of the authorities of the IRB except that they may not disapprove the research.

**Expedited Review Categories:**

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5 Publicly available refers to record sets that are readily available to the broad public, such as census data, federal health, labor, or educational statistics. An investigator should not assume information qualifies as “publicly available” merely because it has been posted on an electronic website and can be accessed without authorization.
1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant 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 (b) 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.

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

4. 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.)

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

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

7. 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.

The following expedited categories apply only to projects that have been initially reviewed and approved by a convened IRB that now require continuing review (renewal):

8. Continuing review of research previously approved by the convened IRB as follows: (a) 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 (b) where no subjects have been enrolled and no additional risks have been
identified; or (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) 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.

**Full Board (Convened) Review**

Studies that involve **more than minimal risk** to subjects require full board review at a convened meeting at which a quorum (more than 50%) of the membership is present. For the research to be approved, it must receive the approval of a majority of those members present.

Federal regulations do not specifically list categories that require full board review since the criteria for full board review is determined by the risk to subjects potentially being greater than minimal. Studies such as those listed below are normally sent to full board for review when part of the study design involves greater than minimal risk to participants (risks can be physical, psychological, social, economic) and may be determined to be greater than minimal by the investigator or the IRB.

- studies involving clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery procedures
- studies taking place internationally (particularly countries with little or no provisions for protection of human subjects) where subjects may be at physical, psychological or legal risk
- studies in which disclosed information could require mandatory legal reporting (e.g., child/elder abuse, etc.)
- studies involving deception which increase the risk to subjects or others
- studies in which the IRB staff, chair, member, or designee determines risk to subjects or others to be greater than minimal risk
- studies using certain “vulnerable” populations requiring extra protections

**A Reminder…**

**Student investigators should consult with the HRPO if unsure which type of review is required for their research.**

All human subject research whether conducted by student investigators, faculty or staff must obtain IRB approval prior to initiation of any research activity (presuming the study fits the federal definition of “human subjects” and “research” and is not solely a classroom exercise).
Retroactive approval for data previously collected for an unapproved study is not allowed. Failure to seek IRB approval for research may invalidate a study. Many journals will not accept a human subject research paper without proof of IRB approval.

IRB Review Exceptions

Some research that involves investigator interaction with people does not meet the federal definition(s) of “human subjects” and/or “research.” When uncertainty exists, UMass Amherst requires that investigators submit a Determination of Human Subject Research application so that a determination can be made as to whether the study is or is not human subject research. For more information, please see Chapter IV of this handbook.

Coded Data/Specimens

Studies using coded private information or coded biological specimens not collected by the current investigator, nor collected for the currently proposed project, do not require IRB review provided that the current investigator is not able to link the coded data/specimens to individual subjects. Further, if the data/specimen provider has access to the identity of the subjects, the investigator must confirm that under no circumstances will the identity of the subjects be released to him/her.


IRB Approval

IRB project approval for minimal risk research is valid for a maximum period of 12 months. If the research is planned to continue for more than a year, a renewal application (also called a continuing review or application) must be submitted to the IRB to extend approval for an additional year. Renewals are submitted via the e-Protocol system.
VI. Tips for Expedited and Exempt Research

This chapter provides information to assist students in determining the type of IRB review (exempt or expedited) required for their research. **In order for research to qualify for exempt or expedited review it must first be determined that the research is no greater than minimal risk to subjects. Note: Expedited Review is a type of IRB review. It does NOT mean a faster review.**

Minimal risk means “that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.

### How to Decide if a Project is Expedited or Exempt

The federal regulations allow for six exempt and nine expedited review categories (See Chapter V). Designation of a study in either the expedited or exempt research categories is sometimes a judgment call rather than a hard line regulatory decision. These decisions become clearer with experience and dialogue with others. The following section has been designed to help investigators reflect on the distinction between expedited and exempt studies.

First, look at the abstract and methodology and determine if it meets the federal definition of both human subject and research. If the project does not meet both, then it is Not Human Subjects Research (NHSR). A determination form should be submitted and the IRB will confirm the determination. The determination form can be found in Appendix A. Follow the instructions on the form in order to submit it to the IRB for review.

If neither of the two descriptions above fit the project, look at the six exemption categories in Chapter V and reflect on which category the project fits.

If an exemption category seems to fit the project, consider the following questions:

- Will vulnerable subjects be used, such as children or prisoners?
- Will the investigator collect sensitive/private information and keep identifiers or have access to them?
- Is there risk to participants from the information being collected that could potentially be greater than minimal risk?

If the answer to any of these questions is “yes”, then the project may not be exempt and may require Expedited or Full Board IRB review. If the risk to subjects is greater than minimal risk, the study must be approved at a convened meeting of the IRB.

If the project does not appear to fit any exempt category, or there are “yes” answers to the questions above, forward the project as expedited or full board for further determination.
VII. Student Investigators and the IRB Review Process

The UMass Amherst Human Research Protection Office (HRPO) offers assistance for students navigating the Institutional Review Board (IRB) process. Whether conducting human subject research as part of an honors project, thesis or dissertation project, or an independent study, the HRPO staff available to help!

The first step is to determine whether your project needs to be reviewed by the IRB or if it qualifies as a class project that does not require IRB review. Please refer to Chapter IV for guidance on determining whether or not your project needs to be reviewed by the IRB. In the event your project DOES NOT require IRB review, you will receive documentation from the HRPO stating that the IRB has made this determination.

If it is determined that your project DOES require IRB review, you will be required to submit an IRB application via e-Protocol, the web-based system for submission and review of IRB applications. PLEASE NOTE: Access to the e-Protocol system will not be granted until all required human subject protection training is complete. Training is available online through the Collaborative Institutional Training Initiative (CITI). Please see the Training, Education, and Outreach section of the HRPO website for more information regarding training.

HRPO staff are available to consult with students in person regarding their research projects. If it has been determined that your project requires IRB review and you would like assistance navigating the IRB submission process, please fill out the web form at https://www.umass.edu/research/webform/hrpo-student-consultation-form.

PLEASE NOTE: HRPO staff cannot assist in the development of your research project. This should be done with your faculty sponsor. HRPO staff will assist you with your IRB application and other materials required as part of the application process.

Preparation for e-Protocol Submission

UMass Amherst student investigators must have a faculty sponsor who serves as an advisor on research projects. Faculty sponsors bear ultimate responsibility for their students and the ethical conduct of the research. They are responsible for ensuring students are adequately trained in human subject protections and understand the ethical principles underlying the ethical conduct of research.

Once the faculty sponsor has approved the research topic, design, and methods, the project is ready for IRB submission through the e-protocol system. Both the student and faculty sponsor must complete CITI training to obtain access to the e-Protocol system. Instructions for obtaining access to the e-Protocol system can be found in Appendix G, e-
Protocol User Guide. The student and the faculty sponsor can work together to determine whether the project requires exempt, expedited, or full board review. However, the final determination of the review type is made by the IRB.

Students should seek study-related assistance from their faculty sponsors before submitting to the IRB to assure study risks are minimized and that faculty sponsors are prepared to monitor the ethical conduct of the project. Students can seek guidance from the HRPO for help pertaining to the IRB submission process.

Please note that student investigators and their faculty sponsors must fulfill the University’s CITI online training requirement before IRB approval for a study can be obtained. Students whose projects are determined to not qualify as human subject research do not need to complete CITI.

Before You Begin:

- Complete the required CITI online training (required of all study personnel: student investigator, Faculty Sponsor, and research staff)
- Obtain an e-protocol account. (See Appendix G for instructions).
- Determine appropriate type of IRB review (exempt, expedited). If uncertain, it is always best to consult with your faculty advisor or an IRB analyst in the HRPO.
- Allot enough time for the IRB submission and review process. An initial IRB review takes approximately 4-6 business weeks.
- Answer each question on the e-Protocol form. Do not leave questions blank. If you believe a question does not apply to your study, answer “Not Applicable”.
- If your study is being conducted off-site (for example, at a school, hospital or other organization), you will need permission from the site to conduct research there. Site permission should be requested prior to submitting your IRB application.

NOTE: As part of your IRB application you will need to submit a letter of support/permission from the site. The letter of support must be on the official letterhead of the site where you’re conducting research. Alternatively, you may submit a letter of support/permission from an official email address at that site.

Human Subjects Training

All UMass Amherst research team members engaged in human subject research must complete an online training program called the Collaborative Institutional Training Initiative (CITI) Program. This is to ensure that all individuals conducting research with humans are properly trained in human subject protections. The CITI training course is available at...
www.citiprogram.org. The required training modules are divided in two learner groups, Group 1 Biomedical Research Investigators and Key Personnel; and Group 2 Social Behavioral and Education Research Investigators and Key Personnel.

The Biomedical Research course is required for medical, physiological, or pharmacological studies. This includes but is not limited to, research with drugs, devices, or other interventions. The Social Behavioral and Education Research (SBER) course is required for studies on sociological, psychological, anthropological or educational phenomena including observational and survey research and work with population and/or epidemiological studies.

CITI training must be completed before a research protocol is submitted to the IRB for review. Training is valid for a 5 year period. Once the training has been completed, investigators may contact the HRPO to obtain a login for the e-protocol system, the online protocol submission and review system. CITI training is required for any individual listed as personnel on a human subject research protocol.

CITI information can be found at http://www.umass.edu/research/human-subjects-trainingciti-training-course.

Application Submitted to IRB for Review

After the application is submitted electronically via e-Protocol, the faculty advisor must review and sign-off on the application before the IRB will review the study. Through this process, the advisor attests to the scientific merit of the submission, the availability of needed resources, and the department acceptance of the study.

