



Eastern University

Institutional Review Board Guidelines

**Office of the Provost
Eastern University**

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INTRODUCTION

The charge of the EU Institutional Review Board (IRB) is to protect the rights and welfare of human subjects involved in research by minimizing risk and ensuring that subjects agree to participate voluntarily from an informed perspective. This is mandated by federal regulations governing research involving human subjects, but it is undergirded by the commitment of the Office of the Provost (where the responsibility for EU research compliance resides and with which the IRB is affiliated) to provide a climate for research and scholarly activity that is fertile and flexible while protecting the well-being of human subjects.

History

The present system of human-subject research review is the outgrowth of concern about research on human subjects that began decades ago. In 1974 the National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission published The Belmont Report, which set forth the following basic ethical principles for the conduct of research involving human subjects:

- Respect for Persons - Acknowledgment of the autonomy of the individual and the responsibility to provide special protection for individuals with reduced autonomy
- Beneficence - A two-fold responsibility: 1) do no harm, and 2) maximize possible benefits and minimize possible harm.
- Justice - Fairness in distribution of benefits expected to be realized from research as well as its burdens

The applications of these principles resulted in the establishment of review boards at institutions conducting research using human subjects. Those institutional review boards, including the EU IRB, ensure that in the conduct of such research:

- risks are minimized and reasonable in relation to anticipated benefits
- subjects give *informed* consent
- rights and welfare of the subjects are maintained

The regulations are stated in 45 CFR 46; they were first promulgated in 1974 and last in June 2005. Sixteen federal agencies adopted the core of the regulations in a common federal policy in 1991.

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks, an administrative unit within the Department of Health and Human Services

(DHHS), oversees the regulations and provides guidance on ethical issues in biomedical or behavioral research.

NOTE: The EU IRB has attempted in this Guide to present a simplified explanation of the requirements for approval of research involving human subjects, but the federal regulations take precedence. **Federal regulations can be accessed at:**

<http://www.hhs.gov/ohrp/humansubjects/index.html>

Statement of Policy

Any research originating at Eastern University involving the observation of or interaction with human subjects, and which results in data or generalizable knowledge that will or potentially might in the future be disseminated for public use, must be reviewed and approved by the Institutional Review Board (IRB) for the protection of human subjects. In order to protect the rights, well-being, and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of Eastern University, the policy and procedures described below have been established for the conduct of research involving human subjects.

The following general principles apply equally to all research involving human beings, whether carried out solely with college resources or with the assistance of outside funds. Eastern University assumes responsibility for communicating and explaining these principles to University personnel, and for providing guidelines to effect their observance.

- a. Eastern University and the individual members of its faculty, staff, and student body recognize their responsibility for protection of the rights and welfare of human subjects.
- b. Appropriate professional attention and facilities shall be provided to insure the safety and well-being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
- c. Research involving children (persons under 18 years of age), or other persons legally, physically, or mentally unable to give *informed* consent may be approved if there is no risk or suffering for the individual subject. On the other hand, research involving a child, or a person unable to give informed consent should not be approved if there would be a significant risk or suffering without the possibility of benefit to the individual subject. Title 45, Code of Federal Regulations, Part 46, Subpart D, shall be followed for research involving children.
- d. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
- e. Before a subject participates in research involving risk or substantial stress or discomfort, such risk or stress shall be carefully explained; the investigator shall be satisfied that the explanation has been understood by the subject; and the consent of the subject shall be obtained. The elements of informed consent are established by the Federal government and Eastern University.

- f. A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the subject is otherwise entitled, within the limits of the research.
- g. The EU IRB requests that faculty include the following statement regarding human subject research in all syllabi for courses that involve data collection with human subjects.

Any study originating at Eastern University involving the observation of or interaction with human subjects, and which results in data or generalizable knowledge that will or potentially might in the future be disseminated for public use, must be reviewed and approved by the Eastern University Institutional Review Board (IRB) for the protection of human subjects. Consult with your instructor early in the course to ascertain if your project needs to be reviewed by the IRB and/or to secure the appropriate forms and procedures for the IRB review.

ABOUT THE INSTITUTIONAL REVIEW BOARD

What is the responsibility of the Institutional Review Board (IRB)?

Protection of the rights and well-being of human subjects involved in research is a concern of Eastern University (EU) and is mandated by specific provisions in the Code of Federal Regulations (CFR). As required by the federal regulations, the IRB was established at EU to assure protection of human subjects and to ensure compliance with the regulations. Not only is the welfare of human subjects important to EU, but there is a fiscal component as well. Non-compliance with the federal regulations can have an adverse effect on research funding.

All agencies of the federal government that conduct or sponsor research relating to human subjects are concerned with protection of the rights and well-being of the subjects. However, the Office for Human Research Protections (OHRP) of the Department of Health and Human Services and the Food and Drug Administration are the lead agencies for oversight of research involving human subjects. OHRP has general responsibility for the protection of human research subjects and ensures compliance with 45 CFR 46. FDA regulates the use of experimental drugs and medical devices and ensures compliance with 21 CFR 50, 56.

The University's IRB policies and procedures apply to any research activity which involves human subjects, whether such research is undertaken on a large or small scale, whether it is preliminary or fully designed, whether it is student or faculty research, whether it is funded or non-funded, and whether it involves minimal risk or more than minimal risk.

Who is involved in the IRB?

Federal regulations mandate that an IRB be composed of at least five members. At least one member must be from a scientific discipline and at least one member must be from a non-

scientific discipline. Members are primarily faculty, with at least one representative from the community. The makeup of the Board is intended to provide a diversity of viewpoints and to provide complete review of human-subject research activities. An expert is consulted when projects to be reviewed are outside the expertise of the members; this is allowed and encouraged by the federal regulations. The EU IRB consists of at least five faculty members from different disciplines and one member from the community.

What must be approved by the IRB?

In accordance with its charge to protect human subjects involved in research, the IRB must review and approve any research related to human subjects, whether or not it is funded externally, if the research is:

- sponsored by units of EU;
- performed by, or involves, EU faculty, staff, and/or students, regardless of where the study is performed;
- conducted using University-owned facilities or equipment.

EACH PROPOSED RESEARCH PROJECT MUST BE APPROVED **BEFORE** THE RESEARCH IS BEGUN.

What are the rules if the research project is cooperative?

If the principal investigator is affiliated with EU, the EU IRB must review the project and grant approval because:

- culturally dissimilar populations may constitute the sample
- the institutions involved may have different legal or regulatory constraints
- EU may have unique expertise not available at the other institution(s)

In cases where the cooperative institution has granted approval, the EU IRB still reserves the right to review the project. The EU investigator should submit the proposed project to the chair of the IRB for determination.

If the principal investigator is conducting research off the premises of EU, for example, a school or government agency -- assurance of oversight by that entity must be provided to the IRB at the time of application. This must include the following, and any other germane information:

- letter of permission from the lead administrator (or his/her designee) to conduct the study;
- evidence that the administrator or official oversight group has reviewed the protocol and accepted its use at that institution

If an IRB or equivalent exists at the external sites, the approval of the research protocol must be provided to the IRB prior to the start of the research.

What if an External Researcher intends to involve Eastern students and/or faculty as research participants?

External researchers who intend to use EU students as participants must submit a request for permission to conduct studies to the Office of the Vice President for Student Development. This office, in consultation with the Office of Institutional Research (ir@eastern.edu), will review requests and make decisions based on the following criteria: (1) The feasibility of the research methodology; (2) The number of current and upcoming active research projects; and (3) the value of the research subject to the EU community. The outcome of the review will be: (1) Rejection of the request, (2) Revision and re-submission, or (3) Acceptance. If permission is granted by this office and the proposed study meets the criteria of data gathering that does not constitute research (See pp. 8-10), no further approvals are needed. For research involving EU faculty, requests for permission to conduct studies must first be submitted to the Office of Institutional Research (ir@eastern.edu). Decisions will be made as outlined above.

If permission is granted by either of these offices and the proposed study meets the criteria of "What Constitutes Research" (See pp. 8-10), external researchers **MUST** then submit an application to the EU IRB with supporting documents. External researchers, who have received IRB approvals from other institutional review boards, should submit a copy of that approval along with their application.

In most cases that approval will be honored, however, the EU IRB reserves the right to also review the project, particularly if it poses potential risks or involves specialized populations or sensitive topics.

Please note that the number of allowable research projects involving students is limited at any given time so as to avoid "survey fatigue" within the Eastern community.

What if an Internal (EU) Researcher intends to involve Eastern students and/or faculty as research participants?

If the EU researcher plans to contact/use *more than 100* EU students/faculty in their research, they will need to seek permission from the Vice President for Student Development. This office, in consultation with the Office of Institutional Research (ir@eastern.edu), will review requests and make decisions about approval.

If permission is granted by either of these offices and the proposed study meets the criteria of "What Constitutes Research" (See pp. 8-10), EU researchers **MUST** then submit an application to the EU IRB with supporting documents.

WHAT CONSTITUTES “RESEARCH”

According to the federal regulations, research is any systematic investigation designed to develop or contribute to generalizable knowledge. Any activity that meets this broad criterion and that is conducted by EU faculty, staff, or students using EU facilities, personnel, or students is considered research. This is so whether it is part of some other activity -- such as a demonstration or service program -- or whether the research is the entire project.

Following are questions that should help determine whether data gathering as part of training, demonstration, or service projects meets the definition of research as related to human subjects.

- Will the researcher(s) seek out subjects for the project, rather than the subjects seek the service or training?
- Will the findings of the investigation be publicly disseminated?
- Is there is a likelihood that the knowledge gained from the encounter with the subjects will be applied similarly so as to lead to a new procedure or process?

A "YES" ANSWER TO ANY OF THESE QUESTIONS INDICATES A RESEARCH COMPONENT, AND THE PROJECT MUST BE APPROVED BY THE IRB BEFORE ANY WORK IS BEGUN.

What data gathering would NOT be considered research?

By tradition and common practice, some journalistic, literary, and historical inquiries are not considered human subjects research and, therefore, do not need to be reviewed by the IRB.

These are:

- Accepted and established service relationships, such as client-professional and student-teacher relationships, where the sole purpose of the relationship is to provide a service to the client.
 - Studies of material available to the general public, such as published library materials or public documents and records.
 - Studies of historical documents (e.g. letters, diaries, and personally identifiable government forms) that are at least 70 years old.
 - Studies of archeological materials or other artifacts that are at least 70 years old. Note however, that this determination does not exempt the investigator from compliance with Federal NAGPRA regulations.
 - Studies based on records without personal identifiers.
 - Studies based on surveys or interviews with public officials or candidates for public office.
 - Studies of medical specimens without personal identifiers.
- Some forms of data gathering from human beings also do not constitute research within the context of human subjects review requirements. Below are three types of data-gathering activities from human beings that do not require IRB approval on any level.
- Data gathered for classroom training in research or assessment methods for which the only foreseeable purpose is to facilitate the student’s learning of the research or

assessment method, itself. Neither the instructor nor the student intends to publicly disseminate the data gathered. For example, students in a statistics class may gather data on one another or from roommates regarding such things as age, gender, preferred food, and favorite sports if the purpose of such data gathering is only to learn how to statistically analyze the data. Similarly, students in a counseling class may take or administer personality tests to themselves or others if the only purpose of the test administrations is to learn how to administer and interpret the results.

- Data gathered for administrative purposes only -- to learn what is happening within a unit or institution and/or to improve services or operations. For example, administrators may administer a school climate inventory or teaching evaluations if the only purpose of such data gathering is to evaluate program or personnel effectiveness.
- Evaluation of data gathered for a contractor about a project or operation for which he or she is responsible, if neither the researcher nor the contractor intends to publicly disseminate the data. For example, an employer may gather accident records or budget disbursement figures from or on behalf of a contractor.

Note that categories of data gathering from human subjects not considered “research” are very few. MOST DATA GATHERING FROM HUMAN SUBJECTS IS RESEARCH UNDER THE FEDERAL GUIDELINES.

Are thesis and dissertation projects considered research?

Projects involving a thesis or dissertation always are considered research because the University granting the graduate degree disseminates the research findings by placing the document in its library. Therefore, research involving human subjects that culminates in a thesis or dissertation always must be submitted to the IRB for review or for certification of exemption from review.

Would you provide further clarification as to whether student research projects require IRB review and approval?

Yes. Student projects are an area that generates a good deal of questions as to whether they meet the definition of research and therefore require review. Student research that involves human subjects can be classified broadly into two categories:

1. ***Research practica***, where students learn research skills. Students often are required to take courses requiring them to interview, observe, and otherwise work with human subjects. The purpose of such project assignments is to train students in various research methods and to acquaint them with social, educational, and/or psychological processes. This does not require IRB review, since such projects typically do not lead to generalizable knowledge.
2. ***Directed or independent research projects*** – for example, honors or graduate theses that require systematic data collection, with the intent to contribute to generalizable knowledge. Any such research project initiated or conducted by a student and that is

not classifiable as a research practicum does meet the definition of research. Therefore, it must be reviewed and approved by the IRB. This includes, but is not limited to, theses and dissertations.

The EU IRB requests that faculty include a statement regarding human subject research in all syllabi for courses that involve data collection with human subjects. See page 5 for a copy of that statement.

Do pilot studies require review?

If a pilot project is designed simply to help the researcher refine data collection instruments and procedures or perfect the project design, it would not be considered research, since it would not contribute to generalizable knowledge. IRB review, therefore, would not be required.

However, if the investigator intends to publish the results or otherwise disseminate the findings of the pilot project or to use the results in subsequent research projects, then it would be considered research, and IRB review and approval would be required.

Is oral history considered research?

Because the intent of most oral history projects is ultimately dissemination of information (at some future date) about a particular historical period or event that has been gleaned from taped interviews with human subjects, it should be submitted to the IRB for review.

TYPES OF IRB REVIEW

All proposed projects that involve human subjects and that satisfy the definition of research (see What Constitutes “Research”? page 8) *must be reviewed at some level*. Federal regulations prescribe three types of review:

- ***Exempt***: exempt from full or partial board IRB review, but still requires filing an application for approval with the IRB. The Chair of the IRB then determines and confirms the Exempt status of the research.
- ***Expedited***: requires review by the Chair of the IRB and at least one other member of the committee having expertise in the area of the study. After initial evaluation, the reviewers may require review by the entire IRB (full board).
- ***Full Board***: requires review by the full membership of the IRB.

What type of research qualifies for Exempt review?

The Exempt classification is an unfortunate misnomer because it implies that the research is exempt from *any* level of review or filing. This is not so. The conduct of even Exempt research must be reviewed by the IRB for the purpose of affirming that the research is, indeed, Exempt. The apparent purpose of this federal requirement is that someone other than the investigator makes a determination as to the research's Exempt status. Following that determination, the research is then "exempt" from any *further* review by the IRB. Exempt research includes:

- A. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as
- regular and special education instructional strategies (or approaches or techniques);
 - assessment of the effectiveness of, or a comparison among, instructional techniques, curricula, or classroom management methods.

The purpose of this category is to exempt research on educational practices in an educational institution. This category does *not* extend to research conducted in a school setting but not related to the instruction in that institution. For example, an evaluation of two methods of fourth grade classroom instruction in a local school district would qualify as Exempt research. In contrast, a sociometric survey of children's preferences for playmates in the same school and involving the same children would not qualify as Exempt research. As the example indicates, research on minor students can be Exempt if it is merely an educational program evaluation in the sense intended here.

- B. Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior *unless* information obtained from these sources is recorded in such a manner that subjects can be identified (directly or through identifiers linked to the subjects), and disclosure of the subject's responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to his or her financial standing, employability, or reputation.

"Educational tests" refers to standardized tests used for educational purposes, such as a scholastic achievement test. It does not refer to personality tests or clinical evaluations.

"Survey" or "interview" studies qualify as Exempt unless the subjects can be identified from the records *and* there are risks to the subjects due to the sensitive nature of their responses. The federal guideline refers only to risks associated with sensitive aspects of behavior. Eastern University has determined that there are other types of information that might be considered sensitive and damaging if revealed, even though the information is not associated with behavior. For instance, knowledge that a person was at risk for a genetically determined disease might be a factor in denying that person employment. Therefore, Eastern University will not treat as exempt a survey or interview study where subjects can be identified and *any* information is collected that could be detrimental to the subject, regardless of whether or not that information is based on the subject's own behavior.

Studies of publicly observable behavior are Exempt from federal regulations unless there are potential risks of the type described and the data are recorded in a way that could be used to identify subjects. "Public behavior" means behavior that is apparent to an unconcealed observer without the use of any special or surreptitious equipment such as binoculars, microphones, or recording devices. For example, an observation in a shopping mall of how many people choose to take stairs versus escalators would be considered an observation of public behavior.

- C. Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior *unless* the research deals with sensitive aspects of the subject's own behavior that could be damaging to his or her reputation -- such as illegal conduct, drug or alcohol use, or sexual behavior -- *and* the subjects are identifiable. Research that deals with sensitive aspects of the subject's own behavior but for which no subject is identifiable is Exempt.
- D. Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior that is not exempt under the provisions of B, above, but the human subjects are elected or appointed public officials or candidates for public office.
- E. Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior that is not exempt under the provisions of B. above, but federal law requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- F. Research that involves collection or study of existing data, documents, or records 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.)

Situations arise in which records may be excerpted from a data source that does contain identified, sensitive information, but are provided to the investigator without identifiers. For instance, physicians might be asked to provide case summaries without identifiers. Such studies may be Exempt providing that the person excerpting the records already has authorized access to them *for research purposes*, and the investigator has no access to the original records.

"Existing," means that the data are "on the shelf" at the time the researcher develops a proposal for their use. Use of data not already on the shelf is not eligible for exemption.

State and federal laws preclude the use of certain kinds of existing data (including health care information, records of drug and alcohol treatment, and records of psychiatric care)

from use by researchers without human subjects review, regardless of whether they are “existing” or recorded by the investigator in such a way that subjects cannot be identified.

- G. Research that involves collection or study of existing 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).
- H. Research and demonstration projects that are subject to approval of government officials and are designed to study aspects of public benefit or service programs see **45 CFR 46.101(b)(5)**.

The “department or agency heads” referred to are *federal*, not state, local, or college. This category of exempt research refers only to activities sponsored by federal agencies to evaluate their own benefit or service programs.

- I. Taste and food quality evaluation and consumer acceptance studies wherein wholesome foods without additives are consumed.
- J. Taste and food-quality evaluation and consumer acceptance studies wherein food is consumed that contains a food ingredient at or below the level, and for a use, found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

What type of research qualifies for Expedited review?