Upon submission via e-Protocol, the application is routed to the HRPO staff for preliminary review. The IRB grants the final approval of IRB protocols. If a study is exempt or does not qualify as human subjects research, as determined by HRPO staff, no further review is required. However, any study changes must be submitted and approved by the HRPO staff prior to initiation of changes as changes could modify the initial determination made by the IRB.

The chart below provides an outline of the IRB review process, starting with online IRB submission by the researcher and ending with the IRB granting approval of the research.
Schematic of IRB Approval Process

Key:

(1.) **Student Investigator Designs and Submits Study via e-protocol:**
Investigators design their protocol and submit it via the e-Protocol system. Investigators must indicate if the application requires exempt, expedited, or full board review. The final determination of the review category is made by the IRB.

**NOTE:** Student investigators, key personnel and faculty sponsors must fulfill the University’s CITI online training requirement before the IRB will give final approval.

(2.) **Faculty Sponsor Sign-Off:**
Once the application is submitted (via the e-Protocol system) the faculty sponsor must review and sign off on the application by sending a faculty sponsor statement to the HRPO. This sign-off represents consideration of scientific merit, availability of resources, or other issues at the department level.

(3.) **HRPO:**
After department or faculty sponsor approval is obtained, an initial review of the application is conducted by the HRPO staff. At UMass Amherst, the HRPO staff conducts a thorough pre-review of the application to verify the correct type of review, and to evaluate the protocol and supporting documents (e.g., consent documents, recruitment materials, letters of support/permission, surveys, questionnaires, etc.). If a study is approved as **exempt** or determined to be “not human subject research,” no further review is required by the IRB. A letter will be issued to the investigator indicating that the work does not require IRB review.
For studies designated as **expedited** or **full board**, IRB review is required by a designated reviewer or the full board, respectively. (For more information on the IRB Review categories see Chapter V: Types of IRB Review).

The possible determinations/outcomes that can be made on a study are as follows:

- **Approved** – the application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IRB gives approval for the research to be conducted.

- **Approved with Conditions** – the application is complete but there are specific conditions that must be satisfied before the project can begin. Once a satisfactory response to these conditions is received the IRB will grant final approval and the research may then be initiated. *Conditional approval is used in very rare circumstances. For example, conditional approval may be granted when awaiting a certificate of confidentiality from a federal agency if all other conditions for approval have been met.*

- **Deferred** – applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. The researcher is sent a memorandum listing the concerns that must be addressed for approval to proceed. The researcher’s response is reviewed by the IRB and will be approved or deferred until all issues are addressed satisfactorily.

- **Disapproved** – Applications that are found to have risks that outweigh the potential benefits to subjects and/or society will receive a non-approval and the research will not be allowed. This determination can only be made by the full board at a convened meeting. Institutional administrative officials may not override this decision.

(4.) **Study Approved and PI Notified:**

The researcher will be notified through an e-Protocol generated email when the study has been approved.

See **Appendix B** for an overview of the IRB Submission Process.
Revisions and Reportable Events

Once the application is approved, the researcher may begin recruiting subjects and conducting the study. The researcher must let the IRB know if any of the following subsequently occur:

- Changes to the original study must be reviewed and approved by the IRB through a revision to the study via e-Protocol before they are implemented, unless the subject is at immediate risk.
- Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others (harm to subjects or others resulting from the study) must be reported to the HRPO promptly.
- Complaints regarding human subject research (any complaints from the subjects or the study staff must be reported to the HRPO promptly).
- Breach of Confidentiality (Confidential data that has been disclosed by any member of the study staff must be reported to the HRPO immediately, for example, the theft of a laptop containing research data with names and addresses of participants).

Continuing Review: Progress Report/Study Close Out

All active expedited or full board (non-exempt) studies must be reviewed at least once a year. Investigators must submit a renewal application via e-Protocol prior to the study expiration date. The renewal form allows the investigator to provide the IRB with a progress report outlining the number of subjects that have participated since the beginning of the study, and describing any problems and/or complaints that have come up with the research. In addition, the renewal form asks the investigator to indicate the status of the study (e.g. enrolling new subjects, enrollment closed/data analysis only).

If the study is complete, a final report form must be submitted via e-Protocol. This will allow the study to be closed out.

For information regarding what reviewers look for in an e-Protocol application, see Appendix C. For tips for IRB submissions, see Appendix D. For information on how to submit an application using e-Protocol, see the e-Protocol User Guide at Appendix G.

Summary of Student Investigator Responsibilities

Under the direction of the Faculty Sponsor, the Student Investigator is responsible for:

- ensuring the description of the proposal study in the IRB application is accurate and complete prior to IRB submission
- obtaining IRB approval before initiating any research activities
• ensuring the research activity is conducted in accordance with the IRB-approved protocol
• informing the IRB of all proposed changes or additions to the previously approved study before implementing them unless there is immediate risk of harm to the subject
• submitting required continuing review (progress reports) to the IRB
• promptly reporting unanticipated problems involving risks to subjects or others and adverse events to the faculty sponsor and IRB
• informing the IRB of study closure or termination
• meeting with the faculty sponsor on a regular basis in order to monitor study progress.
VIII. Investigator Reporting Responsibilities after IRB Approval

After IRB approval is obtained, the Protocol Director must keep the IRB informed about study changes, problems, or updates. Certain events or circumstances require reporting within a specified amount of time depending on the risk they may pose to study participants. These requirements and guidelines are described below.

Reportable Events

Adverse Events (AE) and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO)

In the event of a Serious Adverse Event (SAE) or an Unanticipated Problem (UP), the student investigator is required to immediately notify his or her Faculty Sponsor. A written report must be submitted to the IRB within 5 business days. The student investigator’s report must contain enough information for the IRB to determine whether the event increases risks to participants or requires a change to the research design.

Definitions

Serious Adverse Event (SAE) are adverse events that are fatal or life threatening; that result in significant or persistent disability; that require or prolong hospitalization; that result in a congenital anomaly/birth defect; or that, in the opinion of the investigators, represent other significant hazards or potentially serious harm to research subjects or others.

Adverse events (AE) are undesirable and unintended, though not necessarily unanticipated, physical, or emotional harm, or occurrences in a human subject.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) includes any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
• **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

• **Unexpected or unanticipated** refers to any adverse event occurring in one or more research subjects where the nature, severity, or frequency of the event(s) is not consistent with the known/foreseeable risk associated with the study procedures described in the IRB approved study, any related study documents, and the IRB approved informed consent document.

• **Protocol Deviation** refers to those occasions when the procedures described in the protocol are accidentally or intentionally not adhered to. Deviations can result when new staff are not adequately trained, or when records are not properly maintained. Protocol deviations should be promptly reported to the HRPO.

Reporting of an adverse event or protocol deviation, must be submitted through e-Protocol. Follow the instructions below for submitting an adverse event report or to report a protocol deviation.

1. Log in to e-Protocol.
2. Click the up arrows on the right-hand end of the box which says “Protocols (Approved)”. This will allow you to access your protocols that have already been approved by the IRB.
3. Click on the protocol number of the protocol you wish to submit a report for.
4. You will get a pop-up box with a number of options.
   a. If you’d like to report an **adverse event**, click “Start Adverse Event Report”.
   b. If you’d like to report a **protocol deviation**, click “Protocol Deviation Form”.
5. The form will open in a new window. Fill out the form and submit it to the IRB.

The HRPO also has a form that is to be filled out in the event of an unanticipated problem. Once you have submitted information regarding an incident (event or deviation) that has occurred, you will be notified regarding whether or not the unanticipated problem form should be submitted as well.

**Proposing Changes to Previously Approved Research Projects**

**Revisions**
A revision is a change to an IRB approved research project. IRB review and approval of revisions are required before investigators can modify IRB approved research projects, except when modification is necessary to eliminate apparent immediate hazards to the subjects. Any proposed change to a previously approved full board or expedited study must be submitted to the IRB as a revision to that project. It may be reviewed by the expedited review procedure (i.e. by one reviewer) or by the convened IRB (i.e. reviewed by a committee), depending on the risk associated with the change. Minor changes are those that do not significantly alter the project’s risk/benefit ratio and these may qualify for expedited review. All revisions must be submitted through the e-protocol system.

Annual Review or Study Closure

Continuing Review

The IRB will conduct continuing review of UMass Amherst human subject research studies at intervals appropriate to the degree of risk, but not less than once per year. Investigators should submit a continuing review application (Renewal Form) before the end of the approval period for their study in order to avoid lapses in IRB approval. Once the approval period for a given study has expired, it is considered a lapsed study and all research-related procedures must stop, except in situations in which doing so would jeopardize the welfare of the subjects. If a study expires, no subjects may be enrolled in the research, no data may be collected, and data analysis must stop. Once a renewal form is submitted and approved by the IRB, a new approval period is established and the study activities may resume.

Study Closure/Completion by Investigators

A research project is closed when subject enrollment and analysis of identifiable data are completed. Investigators who retain a code list that allows linking data to participants, are still engaged in human subject research so the study cannot be closed. Once a study is closed, no further research activity (including interactions with subjects and data) may occur and the researcher is no longer required to submit yearly continuing review applications.

Investigators must notify the IRB that a study is complete through e-Protocol. If your study is complete, submit a “Final Report” in e-Protocol. Once the Final Report is reviewed and approved by the IRB, the investigator is no longer required to submit continuing review applications (renewals). An investigator should only close a study when he/she is no longer enrolling new subjects, using research interventions on existing subjects, collecting data (including follow-up data), analyzing or storing individually identifiable data (i.e. data that can be linked to individuals via a code list), or performing any other tasks that were identified as part of the study. Follow the instructions below for submitting a Final Report.