Expedited research is research that does not qualify for Exempt status but is noninvasive and poses little risk to subjects. Expedited categories include:

- A. Proposed modifications to previously approved research during the period (one year or less) for which approval has already been granted;
- B. Research that poses no more than minimal risk;
- C. Voice recordings made for research purposes, such as investigations of speech defects;
- D. Moderate exercise by healthy volunteers;
- E. Study of existing data, documents, records, pathological specimens, or diagnostic Specimens;
- F. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required;
- G. Research on individual or group behavior, or characteristics of individuals such as studies

of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. "Manipulate" can be interpreted as referring to behavior that would be considered deceptive outside of the research context;

H Collection of any of the following:

- hair and nail clippings--in a non-disfiguring manner
- deciduous teeth
- permanent teeth, if patient care indicates a need for extraction
- excreta
- external secretions, including
 - sweat
 - uncannulated saliva
 - placenta removed at delivery
 - amniotic fluid at the time of rupture of the membrane prior to or during labor
- dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
- blood samples by venipuncture, not exceeding 450 milliliters in an 8-week period, no more often than twice per week, from subjects 18 years of age or older who are in good health and not pregnant

I Recording of data from subjects 18 years of age or older, using noninvasive procedures routinely employed in clinical practice not involving input of matter or significant amounts of energy. These procedures include:

- use of physical sensors applied either to the surface of the body or at a distance
- testing sensory acuity
- electrocardiography
- electroencephalography
- thermography
- detection of naturally occurring radioactivity
- diagnostic echography
- electroretinography

Excluded: exposure to electromagnetic radiation outside the visible range, e.g., x-rays and microwaves.

Federal regulations name the following as **special populations** that require additional protection:

- children
- prisoners
- pregnant women and fetuses
- cognitively disabled persons
- economically or educationally disadvantaged persons

Detailed information regarding these special classes of human subjects is available in the Special Populations.

Research on these special populations is NEVER Exempt. Research on these special populations *may* be classified as Expedited if **minimal risk** is involved. Research on these special populations always will be classified as Full Board review if more than minimal risk is involved.

If an investigator seeks approval for research with one of these special populations and he or she believes the project presents minimal risk, the investigator should note this in the application on the application. A determination will be made as to whether or not the application qualifies for a special-population expedited review. In such cases, the application will be examined by three IRB members, at least one of whom has expertise in the area of the proposed research, to determine if the proposed research poses minimal risk as defined by the federal regulations.

What type of research requires Full Board Review?

All proposed research that does not meet the criteria for Exempt review or Expedited review is classified as Full Board review. Such research projects will be reviewed by all members of the IRB. Full Board review also may be required for research projects initially submitted as Exempt or Expedited review. *The decision as to the final classification of the research rests with the IRB.*

An application requiring Full Board review is first sent to two IRB members who review it for completeness and determine if additional information is needed. After the requested information is submitted or required changes have been made, the application is forwarded to the full IRB for review.

EU is subject to audit by federal agencies supporting research on human subjects, so the IRB reserves the right to audit approved projects after approval to ensure compliance with the regulations.

HOW TO APPLY

Below is an outline of the steps to apply for approval of a research project that involves human subjects. If you have any questions during the application process, contact the Chair of the IRB. Please consult the IRB website (<http://www.eastern.edu/offices-and-centers/institutional-review-board>) for information about the current chair.

- [E-mail: irb@eastern.edu](mailto:irb@eastern.edu)
- Written Queries: Send written inquiries through campus mail to Chair, IRB

1 Determine:

- a. whether what you are proposing to do meets the definition of research on human subjects (see page 8)
- b. potential risks associated with the proposed research project
- c. check the appropriate type of review (see page 10)
 - Exempt
 - Expedited - regular subjects or special populations
 - Full Board Review
- d. whether informed consent (see page 22) is necessary

2 Complete the Application (available online at <http://www.eastern.edu/offices-and-centers/institutional-review-board/irb-downloadable-files-and-forms>). Each question must be answered, even if the response is "not applicable."

NOTE: Answer each question fully. The most frequent reason for delay in the approval process is lack of information. Usually, it is not the protocol or design that is questioned; rather, not enough information has been provided for the IRB to make a decision.

3. If informed consent is necessary for your research, follow the suggested format for the consent form (included in the appendices of this manual). If you are not sure whether informed consent is necessary, contact your advisor if you are a student; all others contact the Chair of the IRB.
4. Follow the checklist on the Application to ensure you have complied with all necessary elements of the application process including supporting documentation of permission to conduct research at the site/sites.
5. If you are a student, have your IRB application reviewed and approved by your faculty advisor. Faculty members should have their department chair approve and sign off on applications.
6. Contact the Chair of the IRB informing him/her of your intent to apply for IRB approval. E-mails must be sent via your Eastern University account. You will be then enrolled as an applicant in the IRB Blackboard website and receive the following automated response:

- You have been added as a student in the IRB BlackBoard Course (ORG_IRB_INSTITUTIONAL REVIEW BOARD)
 - Please upload your complete IRB application packet in assignment on the first page.
 - Ask your advisor to submit a digital approval form (the link will be emailed to you by the IRB Chair)
 - Once submitted, a reviewer will be assigned to your application and you should hear within 10 business days for an exempt or expedited review. Full board review will take 3-6 weeks, depending upon the date of the next IRB meeting, the inherent risks in the study, the age and status of the subjects, etc. Likewise, please note that the IRB board does not meet regularly during the summer months, so review times may take longer (approximately 3-4 weeks). Applicants should plan appropriately for such potential delays.
7. Submit the application online along with all supporting documents from your Eastern University e-mail account.

THE IRB MUST APPROVE THE RESEARCH PROJECT BEFORE THE RESEARCHER(S) MAKE(S) ANY CONTACT WITH SUBJECTS.

Checklist for application submission:

- Research plan or grant proposal (Research plan should be a brief summary of research, the methodology, risks to subjects, and benefits. This plan is generally used for thesis or dissertation research or other unfunded research.)
- Informed consent/assent forms
- Supporting documentation of permission to conduct research at identified sites
- Instrument(s) [questionnaire, survey, test]
- Advisor/Department chair digital approval

APPROVAL PROCESS

How long will the review take?

Time for approval varies by the completeness of the application materials and the type of review required. Assuming that the application contains all required materials, a study eligible for either Exempt or Expedited review will typically be reviewed and approved within 10 business days of receipt. A study requiring Full Board Review requires that the investigator be present at the next regularly scheduled IRB meeting. Thus, Full Board reviews may take 3 to 6 weeks, depending on the date of the next IRB meeting, the inherent risks in the study, the age and status of the

subjects, etc. Likewise, please note that the IRB board does not meet regularly during the summer months, so review times may take longer (approximately 3-4 weeks). Applicants should plan appropriately for such potential delays.

What will the IRB take into consideration in reviewing an application?

The Federal IRB Guidebook (published by the Office of Protection from Research Risks, US Department of Health and Human Services) requires that IRBs:

- consider the qualifications and professional development of the principal investigator and relate them to the degree of protocol complexity and risk to human subjects;
- consider requiring that less experienced research investigators be sponsored by seasoned researchers;
- consider directing that proposals requiring skills beyond those held by the principal investigator be modified to meet the investigator's skills, have additional qualified personnel added, or be disapproved;
- require investigators to prepare protocols, with complete descriptions of the proposed research. The research plan must include provisions for the adequate protection of the rights and welfare of prospective subjects and ensure that pertinent laws and regulations are observed. Samples of informed consent must be included with protocols. Investigators are responsible for obtaining informed consent and ensuring that no human subject will be involved in the research before consent is obtained;
- require that the research plan address quality assurance standards set by the institution as well as applicable external standards;
- require that appropriate reviews for scientific merit be conducted before the research is approved;
- require that mechanisms be in place for monitoring the progress of the research.

What are the criteria for approval?

According to the federal regulations, the following criteria must be met in order for the IRB to approve a proposed research project:

1. Risk Minimization -- Risks to subjects should be minimized by using procedures that
 - are consistent with sound research design
 - do not unnecessarily expose subjects to risk
 - (whenever appropriate) are already being performed on the subject for diagnostic or treatment purposes
2. Risk vs. Benefit -- The risk to the individual subject must be reasonable when measured against
 - the possible benefit to the prospective subject
 - the importance of the knowledge to be gained

3. Subject Selection -- Selection of subjects should be equitable.
4. Informed Consent -- Informed consent must be
 - sought from each prospective subject or his/her legally authorized representative
 - appropriately documented
5. Safety -- Adequate provisions must be made for monitoring the data collected to ensure the safety of subjects, when appropriate.
6. Privacy -- Appropriate safeguards must be provided to protect the privacy of subjects and to maintain the confidentiality of data gathered.
7. Undue Influence -- If some or all of the subjects (such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons) are likely to be vulnerable to coercion or undue influence, additional safeguards must be included in the study to protect the rights and well-being of these subjects.

How long is IRB approval valid?

The IRB is required to review research on an ongoing basis, and the interval of review is determined by the degree of risk. Approval is granted for a maximum of one year from the date of the initial approval.

Must an investigator reapply for IRB approval if the project continues beyond one year?

Yes. (See below.)

What kind of review is required for application for continuation?

The federal regulations require the same type of review for continuation as for the initial application. The IRB must review the protocol and any amendments as well as a status report on the progress of the research, including:

- summary of enrollment of subjects and their status, a description of any:
 - change in key personnel with copies of their vitae
 - adverse events or unanticipated problems involving risks to subjects or others and how the principal investigator handled the event(s)
 - withdrawal of subjects from the research and reason for withdrawal
 - complaints about the research
- a summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research

- a copy of the current informed consent document

The investigator will be informed in writing of approval for continuation.

What is required if there are modifications?

If there are *any* modifications, e.g., change in the title, principal investigator, methodology, subjects' status, etc., the principal investigator must submit a Protocol Amendment . *The researcher should keep in mind that approval of a modification(s) does not change the original period of approval.* Approval can only be granted for a maximum of one year from the date of the initial approval.