1. Log in to e-Protocol.
2. Click the up arrows on the right-hand end of the box which says “Protocols (Approved)”. This will allow you to access your protocols that have already been approved by the IRB.
3. Click on the protocol number of the protocol you wish to submit a final report for.
4. You will get a pop-up box with a number of options. Click “Final Report”.
5. The form will open in a new window. Fill out the form and submit it to the IRB.

Protocol Deviations and Noncompliance

Failure to follow the regulations governing human research, requirements or determinations of the IRB, or institutional policies constitutes noncompliance. This definition may include action of any University employee or agent, such as investigators, research staff, IRB member, IRB staff, employees or institutional officials.

Protocol deviations that occur during the course of research are considered a form of noncompliance and may be considered significant when the deviation compromises the rights and welfare of subjects. Student investigators should report all protocol deviations and noncompliance to their Faculty Sponsor and the HRPO as soon as it is discovered.

All reports of alleged noncompliance or inappropriate involvement of human subjects in research may come to the attention of the IRB from different sources and by various means. Alleged noncompliance reports may come from an IRB member, an investigator, a subject or subject’s family member, institutional personnel, institutional committees, the media, anonymous sources, or the public. Reports must be submitted in through e-Protocol. Reports of alleged noncompliance or inappropriate involvement of humans in research are investigated by the IRB, HRPO, or both when appropriate.

Study Suspension and Termination: PI and IRB Role

Suspension of a Study by the IRB

In cases of Serious Adverse Events (SAEs), Unanticipated Problems Involving Risks to subjects or others (UPIRTSO), researcher noncompliance, or protocol violations reported to the IRB, the IRB may suspend a study to ensure subject safety.

Termination of a Study by the IRB

Upon investigation of any SAE, UPIRTSO, noncompliance, or protocol violations, the convened IRB may vote to terminate a study. A PI can address the issues that caused a termination via a revision in e-protocol unless the IRB specifically requires that the PI submit a new study.
Appendix A: Determination Form

The UMass Amherst IRB is required to prospectively review and approve all research involving human subjects. This application helps determine if your project involves human subject research as defined by federal regulations.

**INSTRUCTIONS for INVESTIGATORS:**

1. See Determining Whether IRB Review is Required for an Activity.
2. If the investigator is faculty, complete this form in its entirety and submit via email attachment to the Human Research Protection Office at humansubjects@ora.umass.edu
   If the investigator is a student, forward the completed application to your Faculty Advisor for review and approval. The Faculty Advisor then submits the form to the HRPO via email with his or her endorsement of the project or activity.
3. The UMass Amherst IRB will determine whether your research needs additional IRB review and notify you with a Memorandum of determination in an email attachment.
4. Do NOT begin data collection prior to receiving IRB determination.

<table>
<thead>
<tr>
<th>(HRPO Use Only) Determination based on following rationale:</th>
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</thead>
<tbody>
<tr>
<td>IRB use only</td>
</tr>
<tr>
<td>IRB No. ____________________</td>
</tr>
<tr>
<td>Received email notification</td>
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<tr>
<td>Emailed IRB determination</td>
</tr>
<tr>
<td>☐ Project does NOT need IRB review.</td>
</tr>
<tr>
<td>Date: _______________ Initials: ________</td>
</tr>
<tr>
<td>☐ Project DOES need IRB review.</td>
</tr>
<tr>
<td>Date: _______________ Initials: ________</td>
</tr>
</tbody>
</table>

**Investigator Information**

<table>
<thead>
<tr>
<th>Investigator Name:</th>
<th>UMass Affiliation:</th>
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<tbody>
<tr>
<td>Department:</td>
<td>Email:</td>
</tr>
<tr>
<td>Faculty Advisor (if applicable):</td>
<td>Department:</td>
</tr>
<tr>
<td>UMass Affiliation:</td>
<td>Email:</td>
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**Project Information**

<table>
<thead>
<tr>
<th>Project Title:</th>
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</table>

Is project supported by funding?

☐ No
☐ Pending * Please identify your anticipated funding source:
☐ Yes * Please identify your funding source:
   * If federally funded, provide copy of grant proposal with this form.
**Purpose of the project:** Provide a 5-10 sentence lay description and what you hope to learn from this project

Describe the location where the project will take place and all project procedures:

**Instructions:** Complete Section A as applicable to determine if activities in which you will be engaged meet the definition of human subject research.

### SECTION A: Activities Determined by the UMass Amherst IRB not to Represent Human Subject Research

1. **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data is collected as part of a routine class exercise or assignment and is **not intended** for use outside of the classroom. However, if students practice research methodologies on human beings, they should still be instructed in the ethical conduct of such activities and be advised to obtain informed consent from their practice subjects.

   **NOTE:** IRB approval **is** required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

2. **Oral History:** The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

   **NOTE:** IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories).

3. **Journalism/Documentary Activities:** The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

   **NOTE:** IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

4. **Information-gathering interviews:** The activity focuses exclusively on interviewing or surveying participants about his or her expert knowledge about products or policies rather than people or their thoughts regarding themselves (e.g. interviewing librarians about inter-library loan policies or rising journal costs).

   **NOTE:** Interview questions will need to be reviewed by the HRPO. If the activity involves collecting demographic information about participants it may require IRB approval.

5. **Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.

   **NOTE:** For case reports, HIPAA requires that the disclosure of an individual’s protected health information must be authorized by that individual. If a case report contains any of the 18 protected health information identifiers as defined by the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.

6. **Program evaluation /Quality Improvement/Quality Assurance Activities:** The activity is conducted to assess, analyze, critique, and improve current processes within the institutional setting to include projects designed to improve current
processes involving health care delivery in the institutional setting. The intent is not to generate conclusions that can be applied universally outside of the immediate environment where the project occurred.

a. ☐ The activity does not involve randomization into different treatment groups.

b. ☐ The activity is not designed to be applied to populations beyond the specific study population.

Note: Quality improvement projects are designed to improve the performance of any practice in relation to an established standard. Quality assurance projects are activities that are designed to determine if aspects of any practice are in line with established standards. Service surveys issued or completed by University personnel for the purposes of improving University services/programs or for developing new services or programs for student, employees or alumni may fall into this category. Investigators who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site at which the activity will occur.

7. ☐ Evidence Based Practice Intervention: The project or activity is designed to use best available evidence to make patient care decisions. The project is focused exclusively on translating evidence and applying it to clinical decision-making to improve health care delivery, i.e. it is designed to close the gap between research being conducted and the practice.

Note: “Practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success.

8. ☐ Public Use Datasets: The project is limited to analyzing de-identified data contained within a publicly available dataset. Below are examples of data sources that qualify as not human subjects research (unless the researcher has received restricted use data):

- Bureau of Economic Analysis: http://www.bea.gov/
- Center for Disease Control (CDC): http://www.cdc.gov/
- Consumer expenditure Survey: http://www.bls.gov/cex/
- General Social Survey: http://www3.norc.org/GSS+Website/
- National Center for Education Statistics (NCES): http://nces.ed.gov/
- Survey of Income and Program Participation: http://www.census.gov/sipp/
- Other:

NOTE: IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects. In both cases, Exempt Category #4 may apply.

9. ☐ De-Identified Private Information or Human Biological Specimen: The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if you can confirm the following:
a. ☐ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**

b. ☐ The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; **and**

c. ☐ The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers. **and**

d. ☐ Specimens are **not** being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and**

e. ☐ The records/images/charts that are being collected for this study are **not** from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

<table>
<thead>
<tr>
<th>10. ☐ Coded* Private Information and/or Human Biological Specimens:</th>
<th>The project is limited to the use of existing and/or prospectively collected coded private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if all of the following conditions apply to the project:</th>
</tr>
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<tbody>
<tr>
<td>a. ☐ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; <strong>and</strong></td>
<td></td>
</tr>
<tr>
<td>b. ☐ The investigator(s)** cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:</td>
<td></td>
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<tr>
<td>(1) ☐ The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that HHS regulations do not require that the IRB review and approve this agreement);</td>
<td></td>
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<tr>
<td>(2) ☐ There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or</td>
<td></td>
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<tr>
<td>(3) ☐ There are other legal requirements prohibiting the release of the key to investigators, until the individuals are deceased, <strong>and</strong></td>
<td></td>
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<tr>
<td>c. ☐ Specimens are <strong>not</strong> being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, <strong>and</strong></td>
<td></td>
</tr>
<tr>
<td>d. ☐ The records/images/charts that are being collected for this study are <strong>not</strong> from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.</td>
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From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2008:

*Coded means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
**Investigator** includes anyone involved in conducting the research. The act of solely providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in the conduct of the research. If the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the investigators who receive such information or specimens, then the IRB would consider such additional activities to constitute involvement in the conduct of the research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.

11. **Decedents:** The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

   a. ☐ The use will be solely for research on the information of a decedent; and

   b. ☐ The Principal Investigator has documentation of the death of the individual about whom information is being sought, and

   c. ☐ The information sought is for the purposes of the research

**Note, however, that** this exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse.

**Instructions:** If your activity does not fall into the categories described in Section A, continue to Sections B and C to assess whether your activity is defined as research per regulations set forth by the Department of Health and Human Services (DHHS) and/or the Food and Drug Administration (FDA).

**Section B. Activities Subject to HHS Human Subject Regulations (45 CFR 46)**

1. **Is the activity RESEARCH: a systematic investigation designed to contribute to generalizable knowledge?**

   TIP: If the activity is characterized by a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question and the intention of the investigation is to generate conclusions that can be applied universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, hospital, department), then the activity meets the definition of research.