The request for any modification should refer to the project number assigned by the IRB, which appears on the approval letter. It should also provide a means for communication: phone number and/or e-mail address of investigator/applicant.

NOTE: Federal regulations require prompt reporting to the IRB of changes in a research activity. Completion is change, so the investigator should notify the IRB of the closure of the project as well as other changes.

What if I disagree with the IRB Decision? Can I appeal?

If a subcommittee of the IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by entire membership of the IRB.

If the entire membership of the IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator should first discuss the matter with the Chair of the IRB, taking care to explain the reasons for believing that the proposed procedures are in compliance with EU policy and with Federal regulations. If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision of the committee, in writing, to the Provost.

Upon receipt of an appeal the Provost shall convene an *ad hoc* committee constituted so as to fulfill the Federal requirements pertaining to Institutional Review Boards, and with a majority of the members being past but not current members of the IRB at Eastern University. The *ad hoc* committee shall consider the appeal and issue a recommendation within no more than sixty days from receipt of the appeal by the Provost. The *ad hoc* committee shall give the investigator an opportunity to present orally and/or in writing the reasoning underlying the appeal. Upon completion of the review, the *ad hoc* committee shall communicate its decision in writing to the Provost, giving the reasoning for the decision. A copy of the decision of the *ad hoc* committee

shall be given to the investigator. The decision of the *ad hoc* committee shall be treated as a decision of the EU IRB.

How long should records be retained?

HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS and FDA at reasonable times and in a reasonable manner.

SUBJECTS

What must be included in the application to give the IRB a clear understanding of the proposed sample and its usage?

The application must include at least the following:

- description of the sampling procedure
- the population from which subjects will be sampled
- the number of subjects expected to participate
- the follow-up sampling procedures, if applicable
- how long subjects will be expected to participate
- the study sites
- the expected risks
- the expected benefits

What can I do to ensure that prospective subjects do not feel coerced?

Investigators must be careful not to put undue pressure on prospective subjects, either directly or implicitly by virtue of an imbalance of power inherent in roles, e.g., teacher-student or supervisor-employee. *Please note that if you offer participants extra credit in courses for their research participation, you will need to offer multiple ways for students to receive extra credit aside from their participation in your research project.*

In the case of students as prospective subjects, a teacher/investigator must be very careful to assure students that their grade will not be affected by either participation or non-participation and that they can decline without any penalty whatsoever.

When employees are considered potential research subjects, an investigator must be careful not to place colleagues, subordinates, or peers in an uncomfortable situation (e.g., fear of retribution) if they decline to participate.

What steps should be taken to ensure the confidentiality of subjects?

- computer files should be password-secure

- data should be:
 - reported in the aggregate
 - stored separately from identifiers
- destroyed following completion of project unless there are extenuating circumstances, e.g., data will be used in a future research project
- destroyed completely, i.e., if it is in physical form, it should be shredded, and if it is in electronic form, it should be deleted entirely

INFORMED CONSENT

The EU IRB has attempted below to present a simplified explanation of the requirements governing informed consent, but federal regulations take precedence. (See **45 CFR 46** and **21 CFR 50** and **56**.)

What is informed consent?

Informed consent is the process by which prospective human subjects, or their legal representatives, are:

- informed of the nature and purpose of the proposed research, including risks, in a manner appropriate to their level of understanding and in non-technical language
- informed that they have the right to decline to participate or to withdraw from participation at any time without penalty
- given adequate time to decide if they want to participate

The investigator should meet with the prospective subject, determine if he or she is capable of giving consent, and then explain the study, covering the elements of informed consent (see below). To give valid informed consent, a potential subject must understand to what he or she is giving consent to. So it is vitally important that the researchers *communicate*, rather than just provide information. Asking questions in order to elicit questions or comments from the prospective subject is a good way to ascertain that he or she really understands what is being proposed.

Procedures for obtaining informed consent should *not* include a *guarantee* of confidentiality. Rather, the researcher should explain how he/she will make every reasonable effort to protect the confidentiality of the participant.

What should be included in informed consent?

An investigator should cover the essentials of informed consent in his/her oral explanation to the prospective subject. Following are the basic “elements” as set forth in 45 CFR 46:

- Statement that the study involves research and is being conducted through EU. Explanation of the purposes of the research and the expected duration of the subject’s participation

- Description of the procedures to be followed
- Identification of any procedures that are experimental
- Description of any reasonably foreseeable risks or discomfort to the subject
- Description of any benefits to the subject or to others that reasonably may be expected from the research
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- Statement that the research has been approved by the IRB and that participants can contact the IRB [at irb@eastern.edu](mailto:irb@eastern.edu) for details about their rights
- For research involving more than minimal risk, an explanation as to:
 - whether any compensation is available if injury occurs
 - whether any medical treatments are available if injury occurs
 - if such treatments are available, what they consist of and where further information can be obtained
- Explanation of whom to contact about:
 - the research
 - research subjects' rights
 - research-related injury to the subject
- Statement regarding participation:
 - that it is voluntary
 - refusal to participate will not involve a penalty or loss of benefits to which the subject is otherwise entitled
 - termination of participation at any time will not involve a penalty or loss of benefits to which the subject is otherwise entitled

Are there additional elements of informed consent?

Yes. When appropriate, one or more of the following elements of informed consent should be provided:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are unforeseeable at present
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- Consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject
- Statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- Approximate number of subjects involved in the study

Are any of the elements for written informed consent ever waived?

The IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent set forth above, or it may waive the requirement to obtain written (signed) informed consent. In order to do so, *the IRB must be able to document both of the following:*
The research or demonstration project

- is designed to study aspects of public benefit or service programs and is subject to approval by state, local, or tribal government
- would be impractical to carry out without the waiver of signed informed consent

In such cases, *the IRB must be able to document the following for the proposed research:*

- it involves no more than minimal risk (see page 47) to the subjects
- it would be impractical to carry out without the waiver of signed informed consent
- the waiver of written consent or alteration will not adversely affect the rights and welfare of the subjects
- acceptable alternatives to written consent are in place that satisfy federal regulations for informed consent. This could include, for example, public notice, oral consent following appropriate explanation of the project, and its benefits vs. risks.
- whenever appropriate, the subjects will be provided additional information after participation

What is involved in documentation of informed consent?

Following an adequate explanation and allowance of sufficient time for the subject to decide whether or not to participate, the investigator should provide a consent form for documentation. (A sample format for a consent form is included in this Guide. See page 69)

The subject or his/her legal representative should sign the consent form. The person who signs the form should receive a copy of the document.

The investigator can choose from either of the two formats for documentation explained below:

- A written consent form that contains the elements of informed consent noted above and required by **45 CFR 46.116**. This form may be read to the subject or his/her legally authorized representative. The subject or representative should be provided ample time to read the document before signing.
- A short-form written consent document that states that the elements of informed consent explained above and required by **45 CFR 46.116** have been presented orally to the subject or his/her legally authorized representative.

When this method is used, the following requirements must be met:

- A witness must be present at the oral presentation.
- The IRB must approve a written summary of what is to be said to the subject or

- representative.
- The subject or representative signs the short form and receives a copy of it and the summary.
 - The witness must sign both the short form and the copy of the summary.
 - The person obtaining consent must sign the summary.

Are there other requirements for documentation of consent?

Yes. If the study is conducted off the EU premises, written permission from the administrator should accompany the application and supporting documents. This permission must include a description of oversight procedures to be utilized at the study site.

What are the requirements for consent if a subject can't read?

Federal regulations permit the reading of the elements of informed consent to illiterate persons who understand English, who then may “make their mark” on the summary. Both the witness and the person conducting the consent interview must sign the form. The short form is not required in this instance.

Investigators should be cautious when enrolling subjects who may not truly understand what they are agreeing to do. The IRB considers illiterate persons as likely to be vulnerable to coercion and undue influence. Investigators should make sure additional safeguards are in place to protect the well-being of this vulnerable population.

Is the requirement to obtain a signed consent form ever waived?

If responses are anonymous and no identifiers are ever obtained, a *written* consent form is not necessary, although informed consent is always necessary. An IRB may waive the requirement for a signed written consent form for **either** of the following reasons:

- The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject is to be asked whether he or she wants documentation linking him/herself with the research; the subject's wishes are to govern.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

If the requirement for written documentation is waived, the IRB may require that the investigator provide subjects with a written statement regarding the research.

The most important thing to remember is that it is the researcher's responsibility to ensure that each subject has been made fully aware of the elements required in an informed consent, as

specified in the federal guidelines. The IRB will, under certain circumstances, permit exceptions to a signed informed consent if these conditions are met.

What is the IRB policy on deception of subjects?

Although the IRB occasionally has approved projects involving deception of subjects, it scrutinizes such projects to determine whether deception is necessary and if so, to what extent.

SPECIAL POPULATIONS

Are there special requirements for certain classes of subjects?

Yes. The following are considered “vulnerable populations” that require special protection:

- children
- prisoners
- pregnant women and fetuses
- mentally disabled persons
- economically or educationally disadvantaged persons

CHILDREN

What are some of the basics in conducting research with children?

- Federal guidelines specifying protection for children as research subjects can be found in **45 CFR 46.401-409**.
- Surveys and interviews with children require either expedited or full board review.
- A child is anyone under the age of 18.
- Assent must be gained from the child as well as permission from at least one parent or guardian.
- “Assent” means a child’s affirmative agreement to participate in the research, but mere failure to object does not imply consent. See below for more detail on this.
- “Permission” means the agreement of the child’s parent(s) or guardian for the child to participate in the research.
- A “parent” is the child’s biological or adoptive parent.