   ☐ Yes, Go to #2 ☐ No, Go to FDA Section C

2. **Does the research involve obtaining information about LIVING individuals?**

   ☐ Yes, Go to #3 ☐ No, Go to FDA Section C

3. **Does the research involve collecting data through intervention (i.e., physical procedures or manipulation of the environment) or interaction (i.e., communication or interpersonal contact) between investigator and person) with the individuals?**

   ☐ Yes, IRB review required. 
   ☐ No, Go to #4

   Go to FDA section C to assess if FDA regulations apply to your study.

4. **Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?**

   ☐ Yes, Go to #5 ☐ No, Go to FDA Section C

5. **Is the information private?** (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)

   ☐ Yes, Go to #6 ☐ No, Go to FDA Section C
Section C. Activities Subject to FDA Human Subject Regulations: If your answer is “yes” to any of the three questions below, IRB approval is required and the FDA regulations apply to your study.

1. Is this an experiment that involves a test article and one or more human subjects, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit? A subject is an individual (either health or a patient) who is a recipient of the test article or a control.

   - Test article *Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act.

   - Yes, IRB review required
   - No

2. Is this a clinical investigation or research involving one or more human subjects to determine the safety or effectiveness of a device? A subject is an individual (healthy or has a medical condition or disease) on whom or on whose specimen an investigational device is used, or who participates as a control.

   - Yes, IRB review required
   - No

3. Is this an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects? This excludes the use of a marketed drug in the course of medical practice. A human subject is an individual (healthy or patient with a disease) that participates either as a recipient of the investigational new drug or as a control.

   - Yes, IRB review required
   - No

Instructions: If IRB review is required, you must submit a NEW STUDY application to the IRB in e-protocol.

Section D. Investigator Responsibilities and Assurances

- I certify that the information provided in this determination form and in all attachments is complete and accurate.
- I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants and for the ethical conduct of this activity.
- If determined to meet the regulatory definition of human subject research, I agree to comply with all UMass Amherst policies and procedures, the terms of its Federal-wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.
- I certify that the proposed project has not yet been done, is not currently underway, and will not begin until IRB determination and/or approval has been obtained.

Investigator Signature

Name: ___________________________ Date: ___________________________
Appendix B: IRB Submission Process

Pre-submission

Student works with faculty sponsor to develop Human Subjects Research Project.

Student Project Director (PD) completes e-protocol application.

Student submits the study to the IRB via e-protocol. The Faculty sponsor is automatically notified that study has been submitted.

Faculty Sponsor Review

Faculty Sponsor must review the study and submit a Faculty Sponsor statement to the HRPO before IRB review process will begin.

Preliminary Review

Preliminary review is conducted by HRPO Staff. The study is sent back to the PD for editing if additional information or clarifications are needed. PD responses are reviewed by HRPO staff. Preliminary review may involve more than one cycle of comments and responses between the PD and HRPO staff. Once the HRPO staff has no further concerns, the study is ready for IRB review.

Final Review by IRB Member or Committee

Exempt and expedited studies are forwarded to a single IRB committee member for final review and approval. Full board studies are forwarded to the full IRB committee. The study may be returned to the PD for further clarification.

IRB Approval

Once all IRB member/Full Committee concerns have been satisfactorily addressed, the study is approved. The IRB approval notification is sent to the student PD and Faculty Sponsor via e-protocol.
Appendix C: What do the Reviewers Want?
Things to Consider when Submitting a Protocol

The IRB Application/e-Protocol Form

*Source material for this section was provided by UNC IRB, Cornell University IRB, Cal-Poly Pomona IRB, and DHHS. The UMass Amherst IRB gratefully acknowledges this support.

The IRB evaluates every research protocol according to the ethical principles described in the Belmont Report. This means the IRB considers whether the risks and benefits of a study are acceptable and managed appropriately, and whether individuals being asked to participate are adequately informed about the research and its possible risks.

Considered another way, investigators could look at their plans from the point of view of a subject, or an observer concerned about responsible research. Who are the subjects and how are they recruited? Could they be lured or coerced into participation? Is the research being conducted through an institution that may have responsibilities toward them (e.g., a school or hospital) and should be consulted? Do they understand, in advance, what they are agreeing to participate in and give their consent willingly? What will they actually do, and what is done to them during the study? Is it possible that the experience might be injurious, painful, uncomfortable, needlessly boring, embarrassing, offensive, or otherwise stressful? Might there be long-term consequences? Could the subject be endangered, compromised or embarrassed if collected information were leaked?

There are many possible considerations, but they should not be difficult to understand if one assumes the subject’s perspective. The IRB’s role is to find a balance between the benefits of the research and the risk to the subjects in the study. The following guidance is intended to help investigators create a comprehensive protocol and facilitate timely review by the IRB.

Purpose of the Study

Provide a brief lay summary of the purpose of the study. This should be a clear statement of what question(s) you’re asking or hypothesis(es) you’re testing and the supporting rationale. Along with your study purpose you’ll be prompted to address what you hope to learn from the study.

Study Procedures

In this section, please detail all study procedures that involve human subjects. This is often where protocols get held up – if not enough detail is provided in this section about study procedures, then the IRB cannot safely assess what risks the participants might be exposed to. Providing as much detail as possible in terms of how the participants will be involved in the study will help to expedite the review process. Avoid using jargon or acronyms whenever possible. If using jargon or acronyms is necessary, please define them the first
time they are used.

Here are some additional points to consider regarding this section:

1. Provide a sequential, step-by-step description of everything participants will be asked to do in your study.

2. Describe the physical setting and location in which the data collection will take place. For example, are you interviewing participants in a public place? Their home? Your office? Is the study being conducted online? This information should be clearly stated in the study procedures.

3. Describe any tools you will use such as questionnaires, surveys, or any other data collection devices.

4. Indicate whether you will be using audio or video taping. Describe the procedures associated with the audio and/or video and provide rationale for why you are audio/video taping. Be sure to indicate whether being audio or video tape is a requirement for participation in the study.

5. The study procedures section also asks about deception. If your study involves deception or incomplete disclosure, justify it here. Explain why the deception or incomplete disclosure is necessary to achieve the goals of the study. Also explain the debriefing process. When will participants be debriefed? Who will debrief them, and how will they be debriefed?

**Background**

Describe past findings leading to the formulation of the study. A complete literature review is not necessary. However, a clear explanation of why this research is needed and how it fits into what is already known about the topic should be discussed. Explain why more research is needed, the potential benefits of the research, and include a description of what gap you hope to fill in the research.

**Subject Population**

Information in this section is crucial to understanding how participants will be identified, recruited, compensated, etc. Providing as much information and detail as possible in this section can help to expedite the review process. Two very important components of this section are recruitment and compensation.

*Recruitment*

All aspects of recruitment should be described. Be sure that your description includes the following:
1. Describe where you will recruit. Are you recruiting on campus? In a public place? From a particular course during class time? Be clear about where you will seek potential participants.

2. Describe in detail how participants will be recruited. Will there be flyers advertising your study? If so, where will they be posted? Will participants be recruited by email? Will you approach potential participants in person? Give a clear description of how potential participants will be made aware of the study.

3. The IRB needs to see all materials that will be seen by potential participants. So if you’re using a flyer, text, or email to recruit, a copy should be attached in the attachments section of the protocol form. If you are speaking with people in person about the study, you’ll need to attach an oral script, outlining exactly what you will say to potential participants about the study.

Compensation

Please detail what compensation, if any, will be provided to participants. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.) and include a schedule for compensation as well as provisions for prorating, if applicable.

***If you are planning to offer course credit or extra credit as compensation, it is important that an alternate means of earning course credit or extra credit is provided to students who choose not to participate in research.

Risks

The IRB is required to ensure that the potential risks to participants (however minimal) are clearly justified by the potential benefits of the research. This section of the protocol form asks that you delineate any potential risks to subjects. These questions should not be answered “N/A”. Below are some tips for filling out this section of the protocol form.

1. A statement such as “There are no foreseeable risks” or “There are no known risks” may be acceptable and is likely to be the case for some risk categories for some research studies. This may be the case when risks encountered in the research are no greater than those normally encountered in everyday life.

2. There is almost always a minimal risk of breach of confidentiality which should be addressed in this section of the protocol form. If you have outlined in the protocol and consent document the steps you will take to ensure the confidentiality of the data, then this section should contain a description of that particular risk.

3. Think carefully about any discomfort a participant might experience during the course of
your study. For example, the discomfort of having their views challenged by others in a focus group, the stress one may encounter when completing an exam-like instrument, the anxiety one might experience when discussing or answering questions about sensitive topics, or the discomfort or physical fatigue associated with exercise. These should be addressed as risks in the protocol form.

Benefits

It is possible that participants will benefit directly from their participation in research by gaining knowledge or skills. However, if the participants will not DIRECTLY benefit, this should be stated plainly. Indirect benefits can also be mentioned in this section (for example, benefits to the discipline as a result of what is learned from the research project.

Compensation is not considered a benefit of participation and as such should not be referred to in this section of the protocol form.

Procedures to Maintain Confidentiality

The following should be included in this section:

1. An explanation of where the data will be stored (in a locked filling cabinet in a locked office? On a password-protected computer?)

2. A list of individuals who will have access to the data. If the data will be stored in a locked office, who has a key to the office?

3. A description of how the identity of participants will be protected. Will data be recorded by geographical area or group rather than by individuals? Will numeric identifiers or pseudonyms be used?

4. A statement indicating how long data will be kept before it is destroyed.

The terms “anonymous”, and “confidential”, often present problems in this section of the protocol form. See below for an explanation of each.