- “Guardian” means an individual authorized by law to consent on behalf of a child to general medical care.
- The federal regulations specify four categories of risk to children as subjects:
 - Minimal risk
 - Greater than minimal risk, but direct benefit to individual subject
 - Greater than minimal to child, with no direct benefit to individual subject, but likely to yield generalizable knowledge about subject’s disorder or condition
 - Otherwise not approvable, but presents opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

If there is only minimal risk, what are the requirements for research dealing with children?

If only minimal risk is posed, the IRB requires both assent of children and permission of their parents or guardians.

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.

If the proposed research involves greater than minimal risk to children but presents the prospect of direct benefit to the individual subject, what is required for approval?

- The risk is justified by the anticipated benefit to the subjects
- The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

If the proposed research involves greater than minimal risk to children and presents no prospect of direct benefit to the individual subject but is likely to yield generalizable knowledge about the subject’s disorder or condition, what is required for approval?

- The risk represents a minor increase over minimal risk
- The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
- The intervention or procedure is likely to yield generalizable knowledge about the subjects disorder or condition that is of vital importance for the understanding or amelioration of the

their disorder or condition

- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians

If the proposed research is not otherwise approvable but it presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, can it be approved?

It is extremely rare that the IRB can approve proposed research dealing with children if it does not meet the requirements of the first three categories. However, if an investigator has a project that falls into this fourth category, he or she should contact the IRB office (610-341-1313) for guidance.

Is any research involving children exempt from Full Board review?

According to the federal regulations, some types of research involving children do not need Full Board review. EU's policy is to require an Expedited review for the following types of research involving children.

- A. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as
 - regular and special education instructional strategies (or approaches or techniques)
 - assessment of the effectiveness of, or a comparison among, instructional techniques, curricula, or classroom management methods
- B. Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior **unless**: information taken from these sources is recorded in such a manner that subjects can be identified (directly or through identifiers linked to the subjects), and disclosure of the subject's responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to his or her financial standing, employability, or reputation. Observation of public behavior is included in this exemption only if the investigator(s) do(es) not participate in the activities being observed.
- C. Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior unless the research deals with sensitive aspects of the subject's own behavior that could be damaging to his or her reputation--such as illegal conduct, drug use, sexual behavior, or use of alcohol. Observation of public behavior is included in this exemption only if the investigator(s) do(es) not participate in the activities being observed.
- D. Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior that is not exempt under the provisions of B. above, but federal law requires without exception that the confidentiality of the personally identifiable

information will be maintained throughout the research and thereafter. Observation of public behavior is included in this exemption only if the investigator(s) do(es) not participate in the activities being observed.

- E. Research that involves collection or study of existing data, documents, or records 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)
- F. Research that involves collection or study of existing 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)
- G. Research and demonstration projects that are subject to approval of government officials and are designed to study aspects of public benefit or service programs (see **45 CFR 46.101(b)(5)** for more detail)
- H. Taste and food-quality evaluation and consumer acceptance studies wherein wholesome foods without additives are consumed
- I. Taste and food-quality evaluation and consumer acceptance studies wherein food is consumed that contains a food ingredient at or below the level, and for a use, found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

What are the requirements for assent by children and permission by parents or guardians?

The requirements for informed consent are the same for both adults and children, but parental/guardian permission is required as well. That is:

- ***Assent*** of the child must be obtained if, in the judgment of the IRB, he or she is capable of giving assent.
 - Elementary school-age children should provide oral assent to participate after the elements are explained at their level of understanding.
 - Middle school-age children and older can provide written assent.
- ***Written permission*** must be obtained from parents or guardians if a child is to participate in a research project. The degree of risk to the subject determines the number of signatures required.
 - For studies not involving greater than minimal risk or those involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (see above), the signature of only one parent or guardian is sufficient.

- For any other category of research that involves children, the signature of both parents or guardians is required unless:
 - one parent or guardian is deceased, unknown, incompetent, or not reasonably available
 - only one parent or guardian has legal responsibility for the care and custody of the child.
- The elements of informed consent must be included in the investigator's explanation of the project to the child and his or her representative.

It is important that the investigator explain the study at a level the child is capable of understanding, as valid assent can be given only if the child understands what he or she is agreeing to do. Asking questions in order to elicit questions or comments from the child is a good way to ascertain that he or she really understands what is being proposed.

What is required for documentation of assent/permission for research involving children?

See the explanation of documentation in the Informed Consent section of this Guide.

WARDS

Can children who are wards of the state or other entity be included in research projects?

Yes, but certain stipulations are made for research that poses greater than minimal risk and that does not present the prospect of direct benefit to the subject:

- The research must be related to their status as wards **or** it must be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- If the proposed research meets the stipulations above, then the IRB must require appointment of an advocate for each child who is a ward; this is in addition to any other individual who acts on behalf of the child as guardian or *in loco parentis*. One individual may serve as advocate for more than one child. The advocate should be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way--other than the role of advocate or member of the IRB--with the research, the investigator(s), or the guardian organization.

PRISONERS

How is “prisoner” defined?

According to federal regulations,

Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

What are the criteria to receive IRB approval to conduct research using prisoners?

- A. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited-choice environment of the prison is impaired.
- B. Risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.
- C. Procedures for the selection of subjects within the prison are fair to all prisoners and are immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners, who meet the characteristics needed for that particular research project.
- D. Information is presented in language understandable to the subject population.
- E. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
- F. If a follow-up examination is required or care of participants is necessary after the end of their participation, adequate provision has been made for such examination or care (considering the varying lengths of individual prisoners’ sentences) and for so informing participants.
- G. The proposed research is limited to any of the following:
 - study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk (see below), and no

more than inconvenience to subjects

- study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk, and no more than inconvenience to subjects
- research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis [more prevalent in prisons than elsewhere], and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)
- research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject.

Note: All research involving prisoners requires the inclusion of a prisoner advocate as a member of the IRB. This person must either be a prisoner themselves or must qualify under Office of Human Research Protections (OHRP) guidelines as a prisoner advocate.

PREGNANT WOMEN

The federal regulations specify that:

- no pregnant woman may be involved as a subject in an activity unless the purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs **or**
- the risk to the fetus is minimal

A plan should be developed for intervention in the event of unanticipated risks or adverse effects.

Detailed requirements pertaining to this special population can be found at **45 CFR 46.201-211**.

ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED PERSONS

Federal regulations permit the reading of the elements of informed consent to illiterate persons who understand English, who then may “make their mark.” Both the witness and the person conducting the consent interview must sign the form.

Investigators should be cautious when enrolling subjects who may not truly understand what they are agreeing to do. The IRB considers illiterate persons as likely to be vulnerable to coercion and undue influence. Investigators should make sure additional safeguards are in place to protect the well-being of this vulnerable population.

ADVERSE EFFECTS

Adverse effects are events or circumstances that were unintended and unanticipated. In order to comply with the regulations, these events must be reported immediately to the IRB chair and to the federal agency funding the research, if applicable.

ADMINISTRATION OF ALCOHOL OR ILLEGAL DRUGS

Investigators whose research requires the administration of alcohol or illegal drugs to human subjects should take special care to screen out inappropriate subjects, to provide information about the administration of alcohol or illegal drugs to subjects in the informed consent statement, to protect subjects against risks that may be entailed in experimentally induced intoxication, and to protect subjects against post-experimental risks.

1. Screening subjects

Investigators should be very cautious about including members of populations for whom alcohol or illegal drug use may be contraindicated. In applying for human subjects' approval, investigators should show sensitivity to this issue and provide cogent justification for the inclusion of members of high risk populations such as the following:

- a. Alcoholics or former drug users who are currently choosing to abstain from alcohol or drug use;
- b. Persons who are currently in treatment for alcoholism, drug addiction, problem drinking or drug use, or alcohol- or drug-related medical problems (unless the administration of alcohol or drugs is an integral component of the treatment of alcohol or drug abuse);
- c. Persons who have a history of past or present drug dependency involving substances cross-tolerant with alcohol (e.g., barbiturate abusers);
- d. Females who may be pregnant or who are pregnant. Such persons should not be included in research that involves the administration of alcohol or illegal drugs. If there is doubt concerning pregnancy, a medical clearance for alcohol use should be obtained prior to the participation of the subject;
- e. Persons who have a history of adverse reactions to the type of alcoholic beverage or drug or the amount of alcohol or drug to be used in the study;
- f. Persons who are presently taking medication that may interact with alcohol or illegal drugs;

- g. Persons who are presently abusing other psychoactive substances; and
- h. Persons who have any type of neurological defect.

2. Informed Consent

When alcohol or illegal drugs are administered the consent process should include the following:

- a. Subjects should be informed of the type of alcohol or illegal drugs to be administered and of the amount unless consumption is ad lib;
- b. When a placebo or nonalcoholic beverage is administered to some subjects, the subject should be informed that he/she might receive either an alcoholic or nonalcoholic beverage or active or inactive drug as part of the experimental procedure;
- c. When subjects receive alcohol or drugs, a cautionary statement about post- experimental activities is required. An example is: "You should not drive a car or use any dangerous equipment, or do any work which requires muscle and mental coordination for at least four hours after the study." The period of caution should be extended to be appropriate to the Blood Alcohol Level obtained or the half-life of the drug.