1. A study is anonymous if there is no way of tracing the data back to the participant from whom it was obtained. No study that involves the creation of a code can be considered anonymous as the identity of the research subject could be linked to the data. Generally, online surveys can be considered anonymous if no participant names, email addresses, or IP addresses are collected.

2. A study is confidential if data can be linked back to participants. Thus, any data collected face-to-face (consumer survey, focus groups, standing in front of a classroom, etc.) is automatically considered in the category of being “confidential” as opposed to “anonymous”. This is true even when the researcher assigns a coding number to the subject – and this number cannot be traced back to the subject – because the
researcher him-/herself knows who provided the data.

Be sure that the description of procedures to maintain confidentiality uses “confidential” or “anonymous” appropriately. These two terms are independent of each other.

Please remember that it is almost always impossible to guarantee confidentiality. Information submitted electronically or in a group setting cannot be considered secure. Confidentiality can also not be guaranteed when there is suspected mistreatment of children and serious threats against self or others. It is also possible that a court might order the release of data or a list of subjects. Because of this, it is important to focus on the steps you will take to maximize confidentiality rather than guaranteeing that confidentiality will be maintained.

Conflict of Interest

The department of Health and Human Services recommends that investigators conducting human subject research consider the potential effects that a financial relationship of any kind might have on the research or on interactions with research subjects. This section of the protocol form asks questions about any financial connections an investigator may have that could potentially influence the research.

For more information about Conflict of Interest procedures at UMass Amherst, please visit http://www.umass.edu/research/conflict-interest.

Informed Consent

The e-protocol form has questions regarding the consent process that each investigator should answer. When uploading a consent document in e-protocol, the questions will be presented below the attached document. Additional guidance on informed consent as well as templates can be found at http://www.umass.edu/research/informed-consent-guidance.

Below are some points to consider when drafting your consent document.

1. The consent document is written for the participants in the research. Make sure it is written in the second person throughout (i.e. “You will be asked to…”)

2. Try to avoid phrases like “You will be required to” or “You will be expected to”. Participation is voluntary and participants have the right to withdraw from the study at any time. This should be clear in the consent document.

3. Be sure to outline all exclusion/inclusion criteria for the study. If criteria for participation were outlined in the e-protocol form, the same criteria should be found in the consent document.
4. If you are using audio or video recording be clear about whether or not this is a requirement for participation in the study. In other words, can people who don’t agree to be video or audio taped still participate in the study?

5. When describing what participants will be asked to do during the study, be sure to describe everything participants will do. Often the e-protocol form contains information that is not included in the consent document. If a research activity is mentioned in the e-protocol form, it should also be included in the consent document. Also, if a research activity is mentioned in the consent document, it should also be described in the e-protocol form.

6. In the section of the consent document that discusses benefits of participation, do not mention compensation. Compensation is not considered a benefit.

7. If your study involves multiple activities describe each activity clearly in the consent document AND provide an estimation of the amount of time it will take to complete each activity.

**Assent**

One of the most important things is that assent be written at an appropriate reading level for the age group being targeted. You can check reading level using Microsoft Word or by entering text at https://readability-score.com/.

If you are recruiting participants under the age of 18, you will need to obtain parental permission as well as the assent of the minor. If your study is recruiting people both above and below the age of 18, please note that you will still need a separate parental permission document along with the consent document you will use for participants 18 years of age and older. For general guidelines and an assent template visit http://www.umass.edu/research/assent-guidance-and-assent-template.

**Attachments**

All study related materials should be attached in this section of the protocol form (with the exception of consent and assent documents which should be attached in their appropriate sections). Any document referenced within the protocol form should be attached in this section.

Below is a list of commonly attached documents.

1. Recruitment materials (flyers, email, oral scripts)
2. Letters of support or approval from outside organizations
3. Surveys/questionnaires
4. Visual stimuli that will be presented to participants
5. Debriefing Documents
6. Grant Proposals
Appendix D: Tips for Better IRB Submissions

The following is an overview of issues that frequently arise from student submissions to the IRB. UMass Amherst student research varies greatly, and thus not all issues apply to every study, but it is useful to note commonly identified IRB concerns. Using these tips to avoid common problems can speed up the IRB review process.

**Anticipating Questions from the IRB:**

The questions below reflect items the IRB will evaluate in reviewing the research application. Careful consideration of these questions, when applicable, will help expedite the submission process and can prevent IRB requests for clarification or additional information.

- Are you using vulnerable subjects?
- Are you collecting identifiable data?
- How will you protect confidentiality of data?
- Do you need informed consent? What type?
- Have you minimized risk to subjects and maximized benefits?
- How have you determined the level of review?
- Are you doing international research?
- Are there cultural or language issues?
- Are you collecting data you don’t need?

**Justify Data Collection Methods:**

When designing a project, investigators should use only those procedures necessary for answering the hypothesis and avoid implementing unnecessary procedures or obtaining data that will not be used.

Removing unnecessary procedures can save investigators considerable amounts of time in gaining IRB approval. The following procedures should be used only when required to answer the hypothesis or fulfill scientific goals:
• Audio-taping of interviews
• Collecting identifiers when recording data
• Retaining identifiable material once the study is completed
• Quoting subjects by name in reports
• Interacting or intervening with vulnerable populations (children, pregnant women, prisoners)
• Collecting sensitive information/data
• Video-taping or photographing human subjects in field observations
• Using experimental techniques
• Employing deception as part of study design
• Physical or psychological intervention or treatments

Avoiding Pitfalls:

The following section lists common errors students encounter when submitting an application to the IRB.

• Not allowing enough time for IRB review and approval

• Failure to provide complete answers to questions on the e-protocol form

• Submitting inconsistent information between the e-protocol form and informed consent document, and/or debriefing document

• Lack of clarity regarding the sequence and timing of procedures within the study

• Failure to obtain letters of support/permission when conducting research at non-UMass Amherst sites

• Failure to provide enough detail regarding participant recruitment procedures

• Failure to define inclusion/exclusion criteria for the study

• Submitting consent and/or assent documents containing language too complex for participants

• Failure to fully describe risks for all procedures
Who Can Help?

A Faculty Sponsor is a very important student resource. Faculty Sponsors should maintain close oversight of student research before it is submitted to the IRB and oversight should continue throughout the life of the study.

HRPO staff are also available for individual consultations with students. Please visit https://www.umass.edu/research/webform/hrpo-student-consultation-form to schedule an appointment.

Students may also contact the UMass Amherst Human Research Protection Office directly for assistance.

UMass Amherst Human Research Protection Office
Tel: (413) 545-3428
Fax: (413) 577-1728
E-mail: humansubjects@ora.umass.edu
http://www.umass.edu/research/human-research-protection-office-hrpo
Appendix E: Helpful Links

**Department of Defense Directive (DoD)**: Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research

**Food and Drug Administration (FDA)**

**Office for Human Research Protections (OHRP)**

**National Science Foundation (NSF)**
- National Science Foundation (NSF) - Social, Behavioral & Economic Sciences
- NSF - Frequently Asked Questions and Vignettes (Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research)

**National Institutes of Health (NIH)**
- NIH - Human Subjects Research and IRBs
- NIH - Recombinant DNA Advisory Committee (RAC) on Recombinant DNA and Gene Transfer
- Certificates of Confidentiality
- National Human Genome Research Institute
- OER Human Subject Web Site: FAQs from Applicants (Office of Extramural Research)

**U.S. Department of Education**
- U.S. Department of Education Protection of Human Subjects in Research Website (Research involving minors in school settings)
- Protection of Pupil Rights Amendment (PPRA) 34 CFR Part 98 (Research involving surveys with minors in school settings)
- Family Policy Compliance Office

**U.S. Department of Energy - Protecting Human Subjects Homepage**

**U.S. Department of Health and Human Services (DHHS)**
- Office of Research Integrity (ORI)
- Office of Research Integrity Policies, Regulations and Statutes

**Other Federal Agencies and Guidance**
- Code of Federal Regulations Index at the General Printing Office
- National Bioethics Advisory Commission (NBAC)
Appendix F: Glossary of Common IRB Terminology

ADVERSE EVENT/EFFECT (AE)
Any untoward physical or psychological occurrence in a subject participating in research. An AE can be any unfavorable or unintended event including an abnormal laboratory finding, or a symptom/disease associated with the research. Adverse events may or may not have a causal relationship with the research.

ASSENT FORM
An assent form is used when subjects are between 7-17 years of age. Assent is a minor's affirmative agreement to participate in research. The assent form must include simple language written at the appropriate reading level of the youngest subject in a given age range.

BENEFITS
Most research does not provide direct benefit to subjects. Furthermore, it may be many years before the results of the research are publicly known and/or made useful to society or to affected subjects. Vague promises to benefit science or society are not adequate descriptions of benefit whether in a consent form or a research application. When there is no direct benefit, subjects should be told that they will not benefit from participation. However, they can also be so informed when their participation may benefit society. Compensation to subjects is not considered a benefit.

BIAS
Occurs when objectivity is impaired by personal gain or personal judgment. In clinical studies, bias is minimized by blinding and randomization.

BIOLOGICS (OR BIOLOGICAL PRODUCTS)
Biologics, as regulated by the U.S. Food and Drug Administration, are made from a variety of natural sources. Like drugs, biologics are used for the prevention, treatment, or cure of disease or injury. Examples include vaccines, blood and blood products, allergenic extracts, human cells and tissues, gene therapies and test to screen potential donors for infectious agents.

CERTIFICATES OF CONFIDENTIALITY
Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifiable information from research participants to any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or
local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

COGNITIVELY IMPAIRED
Having a disorder (psychiatric or developmental) that affects cognitive or emotional functions that impair the capacity for sound judgment and reasoning. Other conditions that may impair judgment and reasoning are: being under the influence of drugs or alcohol, having a degenerative disease, having a terminal illness or disability.

CODIFIED PRIVATE INFORMATION
Coded private information means that all identifying information that would enable anyone to ascertain the identity of the individual to whom private information or specimens belongs to is coded with a letter or symbol.

Note: A key to the code enables linkage of private information or specimens. A study may qualify as not human subjects research (NHSR) if the coded data was not collected for the proposed study AND the investigator does not have access to un-link the coded information. The IRB must make this determination. Guidance regarding coded private information and the IRB process can be found at:

CONFIDENTIALITY
Confidentiality refers to the process of protecting private data or specimens and its use. Plans for managing data in a confidential manner must be appropriate to the study being proposed.

Care should be taken to explain a plan to maintain confidentiality in the e-protocol form (e.g., the use of numbering or code systems, encryption of data, the use of passwords for electronic data access, or safely locked files in private offices). Replacing names with pseudonyms or codes also adds protection. Furthermore, the investigator should describe who has access to the data and under what circumstances, if any, a code system may be broken. Subjects should be informed whether the data collected will be retained, and, if so, for what purpose, what period of time, and whether (and when) data will be de-identified or destroyed.
CONSENT FORM
A consent form is used in a study when the subject is 18 years of age or older and competent to make the decision to participate. Parents/legal guardians of minors must provide permission to allow their children to participate in a study.

CONTINUING REVIEW
A periodic IRB review of a research study to evaluate whether risks to participants remain reasonable in relation to potential benefits and to verify that the study continues to meet regulatory and institutional requirements. Continuing review should be conducted at intervals appropriate to the degree of risk but not less than once per year. (45 CFR 46.109(e); 21 CFR 56.109(f))

DEBRIEFING
Occurs when subjects are provided with previously undisclosed information about the research project.

DECEPTION
Deception is the intentional misleading of subjects or the withholding of full information about the nature of the study. Use of deception increases ethical concerns of a study because it interferes with the ability of the subject to give informed consent. Deception is arguably necessary for certain types of behavioral research, because full knowledge by the subject might bias the results.

Subjects have the right to full disclosure as soon as possible after participation in deception research. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects must still receive full disclosure of the purpose of the study as soon as possible. Deception in research should be used rarely and may only be employed with the approval of the IRB.

DEVICE/MEDICAL DEVICE
A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Examples of devices are diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic equipment.

ELIGIBILITY CRITERIA
These are defined requirements for subject inclusion in a given experiment. Eligibility criteria examples are age, sex, state of health, a defined range for a biologic measure (e.g. glucose level or cholesterol), blood cell counts, etc.
ETHNOGRAPHIC (FIELDWORK/ANTHROPOLOGY RESEARCH)
Ethnography is the study of people and culture. Ethnographic research involves observation of a person or group in their own environment, often for long periods of time.

EXEMPT RESEARCH
Exempt research is Human Subjects Research that meets one of the minimal risk categories in the federal regulations (45 CFR 46).

EXPEDITED REVIEW
A review of proposed or continued research involving no more than minimal risk and/or for minor changes in approved research. Review is performed by IRB Chair or designee, rather than the full board.

FULL BOARD REVIEW
Review of proposed or continuing research (primarily greater than minimal risk research) by a convened IRB meeting, at which a majority of the voting membership is present.

GRANT
Financial support provided for a research study. Fund givers typically do not exercise strict control over the grants they have awarded (whereas contracts are prescriptive).

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)
HIPAA’s Privacy Rule of 2003 prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from disclosing protected health information without written authorization from the individual (HIPAA Authorization).

IDENTIFIABLE PRIVATE INFORMATION
Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place,” (such as a public restroom) “and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public” (for example, a health care record) (45 CFR 46.102(f)(2)). “Identifiable” means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual (e.g. Social Security #).

INCLUSION/EXCLUSION CRITERIA
The pre-determined conditions of a clinical trial that allow or excludes subject participation. These criteria are factors such as age, gender, type and stage of a disease, previous treatment history, and/or other medical conditions.
INFORMED CONSENT
Informed consent is the process of informing potential subjects about the key facts of a research study. Subjects in a study must be informed of the details of their participation, the possible risks and benefits of study participation and the voluntary nature of their participation. The process of informing and discussing research with potential subjects is a critical ethical principle in human subject research. The informed consent document serves as documentation that consent was provided by the subject or legal representative, before any study procedures took place.

INSTITUTIONAL REVIEW BOARD (IRB)
A specially constituted review body designated by an entity to review human subject research protocols to protect the welfare of human subjects participating in research.

INTERNATIONAL STUDIES
International research must adhere to recognized ethics codes or regulations such as: 45 CFR 46 (Policy for the Protection of Human Research Subjects), the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. Consent and recruitment documents must be in the language of the subjects and be readable and understandable by the subjects.

Ethical regulatory responsibilities for research involving human subjects may differ outside the United States from those set forth in federal and institutional policies. Differences in language, cultural and social history, and social mores can be challenging for U.S. researchers. In addition, national policies such as the availability of national health insurance, philosophically different legal systems and social policies may make U.S. forms and procedures inappropriate. However, federally funded research activities in a foreign country may be approved if accommodations to U.S. regulations are made.

Note: the U.S. Health and Human Services agency has yet to deem another country’s policies “equivalent” to those of the U.S.

The investigator is encouraged to contact the IRB to discuss these issues. Investigators will be required to obtain a research ethics review board (IRB equivalent) approval letter for research conducted outside the U.S. for studies that are more than minimal risk. Many institutions outside of the United States have ethics committees to review and approve research. For minimal risk studies an approval letter or permission letter from the research site may be acceptable by the UMass Amherst IRB; however, this decision will be determined on a case-by-case basis.

MINIMAL RISK
The federal regulatory definition of minimal risk is that the “probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46).
MINORS
Persons who have not attained the legal age to consent to treatment or procedures in research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

PLACEBO
A chemically inert substance used in controlled clinical trials to provide data that helps distinguish and determine whether improvement and side effects reflect imagination or anticipation rather than the actual power of a drug.

PRIMARY DATA
Primary data is data obtained from direct contact with, or observation of, one or more people for the purpose of collecting data from or about them.

PRINCIPAL INVESTIGATOR (PI)
The scientist or scholar with ultimate responsibility for the design and conduct of a research project.

PRIVACY
Privacy refers to a research participant’s willingness to allow access to themselves and their personal information. Privacy considerations include the timing and setting where private information is obtained, the nature of the information requested or obtained, and who receives/uses this information.

The IRB considers the protection of subject data/privacy during all stages of a study. The manner in which subjects are identified and approached for participation in research may be also be of concern. For example, a participant might not want to be identified in a place that could potentially embarrass them, such as a pregnancy counseling center or drug rehabilitation facility.

The IRB requires investigators, or other relevant parties, to explain how the privacy of study participants and their private data will be maintained during the course of the study and how study data will be retained after study closure. Investigators are required to provide this information in the IRB application.

PROSPECTIVE STUDIES
A study designed to follow groups of subjects for an extended period of time with defined outcomes.

PROTECTED HEALTH INFORMATION (PHI)
PHI is health information transmitted or maintained in any form or medium that includes ALL of the three following parts:
- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
• relates to the past, present, or future physical or mental health or condition of an
individual; the provision of healthcare to an individual; or the past, present, or
future payment for the provision of healthcare to an individual.

PROTOCOL
The formal design or plan of an experiment or research activity.

RANDOM ASSIGNMENT (RANDOMIZATION, RANDOMIZED)
A method of assigning subjects to different treatment groups based on chance.

RECRUITMENT/RECRUITMENT MATERIALS
Recruitment is a process by which potential subjects are informed about study
participation. Recruitment materials, such as fliers, email messages, newspaper ads,
and phone calls, must accurately describe the study and be non-coercive. The use of all
recruitment materials in a non-exempt research project must be approved by the IRB
before use.

RESEARCH
Systematic investigation, including research development, testing, and evaluation,
designed to develop or contribute to generalizable knowledge [45 CFR 102(d)].

RETROSPECTIVE STUDIES
Research conducted by reviewing records from the past (e.g., birth and death
certificates, medical records, school records, or employment records) or by obtaining
information about past events elicited through interviews, surveys or measurements.

RISK
Risk is the probability of harm or injury (physical, psychological, social, or economic)
occurring as the result of participation in a research study. Both biomedical and
behavioral research may entail some levels of risk to a person's health or physical or
social well being. Student researchers must consider the following risks when
conducting their study:

STRESS FROM STUDY QUESTIONS/SURVEYS
Subjects may feel stress caused by the research questions or procedures.
Questions can raise painful memories, embarrassment, or unresolved issues.
Interviews with survivors of personal or state violence may be at risk. Questions
about illegal behaviors or immigration status may cause embarrassment, feelings
of guilt or distress or raise legal concerns.

Although most psychological risks are minimal and transitory, investigators must
be aware of the potential for harm. The IRB will want to know how such
outcomes will be minimized or addressed.

BREACH OF CONFIDENTIALITY
A breach of personal confidentiality is often the greatest risk to participants in
social and behavioral human subject research. Reputation or employment may
be affected or insurance coverage may be jeopardized if confidentiality is compromised.

Information about subjects' activities may place them at risk of legal action. For example, if a researcher asks children about discipline, information about child abuse may be disclosed and must be reported to the appropriate authorities. Similarly, if subjects divulge information about gang activities, disclosure of that information could place the subjects at risk of harm or legal action.