3. Risks

- a. Due consideration should be given to individual variation in rates of alcohol and drug absorption. In order to decrease individual variation in the maximum blood levels attained by subjects, alcohol and drugs should be administered in the post-absorptive state, that is, after a 4 to 10 hour period without food or fluid.
- b. Blood alcohol level (BAL) or drug levels should be determined by standard methods. Commonly used methods of measuring BALs include breath analyzers, intoximeters, and gas chromatography.
- c. Persons who are given enough alcohol to produce a blood level of 0.05 gm% or above should be under continuing supervision. Should a subject with a BAL of 0.05 gm % or above have to be left alone in the laboratory, a signal by which the subject can immediately communicate with the experimenter should be arranged.
- d. Persons with BALs below 0.05 gm % may be supervised at the discretion of the investigator. In deciding on the need for supervision, the investigator should consider such factors as the behavior of the subject, the subject's report of any untoward reactions to alcohol, and the subject's drinking and drug use history. It is recommended that special precautions be taken with subjects who are naive to the effects of alcohol or drugs or who have a low tolerance for alcohol or drugs.

4. Protection against post-experimental risks

- a. At the termination of the experiment, persons who have been given enough alcohol to produce a blood level of 0.05 gm % or above or who have been given illegal drugs should be given the choice of one of the following:
 - (i) To be escorted by the experimenter or designated assistant to the subject's place of residence; or
 - (ii) To remain in the laboratory setting under supervision until such time as the blood alcohol level falls below the 0.03 gm % level (or lower if Federal guidelines are modified to so require).
- b. Subjects should be given written information concerning their blood alcohol level at the end of an experiment. They should be reminded of possible risks at that level and of potential problems if they proceed to consume more alcohol or illegal drugs. They should be given an estimate of the number of hours before they are likely to reach a blood alcohol level of 0.0 gm
- c. If deception is a necessary part of research in which alcohol or illegal drugs are administered, the nature of and the reason for the deception should be explained to the subject following the experiment. If appropriate, the debriefing should also be designed to relieve any anxiety the subject may have about his or her performance in the experiment.

5. Additional information

For additional information, contact a member of the IRB.

- a. Research using records and stored biological specimens:

IRB approval must be obtained in most cases in which research activities include the use of data from records or stored specimens (blood, urine, tissue, and other human products). For purposes of this discussion, health care information records (including financial records, pharmacy records, x-rays, CT scans, MRI and other images and recordings), diagnostic specimens, pathological specimens and residual specimens are treated as health care information.

- b. Using health care records and information with written consent:

Explicit written consent should be obtained from the patient/subject before his or her records or materials (specimens, x-rays, billing information, etc.) are used for research purpose. The consent must state the name of the person(s) who want to use the information, the purpose for which the information is to be used, and must be dated. This release may be included in a standard consent form as long as all the necessary elements are included.

If the research otherwise qualifies as exempt (information to be used must “exist” at the time the research proposal is formulated) from review by the IRB, and the patient's explicit written consent is obtained for the use of health care information, the research may obtain an “exempt” review.

c. Using health care records and information without consent:

The IRB may allow a waiver of the requirement to obtain written consent to use health care information.

Although explicit written consent is always preferred, such a waiver should be requested if it is truly not feasible or practicable to obtain written consent for the use of health care information. The researcher must complete an Application for Review of Human Subjects Research so that the IRB may determine that the benefits of the research outweigh the risks posed by waiving the requirement for written consent -- invasion of privacy and breach of confidentiality.

If the research activity consists solely of the use of health care information, or if its other components also qualify, the application will be reviewed as "minimal risk." The IRB will review the application and, if it is approved, will draft a Confidentiality Agreement to be signed by the researchers and by the authorized EU official.

For additional information on legislation governing confidentiality of records, investigators may consult with the personnel of the Eastern University IRB.

d. Confidentiality

Confidentiality of the identity of subjects and of information from subjects is an important part of any research activity. Especially in behavioral research, but also in bio-medical research, breach of confidentiality and invasion of privacy may pose the greatest risks of harm associated with the research. Wherever possible, research data should be retained without any identifiers. When this is not possible, as in the case of longitudinal research or research which links data from several sets of data, investigators must take steps to protect the confidentiality of the subjects and the data.

Any unintentional but identifying data or information on data collection forms, questionnaires, and other records usually should be removed, stricken, or otherwise made indecipherable as soon as noted by the investigator.

In those instances where it is necessary to identify respondents, identification on data collection forms, questionnaires, and other records should be by code, with the code translation to be kept separate from the data. The code should not be an identifiable number such as a hospital's patient number, a student identification number, or a Social Security number; rather, a code should be established solely for the purpose of the study. Both the code translation and the data should be kept in a secure place, such as a locked

file cabinet, accessible only to the investigator, to his or her authorized staff, and to others identified in the IRB application form.

Where information will be computerized, no names or other identifying information should be entered. The study code number should be the only computerized identifier. The code translation should not be entered into the computer.

Exceptions to this policy may be made when it is necessary for the conduct of the study to collect and link data on the same individual from more than one source. In such instances the procedures for maintaining confidentiality of both the paper and computerized records should be clearly described and justified in the Human Subjects Review application form.

Social Security numbers need to be collected from subjects who may receive monetary inducements exceeding \$50.00 during a calendar quarter. The list of subjects, Social Security numbers, and payments should be kept in a secure place separate from the data.

Because subject anonymity is an important part of exempt research, a brief discussion of it is in order. The phrase "identifiers linked to the subject" appears in the Federal regulations. This means any name, code, or reference that could be used to identify the subject outside of the context of the research setting. Names, student numbers, and Social Security numbers are obvious examples of identifiers. An identifier that links a subject to a list of names or identifiers kept elsewhere is also an "identifier linked to the subject." For instance, numbering data records and keeping a list of subject names and record numbers creates an identifier linked to a subject, even if the list is well guarded. Similarly, if records are linked to a second set of records (e.g., test scores linked to school grades) and the second set of records is identified, then the first set would also be identified. The key question is, "Is there any way that anyone, including the investigator, could start with a data record and trace it back to the person being studied?" If the answer is yes, then there is an identifier linked to the subject.

Records may be numbered so that they can be associated with each other without creating an identifier linked to the subject. For example, if a study extends over several sessions, the data from one subject can be assigned a unique number without creating an identifier providing that there is no way that the record number can be associated with a person.

Investigators frequently have to know a participant's identity in order to schedule appointments and otherwise arrange for data collection. Ordinarily this sort of temporary identification does not create an identifier providing that the data collected cannot be traced back to an individual subject. In certain cases, however, the information that the subject participated in the research at all might be considered confidential and sensitive. For instance, this situation would occur if the study were of persons who have committed illegal acts. When the fact of participation is itself sensitive, any record identifying the subject is considered sensitive and confidential.

Investigators who collect sensitive information from subjects who may be identifiable as study participants may apply for a federal Certificate of Confidentiality. The Certificates are available to all investigators, whether or not their research is funded by the federal government, and regardless of the kind of sensitive information being collected. The Certificate is intended to protect identifiable research data from disclosure through subpoena, warrant, or court order. There are exceptions to the Certificate's coverage. For further information about Certificates, please contact the EU IRB.

RESEARCH RELATED MISCONDUCT

The Institutional Review Board will also serve as the recipient for any and all allegations of research misconduct, whatever the nature of the research. The IRB will be responsible for investigating such allegations and for notifying appropriate grantors of such allegations and of the outcomes of the investigation. The mechanism for members of the community to report suspected research misconduct will be posted on the intranet along with the other policies of the IRB.

The policy for investigating such charges includes the following:

1. Prompt response: the IRB will initiate an investigation within seven days of receiving a complaint and complete it within sixty days. Initiation of an investigation includes complying with any reporting responsibilities of granting agencies.
2. Protection of complainant: the IRB will protect, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.
3. Protection of researcher: the IRB will conduct the investigation of alleged misconduct in a manner that maintains confidentiality during the investigative phase.
4. Documentation of results: the IRB will prepare, within sixty days of receiving a complaint, a written report documenting what evidence was examined, summarizing relevant interviews, and describing the conclusions of the inquiry. This report shall be given to the individual(s) being charged with misconduct. If the researcher(s) choose to comment on the report, their responses must be part of the official record.
5. Disciplinary Sanctions: if the charges of research misconduct are upheld, the official report will be submitted to the Provost with a recommendation from the IRB for institutional disciplinary sanctions. Depending upon the nature of the misconduct, those sanctions may include - but are not limited to the following:
 - a. Disciplinary probation, during which time the individual may not participate in research activities nor seek funding;
 - b. Repayment of costs incurred by the institution as a result of the misconduct;

- c. Leave of absence;
 - d. Suspension (with or without pay) or;
 - e. Dismissal.
6. Appeal of Disciplinary Sanctions: a disciplinary decision may be appealed to the President of the University within one week of written notification of the disciplinary decision. A copy of the appeal letter should be sent to the Chairperson of the IRB. The President will review all written evidence, speak with the IRB and the individual(s) involved, and return a written judgment within thirty days of the filing of the appeal.

IRB RESPONSIBILITIES AND ROLES

Responsibilities of the Institution

The institution bears full responsibility for the performance of all research involving human subjects, covered by this Assurance, including complying with federal, state, or local laws as they may relate to such research.

The institution assures the federal government that the university is in compliance with federal regulations on the use of human subjects in research and that no research involving human subjects is conducted without prior review and approval.

The institution is responsible for ensuring that all institutions and investigators engaged in its U.S. Federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

The Institution will ensure prompt reporting to the Office of Human Research Protections (OHRP) any significant or material finding or action, at least to include the following:

- i. Unanticipated problems involving risks to subjects or others;
- ii. Serious or continuing noncompliance with federal regulations or IRB requirements; and
- iii. Suspension or termination of IRB approval.

Research that has been reviewed and approved by the IRB may be subject to further review and disapproval by officials of the institution. Institutional officials may not, however, approve research if it has been disapproved by the IRB.

The institution will provide the IRB with resources sufficient to effectively carry out their responsibilities under the Assurance.