**RISK/BENEFIT RATIO**
A comparison of the potential benefits to the risks of participating in a research study.

**SECONDARY DATA**
Data that has already been obtained, either individually or in aggregate form. Use and sharing of secondary data which contains personal identifiers are subject to the requirements set forth under federal regulations. Secondary data, which do not contain personal identifiers, are exempt from these requirements (the IRB must make this determination).

**SERIOUS ADVERSE EVENT (SAE)**
A SAE is defined by the FDA as an undesirable experience associated with the use of a medical product in a subject that results in death, a life threatening experience, hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly and/or birth defects or requires intervention to prevent permanent impairment or damage.

**SPONSOR**
A person, federal agency, corporation, or other entity that provides funds for a research project.

**STUDY ARM**
Any of the treatment groups in a randomized trial.

**SUSPENSION/TERMINATION**
IRB approval is suspended/terminated and all research activity is halted as the result of: unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR Part 46, or not following IRB requirements/determinations.

**UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS (UPX)**
Any event that is unexpected, related or possibly related, and suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.
VOLUNTARY
Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's willingness to participate (or to continue to participate) in a research activity.

VULNERABLE POPULATIONS
Any subject may be “vulnerable” when a power differential exists between researcher and subject.

Federal regulations specifically define only groups as vulnerable: pregnant women/fetuses/neonates (45CFR46, Subpart B), prisoners (45CFR46, Subpart C), and children (45CFR46, Subpart D).

Pregnant women, fetuses, and neonates (Subpart B)
Pregnant women, fetuses, and neonates are considered vulnerable because of the shared risk and/or compromised health status.

Prisoners (Subpart C)
Prisoners are considered vulnerable because incarceration impacts their ability to make a voluntary and non-coerced decision regarding whether to participate as subjects in research.

Children (Subpart D)
Children are considered vulnerable because they may not be able to completely understand the information presented, nor the risks and benefits the study may entail.

People who cannot competently understand the information regarding a study and cannot give true consent, (e.g., individuals with psychiatric, cognitive, or developmental disorders, substance abusers, students, and workers) may also be considered vulnerable populations in certain human subject research.
e-Protocol Management System for Human Subjects

The e-Protocol Management System is a web-based system that automates the Institutional Review Board approval processes. It is used for electronic protocol submission, routing, reviewing, and tracking that enables investigators, and IRB members, to process protocol applications online.

Contact Nancy Swett, ncsweett@ora.umass.edu, (413) 545-3428 for more information and for LOGIN AND PASSWORD ACCESS. You will need to provide the following information: Name, Department, Title (Graduate Student, Postdoc, Associate Professor, etc), e-mail and NETID. (Note your NETID is the login that you would use when checking your e-mail through UMAIL). Certification of human subjects training will also be required. Please allow 4-8 weeks for the review process. Key Solutions, Inc. has designed and developed e-Protocol Management System.

PLEASE NOTE: If you believe your protocol is eligible for EXEMPT review, please contact the Human Research Protection Office at S-3428 for confirmation prior to completing your e-protocol application. If incorrectly submitted as exempt, a new form will have to be completed.

Last revised: September 30, 2015
**e-Protocol** is an electronic system for submitting and monitoring the status of **Institutional Review Board** (IRB) submissions. New users should review the process for establishing a login and gaining access to e-Protocol for **human subject research**. e-Protocol for **human subjects research** supports online submission, review, and management of human subject protocol information submitted to the IRB. All requests for approval of human subject research to include revisions and renewals must be submitted electronically through the **e-Protocol** system.

**What you can do in the e-protocol system:**

- Create and edit an electronic application for submission of studies to the Institutional Review Board

- Add investigators and study personnel to an application

- Attach electronic or scanned documents to the study (.pdf, .docx, .pptx and .xlsx documents are allowed)

- Print out a .PDF version of the application

- Track the status of the application (i.e. in preparation, submitted for review, reviewer comments received, PD responses to reviewer comments sent)

- Receive email notifications any time the application is sent back for requested changes by a reviewer

- Receive an email notification once the study is approved

- Download a copy of the approval letter and approved consent and/or assent documents

- Submit revisions, renewals, or final reports for already approved IRB studies

- Report study deviations and adverse events
### Table of Contents

- Establish a Login ............................................................................................................................................ 4
- Configuring Your Browser .................................................................................................................................... 4
- Tips for Navigating e-Protocol .......................................................................................................................... 5
- Entering your Application Information .................................................................................................................. 7
- Accessing Reviewers Comments and Editing a Protocol Application ................................................................. 13
- Making Revisions to an Approved Protocol .......................................................................................................... 15
- Renewing an Approved Protocol .......................................................................................................................... 17
- Submitting an Adverse Event (AE) Report ............................................................................................................. 18
- Submitting a Deviation Report ................................................................................................................................ 20
To submit a new protocol through e-Protocol for the first time, please follow the instructions below.

Establish a Login
The CITI human subjects on-line training must be complete before a login can be provided for e-Protocol.

In order to access e-Protocol, you will need to contact HRPO and provide the following information to Nancy Swett, ncswett@ora.umass.edu:

Name:
Department:
Title (graduate student, postdoc, assistant professor, etc.):
E-mail:
NETID (Note your NETID is the login that you would use when checking your e-mail through UMAIL):

If you are a student, you must have a faculty sponsor who will be responsible for the oversight of your project. Your faculty sponsor must also have an e-Protocol login and human subjects training certification.

Configuring Your Browser
1. Use a recommended browser
   1. If you are on a Windows machine, e-Protocol works best when using Internet Explorer.
   2. If you are on a Mac machine, e-Protocol works best using Safari.
   3. You may experience difficulties when using other operating system/browser combinations. Please avoid using Firefox, Mozilla, or Netscape, as these browsers are NOT fully supported.

2. Allow Pop-Up Window
   Pop-up blocking software prevents the e-Protocol application from opening certain windows. You'll need to make sure that your browser has all pop-up blocking software disabled. For instructions on how to enable pop-up windows, please see your browser’s Help guidance.
Tips for Navigating e-Protocol

Avoid using your browser's BACK or FORWARD buttons

1. Instead of the BACK or FORWARD button, use the menus and links within the application to navigate.

2. Each section is listed in the menu on the left. Select the section you wish to view from this menu. e-Protocol will automatically save information when you move from one screen to the next.

3. When you are within the **Protocol Information** section, there are several subsections that must be completed. These subsections DO NOT appear in the menu on the left. To move among these subsections, you must click on the page icons across the top of the page, or use the arrow icons in the top right corner of the screen.
4. When you have completed the **Protocol Information** and **Obligations** sections, you will no longer be able to advance with the arrow or page icons. At this stage, you must click on **Check for Completeness** or another item in the menu on the left, in order to proceed.

![Protocol Application Form](image)

**Note that all fields must be filled in**

If a particular section does not apply to your protocol, DO NOT leave that section blank. Simply type **N/A** in the appropriate box(es).

**Be patient**

Some processes can take a minute to run. Although data is loading, your browser may not indicate activity.

**Be prepared**

Any person listed as study personnel in the IRB application is required to take the human subjects training. Any individual who is interacting and/or intervening with human subjects or handles the personally identifiable data of a human subject is considered study personnel. Study personnel who are involved in the informed consent process should also be included on the IRB study personnel list.
Read the guidance

Many pages in the application offer instructions, guidance or definitions right on the page. You can also use the help documentation for each page by clicking on the question mark icon in the top right corner of each screen.

Entering your Application Information

There are two ways to begin your application: (1) to start a brand new protocol click on Create Protocol or, (2) if you have an existing protocol in the system, you can click Clone Protocol. The first few pages of the e-Protocol submission are critical. Please follow the instructions below to help guide you through these first few steps.

1. As previously mentioned, if you have an existing protocol in the system, you can click on the Clone Protocol icon. This feature allows you to generate an exact copy of an existing protocol, with a new protocol number. You can then edit the cloned protocol and submit it as a new application. However, cloning a protocol will not allow you to change the original review category.

Sign out when done: To protect your private information, always log off and shut down your browser completely (close all browser windows) when you are finished using e-Protocol.
2. To begin a new protocol application, click on the **Create Protocol** icon in the top right corner of the screen.

3. Enter the title of your protocol and click the **Next** button.

   **Note:** The protocol title entered must match the title of the informed consent document.

4. Enter the names of the research staff. Research staff includes those individuals who work directly with subjects, or who handle data with identifiers. **There will be two pages available to list all research staff.** All staff listed on this first personnel page must have an e-Protocol login. If you are a student or a lab manager, you must enter a faculty sponsor on this page. An email will automatically be sent to the faculty sponsor when the application is complete. The faculty sponsor must approve (by email) the application before it will be considered by the IRB.

5. Additional staff may be added later (on the second personnel page, after selecting the review type). Individuals such as undergraduate student researchers without e-Protocol logins can be added on the second page.

   **Note:** Personnel listed under "Other Personnel" will NOT have access to the protocol for editing unless they were entered using their e-Protocol login. Personnel listed under any other category will have the ability to edit/view the protocol.

6. Each individual listed as a member of the research staff must have completed **Human Subjects Training** before the protocol information is submitted. In order to proceed to the next section, the **Human Subjects Training Completed?** checkbox must be filled in for each individual listed.
7. For guidelines on selecting the role for each member, click the help icon (question mark) in the top right corner of the e-Protocol screen.

8. When research staff with an e-Protocol login have been added, click **Next**.

9. Select the category and type. You must decide whether your study falls under the biomedical category or social, behavioral and educational category. You must also select the protocol type.