The Institution provides legal protection for members of the IRB and to principal investigators granted approval to conduct research, provided they have met their obligations in good faith.

The Institution is responsible for investigating incidents or allegations of misconduct pertaining to the use of human subjects in research.

The Institution provides whistle-blowing protection to anyone who reports an activity that violates any regulations or policies on the use of human subjects.

Under the provisions of the Federal Freedom of Information Act, the Institutions is required, upon request, to release to the public documentation on any active or retired research protocol.

Responsibilities of Principal Investigators and Staff

Before initiating, modifying, or extending any research project that uses human subjects, Principal Investigators must submit an application to the Institutional Review Board for Human Research for review and approval.

In both the design and conduct of their studies, investigators are obligated to consider racial, cultural, and gender diversity among the subject populations and be sensitive to community attitudes.

Investigators will not make the final determination of exemption from applicable federal regulations or provisions of this Assurance.

Any serious or recurring problem unanticipated side effect, or adverse reaction experienced by a subject must be reported to the IRB. Problems related to the conduct of a study or patient participation (including those in the recruitment or consent process) must also be reported.

The violation of an experimental protocol or any use of subjects not approved by the IRB must be reported immediately to the IRB.

Any investigator who uses human subjects without IRB approval or who willfully violates the scope of his or her approval may lose legal protection provided by the University and may be held liable for any litigation costs and the costs of any medical care provided to subjects who suffer injury under such circumstances.

Responsibilities of the IRB

It is the responsibility of the IRB to safeguard the rights and welfare of human subjects who

participate in research at Eastern University. To this end, the Board is obligated and authorized to:

- i. Ensure that subjects are adequately informed of the nature of the study;
- ii. Ensure that subjects' participation is voluntary;
- iii. Ensure that the benefits of a study outweigh its risks;
- iv. Ensure that the risks and benefits of the study are evenly distributed among the possible subject population;
- v. Suspend human subjects activity that violates regulations, policies, procedures, or an approved protocol, and report such violation and suspension to the Institutional Official.
- vi. Review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research.
- vii. Conduct initial and continuing review, approving research, and reporting IRB findings to the investigator and the Institution.
- viii. Determine which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review.
- ix. Ensure that changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.
- x. Where appropriate, determine that adequate additional protections are ensured for vulnerable populations as required by Subparts B, C, and D of 45 CFR 46.
- xi. Forward to the Office of Human Research Protections (OHRP) any significant or material finding or action, at least to include the following:
 - a. Unanticipated problems involving risks to subjects or others;
 - b. Serious or continuing noncompliance with federal regulations or IRB requirements; and
 - c. Suspension or termination of IRB approval.

IRE Membership

Membership shall include:

- i. Chair
- ii. Members with experience in research from the various colleges and divisions within those colleges
- iii. An outside community member with experience in research

Members may satisfy more than one of the above categories.

IRB Chair

Elected by the committee members for a one-year term, typically rotated on an annual basis, but may be reappointed for consecutive terms, if necessary. The IRB chair must have been a member of the Eastern University IRB for at least one year and have participated in research as an investigator. The committee will elect a replacement if the Chair cannot complete the designated term for any reason.

As members of the board, IRB Chairs must comply with the overall requirements of board membership and, thus, may have varying backgrounds both scientific and nonscientific and may be selected from the Institution or the community at large, although some IRBs require the Chair to be a member or retired member of the institution staff.

There are no specific educational requirements for the IRB Chair, unless imposed by the rules of the specific IRB, but he must possess sufficient knowledge and understanding of medical research to be able to effectively read, interpret and judge the research proposals under consideration.

In addition, the effective IRB Chair should have extensive knowledge and understanding of federal, state and institutional regulations and policies and any ethical issues involved in all scientific research performed by the institution that falls under the jurisdiction of the IRB.

The Chair must be screened for conflict of interest and may be an employee or volunteer, depending on the structure and bylaws of the specific IRB.

Additional Qualifications

The Chair should be a respected member of the community, both within and outside the institution, who is able to act fairly and impartially in managing the IRB and the activities in which it engages. The Chair must be immune to possible pressures that could be brought to bear by those engaged in research the IRB is reviewing.

S/He must be able to use good interpersonal skills to build trust and to work effectively with the IRB, leading meetings, focusing discussions and directing decision making in a timely but thorough manner. The Chair should also be effective at interfacing with the institutional officer and staff assigned to support the IRB. Good written and verbal communication skills and highly respected ethical and moral values are essential traits for the qualified IRB Chair.

S/He should be comfortable working in stressful and time-pressured conditions and be able to balance and explain the need for rapid and thorough deliberation and decision making. The Chair should be comfortable discussing research directly with researchers, avoid undue influence and

be committed to the ethical principles respecting scientific research laid out by the Belmont Report:

- "Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.
- Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.
- Justice requires that the benefits and burdens of research be distributed fairly."

Role of the Chair

The depth of the role of the IRB Chairperson may vary somewhat according to the specific model used by the institution. Some IRB Chairs are required to be on staff at the institution; some may take a more hands-on role; others may serve part time on a volunteer basis and depend heavily on institution staff for support.

Responsibilities:

- Chair full IRB meetings, directing discussions, leading review and voting on research proposals.
- Take an active role in establishing and reviewing IRB policies and procedures.
- Chair sub-committees of the IRB, if applicable.
- Read research proposals, identify issues needing discussion and direct discussion and decision making.
- Vote as a member of the IRB.
- Conduct expedited reviews with a subset of the full IRB.
- Monitor and report any attempts to influence or coerce IRB members.
- Resolve any issues arising during the work of the board or refer unresolved issues to the institution.
- Ensure accurate records of membership, meetings, decision and research protocols are kept;
- Ensure IRB members are appropriately selected, ensuring that a diverse mix of institutional and community representatives are **present** and that members have been screened for conflict of interest;
- Prepare members for meetings and deliberations and provide any necessary **training**;
- Represent the IRB in communicating with other constituencies within and without the institution, including researchers and government regulators;
- Ensure assessments and audits are conducted as required by the institution and IRB policies; and
- Ensure the membership and proceedings of the IRB comply with state and federal regulations as well as institutional and IRB bylaws.

It should be noted, that as a member of the IRB, in order to avoid conflicts of interest, the chair will pass on 'exempt' category applications being submitted by his/her own students to other reviewers rather than approve them him/herself to avoid concerns about a perceived conflict of interest.

IRB Members

Appointed by the Faculty senate for two-year terms. Members may be appointed to consecutive terms.

Responsibilities:

- i. Attend meetings and plan to be present for the entire meeting.
- ii. Review all material provided.
- iii. Present primary reviewed protocols to the Board as requested.
- iv. Do not review or vote on any issue in which there is a conflict, or perceived conflict of interest.
- v. Protect confidentiality of records provided.
- vi. Act as Chair's designee as required.
- vii. Review IRB submissions and keep IRB members aware of current regulations and issues.
- viii. Advise investigators and study coordinators.
- ix. Prepare reports as required by regulations.
- x. Keep abreast of changes in regulations and communicate changes to investigators.

Members of the IRB may be removed for failure to perform functions and responsibilities.

Other Officer Positions on the IRB

Additionally, members of the IRB may serve in various officer positions in the committee. These position include:

IRB Secretary (Prepares minutes of meetings and disseminates to members)

University Liason (Serves as educational and promotional liaison of the IRB to other constituents of the University, such as faculty, administrators, students, and community members)

Policies and Procedures Officer (Maintains records of policies and procedures of the IRB; Updates as necessary)

Required Training of IRB

The Institutional Official, IRB Chairs and Human Protections Administrator are required to successfully complete the OH RP Assurance Training Module.

IRB Chairs, IRB members, IRB staff involved in the review of human subjects research applications are required to successfully complete the NIH human subjects training (NIH training link: <https://phrp.nihtraining.com/users/login.php>)

. Additional training includes familiarizing IRB members with regulations and Eastern University procedures through an orientation session with an IRB Administrator. Continuing IRB-related education is encouraged.

DEFINITIONS

Adverse Effect: An "adverse effect" is any physical, psychological or social outcome of an investigation, which is detrimental to a subject. Also referred to as "adverse event," or "side effect."

Anonymity: "Anonymity" means that no member of the research group knows the identity of the subject, and that identification of subjects is not possible by the procedures employed or by the information obtained from subjects.

Assent: "Assent" is a child's agreement to participate in research after an adequate explanation has been provided. Assent shall not be assumed simply because a child does not object. See pages 29-30 for a discussion of when a child's assent must be obtained and the methods for obtaining assent. Assent would also be required for other vulnerable populations such as the mentally disabled, economically, or educationally disadvantaged populations

Assurance. An "assurance" is a document negotiated between an institution and the Department of Health and Human Services (DHHS) assuring that the institution conducting research supported by DHHS will comply with its regulations **45 CFR 46** for the protection of human subjects. An assurance is required for each project funded by DHHS. Specific requirements for assurance can be found at **45 CFR 46.103**. For additional assistance, call the IRB chair at 610-341-1313.

Benefit. A benefit is a valued or desired outcome to the study that will be an advantage to the subjects participating.

Certification: "Certification" is a report by the college that the appropriate review body has approved the use of human subjects in the proposed research. The DHHS and other funding agencies generally require such certification.

Confidentiality: "Confidentiality" is the restriction of information that identifies the subject, outside of the research group itself. See pages 36-37 for further information about confidentiality.

Deception: "Deception" occurs whenever information about a research activity is deliberately withheld from subjects. See Section page 26 for a discussion of deception.