   **Important:** The selection of the category and review type determines what information will appear on the application. It is important that you select the category and review type relevant to your application. For definitions of these classifications, click the help icon (question mark) in the top right corner of the e-Protocol screen.
10. When you have selected the appropriate category and review type, click **Create**.

11. If you have selected **Exempt** or **Expedited** review, a window will appear where you will be asked to specify which category your research falls into. Once selected you will be taken to the second personnel page. If you have selected **Full Board** review, you will be taken directly to the second personnel page.

12. Once you are on the second personnel page, your application has been created and saved in the system. If you exit the system prior to this point, your application will not be saved. On this second Personnel page, you may add additional personnel, including individuals who do not have an e-Protocol login. For instructions, click on the help icon (question mark) in the top right corner of the e-Protocol screen.

13. Proceed through the application using the arrow icons or the page icons at the top of the screen.

14. If you need help or further instructions, click on the help icon (question mark) in the top right corner of any e-Protocol screen.
15. Remember to attach your **Consent** and **Assent** (if applicable) documents in sections 9 and 10 of the social, behavioral and educational form respectively (the corresponding sections in the biomedical form are 13 and 14).

**Important:** If your study is a collaboration with another institution, please provide the IRB materials from the collaborating institution. In the **Attachments** page, also include the collaborating institution’s IRB approval.

16. In section 11 of the social, behavioral and educational form, remember to include all other attachments, e.g., flyers, advertisements, questionnaires, etc. (the corresponding section of the biomedical form is 16). If your study is funded, please attach a copy of the grant proposal that was submitted to the sponsor. If recruiting from a school or through an outside agency for participants, letters of support must be included in this section.

17. When all material has been entered, click **Check for Completeness** in the menu on the left before submitting the application. A list of any missing information, with a link to the appropriate page will appear. If all information is complete, you will see the message “Protocol information is complete,” indicating that you can submit your protocol.
18. To submit your protocol, click on **Submit Protocol** in the menu on the left. **Note:** you will not be able to edit your protocol once it is submitted. If you are ready to submit, click **Yes** in the pop-up box. A message will appear telling you that your protocol has been submitted.

19. Once the protocol is checked by the IRB staff and accepted for review, you will receive a confirmation email.

20. You will receive another email once the protocol has been reviewed by the IRB, stating the decision of the IRB. If changes need to be made to the protocol, you will need to login to e-Protocol and open the appropriate protocol for editing by clicking on the item listed for that protocol under **Protocol Status**. Within this protocol you will find comments from the reviewers and/or the IRB staff. You must make all recommended changes and re-submit the protocol. This procedure is described in the next section.
Accessing Reviewers Comments and Editing a Protocol Application

1. If the IRB has requested revisions to an application before it can be accepted, you will receive an email indicating so. In this event you will need to login to e-Protocol and open the appropriate protocol for editing.

2. On the main page you will see the protocol listed and under **Protocol Status** it will say **Comments Received** (Cycle #).

3. Click on **Comments Received** to access the protocol and comments from reviewers.

4. On the next page you will see all comments from the IRB regarding your protocol application. Any comments that are marked as **Response necessary for approval** must be attended to.

5. The section of the protocol application to which the comment is referring will appear at the top of each comment box. If the comment requires a modification to the protocol application, you must go to the appropriate section of the application and make any necessary changes. To make changes to the protocol, click on **Get Protocol** to open the protocol for editing. Go to the
appropriate sections and make your revisions. Sections that have been modified will be indicated to the IRB. You will only see the latest text on your screen. However, for IRB members the changes will automatically be highlighted, and both the original and revised text will be available.

6. You must also write a response in the box under each comment. If you have made a change to the application, it is acceptable to write something along the lines of “see changes in application” in the box. When your response has been entered click Save. Note: The cycle numbers are listed in the top left corner of the screen. Be sure that you are looking at the comments from the most recent cycle. To move to a particular cycle, click on the appropriate cycle number.

   Protocols ID: 2729 (Jorge Guzman)

   [Image of a comment section]

7. When you are ready to send your responses back to the IRB, click on Submit to Manager to submit your revisions and responses to comments.

   [Image of a comment section with a Submit to Manager button]

8. Once the protocol has been approved by the IRB, you will receive an email stating so. You may not begin any part of the research project until you have received such notification.
Making Revisions to an Approved Protocol

1. Go to the e-Protocol website and login. From the main screen, click on the double arrow to the right of Protocols (Approved).

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Principal Investigator</th>
<th>Protocol Status</th>
<th>Initial Approval Date</th>
<th>Last Approval Date</th>
<th>Expire Date</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-2619</td>
<td>Jorge Guzman</td>
<td>APPROVED</td>
<td>09/17/2015</td>
<td>09/17/2015</td>
<td>09/16/2016</td>
<td>UMASS IRB</td>
</tr>
</tbody>
</table>

2. Click on the protocol number that you wish to revise. A window will open with several options. Click the circle beside Start Revision.

3. The protocol will open for you to edit. There will also be a Revision Form where you will summarize the revisions you have made and whether these changes have changed the risk level of your study. Go to the appropriate sections of the protocol and make your revisions. Sections that have been modified will be indicated to the IRB. You will only see the latest text on your screen. However, for IRB members the changes will automatically be highlighted, and the original text will be available.
4. Once your changes have been made, check that all information has been entered by clicking on **Check for Completeness** in the menu on the left. When you are ready to submit your revision, click on **Submit Protocol** in the menu on the left.

5. Once the revision is submitted, the protocol will appear in two places within your account. The originally approved protocol will appear under **Protocols (Approved)**. The revision will appear with the same protocol ID on the main page of your account, with the **Protocol Status** as **Submitted**.

6. Once the revision has been reviewed by the IRB, you will receive an email stating the decision of the IRB. If changes need to be made to the protocol, you will need to login to e-Protocol and open the appropriate protocol for editing, by clicking on the item listed for that protocol under **Protocol Status**. Within this protocol you will find comments from the reviewers and/or the IRB staff. You must make all recommended changes and re-submit the protocol.

7. When the revision has been approved by the IRB, you will receive an email stating so. You may not begin any part of the research project until you have received such notification.
Renewing an Approved Protocol

1. When approval for your protocol is about to expire, you will receive an email indicating that you must submit a renewal or final report form.

2. To renew a protocol, go to the e-Protocol website and login.

3. From the main screen, click on the double arrow to the right of Protocols (Approved).

4. Click on the protocol number that you wish to renew. A window will open with several options. Click the circle beside Start Renewal.

5. The protocol will open with a Renewal Form. Fill out all of the information on the form.

6. Once your changes have been made, check that all information has been entered by clicking on Check for Completeness in the menu on the left. When you are ready to submit your renewal, click on Submit Protocol in the menu on the left.
7. Once the renewal is submitted, the protocol will appear in two places within your account. The originally approved protocol will appear under Protocols (Approved). The renewal form will appear with the same protocol ID on the main page of your account, with the Protocol Status as Submitted.

8. Once the renewal has been reviewed by the IRB, you will receive an email stating the decision of the IRB. If changes need to be made to the protocol, you will need to login to e-Protocol and open the appropriate protocol for editing, by clicking on the item listed for that protocol under Protocol Status. Within this protocol you will find comments from the reviewers and/or the IRB staff. You must make all recommended changes and re-submit the protocol.

9. When the renewal has been approved by the IRB, you will receive an email stating so.

Submitting an Adverse Event (AE) Report

1. To report an adverse event, go to the e-Protocol website and login.

2. From the main screen, click on the double arrow to the right of Protocols (Approved). Click on the protocol number for which you wish to submit the report. A window will open with several options. Click the circle beside File an Adverse Event Report.

3. The protocol will open with an adverse event form. Fill out all of the information on the form. If your adverse event requires changes to the informed consent document, attach the revised document.
4. Check that all information has been entered by clicking on **Check for Completeness** in the menu on the left. When you are ready to submit your form, click on **Submit Form** in the menu on the left.

5. Once the adverse event report is submitted, the protocol will appear in two places within your account. The originally approved protocol will appear under **Protocols (Approved)**. The adverse event report will appear with the same protocol ID on the main page of your account, with the **Protocol Status** as **Submitted**.

6. Once the adverse event report has been reviewed by the IRB, you will receive an email stating the decision of the IRB. If changes need to be made to the protocol, you will need to login to e-Protocol and open the appropriate protocol for editing, by clicking on the item listed for that protocol under **Protocol Status**. Within this protocol you will find comments from the reviewers and/or the IRB staff. You must make all recommended changes and re-submit the protocol.
Submitting a Deviation Report

1. To report a deviation, go to the e-Protocol website and login.

2. From the main screen, click on the double arrow to the right of Protocols (Approved). Click on the protocol number for which you wish to submit the report. A window will open with several options. Click the circle beside Protocol Deviation Form.

3. The protocol will open with a deviation form. Fill out all of the information on the form.

4. Check that all information has been entered by clicking on Check for Completeness in the menu on the left. When you are ready to submit your form, click on Submit Form in the menu on the left.

5. Once the deviation report is submitted, the protocol will appear in two places within your account. The originally approved protocol will appear under Protocols (Approved). The adverse event report will appear with the same protocol ID on the main page of your account, with the Protocol Event as Submitted.

6. Once the deviation report has been reviewed by the IRB, you will receive an email stating the decision of the IRB. If changes need to be made to the protocol, you will need to login to e-
Protocol and open the appropriate protocol for editing, by clicking on the item listed for that protocol under **Protocol Event**. Within this protocol you will find comments from the reviewers and/or the IRB staff. You must make all recommended changes and re-submit the protocol.