Directly or Indirectly Identifiable: Identities of individual subjects are kept by the investigator. If subject's identities are inseparable from data, then data are directly identifiable. If subjects' identities are kept separate from data, with information connecting them maintained by codes and a master list, then data are indirectly identifiable. In either case, investigator must assure that confidentiality will be maintained, and must explain how subjects' identities will be protected.

Emergency Applications: "Emergency Applications" are those which relate to situations where research procedures must begin immediately or the opportunity will be lost.

Human Subjects. A human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, *or* identifiable private information. (See also *Subjects.*)

Incompetent: In the context of the human subjects review process, an individual who is unqualified to give or is incapable of giving informed consent (see definition below) is considered to be "incompetent." An incompetent individual may be a minor, an adult who has been declared legally incompetent, or an adult whose competency may be questioned because of an illness or an unusual circumstance.

Individually identifiable information: Individually identifiable information the identity of the subject is associated with the information or can be ascertained readily by the investigator. (See also, *identifiable information*)

Informed Consent: "Informed Consent" is the agreement of a subject to take part in research after the procedures, costs, and potential risks and benefits have been explained in a manner that the subject can understand. Informed consent is the process by which prospective human subjects, or their legal representatives, are 1) informed of the nature and purpose of the proposed research, including risks, in a manner appropriate to their level of understanding and in non-technical language, 2) that they have the right to decline to participate or to withdraw from participation at any time without penalty; and, 3) given adequate time to decide if they want to participate.

Informed consent is a critical part of the IRB approval process, and it is essential that investigators understand and comply with the regulations. Details are provided in the Informed Consent section of this Guide.

Additional requirements for informed consent exist for special populations such as children and prisoners. Investigators should take care to observe *all* requirements for consent.

Institutional Review Board: "Institutional Review Board" (IRB) is a committee which has been formally designated by an institution to review and approve research involving human subjects. It is also known as the Institutional Review Board at Eastern University.

Interaction: Interaction includes communication or interpersonal contact between investigator and subject. Following are some examples of the more common types of interaction:

- Mail questionnaires or surveys;
- Personal interviews, structured or unstructured, with or without recognized instruments;
- Telephone interviews and surveys;
- Classroom instruments, evaluations, or exercises;
- Examination of private records, e.g., medical, psychological, school, or legal records
- Observations of public behavior by identifiable individuals.

Intermediary: An "intermediary" is an individual or organization that in another capacity has contact with prospective subjects, and that cooperates with an investigator to contact them.

Intervention: Intervention includes physical procedures by which data are gathered and/or manipulation of the subject or the subject's environment.

Intentionally Identified. Subjects' names are to be used in connection with their data when project results are presented to the public. This procedure is common for journalistic-type interview studies, where subjects are public figures or in oral histories. In these cases, the investigator should seek explicit consent from the subjects for the use of their names in connection to their data.

Minimal risk: According to federal regulations, 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. (see also "risk")

Minor: A person under eighteen years of age is legally a minor, unless that person has been declared an "emancipated minor." Investigators who propose to use "emancipated minors" should check with the IRB.

Modifications: "Modifications" are changes in the research after a human subject's application has been approved. See page 20 for additional detail.

Personal and Sensitive Information: This term includes any information about an individual which, if known to unauthorized persons or the general public, might reasonably be expected to cause embarrassment or discomfort, jeopardize that person's prospects of employment or education, or affect his/her financial or social status.

Population: A group of people in society meeting certain criteria to be eligible as subjects in a project's protocol.

Principal Investigator(PI). The PI is the individual (s) with primary responsibility for the design and conduct of a project's protocol.

Prisoner: "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Private information: Private information includes information 1) about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, (2) provided for specific purposes by an individual; and, 3) not reasonably expected by the individual to be made public. (See also: *Individually identifiable information*) the identity of the subject is associated with the information or can be ascertained readily by the investigator

Protocol: The informal design or plan of a study's activity; specifically, the plan submitted to an IRB for review and to an agency for support. The protocol includes a description of the design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen (s), and the proposed methods of analysis that will be performed on the collected data.

Risk: "Risk" is the potential for any physical, psychological or social outcome of an investigation that is detrimental to the subject (i.e. an adverse effect).

"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (from Title 45, Code of Federal Regulations, Part 46.1 02(g)).

Note: There are different types of adverse effects to which human subjects may be at risk that are inherent in various research procedures. Risk is most obvious in medical and

behavioral science research projects involving procedures, which may induce a potentially harmful altered physical state or condition. Some examples of such procedures are: the removal of organs or tissues for study, reference, transplantation, or banking; the administration of drugs or radiation; the use of indwelling catheters or electrodes; or the requirement of strenuous physical exercise.

There is a wide range of medical, social, and behavioral projects in which no risk of immediate adverse physical effects for the subject is involved (e.g. those involving the use of personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data). However, some of these procedures could involve a potential risk of discomfort, harassment, or a threat to the subject's dignity. Also, the information, if not kept confidential, could present psychological, social, or legal risks.

There are also medical and biomedical projects concerned solely with organs, tissues, body fluids, and other materials obtained in the course of routine performance of medical services such as diagnosis, treatment, and care, or of an autopsy. The use of these materials obviously involves no element of physical risk to the subject. However, their use for research, training and service purposes, if known to unauthorized persons or the general public, could present psychological, social or legal risks. In these situations, review may be necessary to determine whether the circumstances under which the materials will be procured are appropriate, and whether appropriate consent should be, or can be, obtained for the use of these materials for project purposes, and that the confidentiality of individuals will be maintained.

Scientific Merit: "Scientific Merit" is the contribution to science and society that a research project may make. In research involving no more than minimal risks, the IRB is not charged with judging the scientific merit of a proposed study. However, in research that involves more than minimal risk, the IRB must balance risks against their judgment of the scientific merit of the proposed study.

In cases in which there would be moderate or high risk and in which there are problems in determining scientific merit, the IRB may use consultants in making this determination. The IRB will not approve research when the risk is significant and the project is judged to lack adequate scientific merit.

Significant Risk: A study's design that presents a potential for serious risk to the health, safety or welfare of the subjects.

Subject: A "subject" is a person whose physical, intellectual, emotional or behavioral characteristics are investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. If a person, such as a family member, employer, or teacher, is asked to provide information about another individual, then both individuals are considered to be subjects. Donors of organs, tissues, and body fluids for research purposes and individuals, whose records are used for research, are also considered to be subjects.

Special regulations apply to prisoners, residents of institutions for the mentally ill and the mentally retarded, as well as pregnant women, the viable fetus, the newborn, children, and the dead. See Part D.5. and Federal Regulations for a description of these regulations.

Note: This definition of "subject" excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to professors, and other clients to professionals, in which the patient, student, or client is receiving aid or services intended only to meet his or her own personal needs. The professional-client relationship has the welfare of the client as the primary objective, whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective.

The normal employee-employer relationship, in which legitimate services are exchanged for salary, wages, or remuneration in keeping with customary written or oral contracts, is also excluded from the definition of "subject." Payment of volunteers, however, does not alter their status as subjects. If doubt exists as to whether the procedures are within the normal limits of the employees' work scope, the employees should be considered to be participating as human subjects and their rights and welfare must be protected.

Subject Advocate: A "subject advocate" is an individual who assists an adult subject who has not been declared legally incompetent, but whose ability to give informed consent is in question. The subject advocate should know the subject well enough to be able to attest to the subject's probable agreement to participate.

APPENDIX: APPLICATION AND SAMPLE FORMS

IRB Project Review Form (Application Form)

Adverse Events Guidelines and Form

Request for Extension Form

Protocol Amendment Form

Consent Forms

Frequently Asked Questions Concerning Consent Procedures

Samples of Forms of Consent

IRB Project Review Form Instructions

1 Complete this form using Microsoft Word

You may use Microsoft Word to fill all requested information. *Please DO NOT leave a question blank. If a question does not apply to your research, please write "N/A".*

2 Prepare all necessary supporting documents and accompanying materials

1. Documentation of consent procedures (one or more of the following must be provided):
 - a. Consent form(s)
 - b. Verbal Consent Script
 - c. Cover letter
 - d. Any survey instruments or questionnaires to be used
2. A list of interview questions or topics, in as much detail as possible (if interviews are used)
3. An electronic copy of NIH human subjects training workshop certificate for the Principal Investigator and Faculty Mentor. **NOTE: THIS POLICY WILL NOT BE IMPLEMENTED UNTIL JULY 1, 2015.**
4. Any other supplementary materials specifically requested in this application form

3 Email this form and supporting documentation to the appropriate address

If you are a student Principal Investigator, email the entire application package to your faculty mentor / research advisor for evaluation before IRB submission. After your faculty has reviewed and given consent to your application and any documents (e.g. interview protocol, consent forms), you then email irb@eastern.edu with your intent to submit. The IRB chair will enroll you in the IRB course site on blackboard. All email communication with the IRB must be from your secure EU email address.

Faculty applicants: Email the IRB (irb@eastern.edu) with your intent to submit and the name and email address of either your dean or department chair. Once you have been enrolled in the course site on blackboard, you will be able to then submit all your documents via blackboard.

Please note that, although most applications can be reviewed and approved simply with an electronic signature, the IRB may, at its discretion, request submission of a signed hard copy. Whereas there is a space for your signature, it is not required. Applying through the secure Blackboard course site serves as your signature. All approvals will be sent as electronic emails, you can print that in case you need a hard copy to show to the research site.

Review Timeline

When your packet has been received by the IRB, it will be checked for completeness. If not complete, you will be requested to submit additional materials necessary for the review. Upon approval, you will receive approval from the IRB by email. *Do not begin collecting data until you receive this approval.*

- **Exempt** reviews will generally take no more than 10 business days to be reviewed.
- **Expedited** reviews will take about 10 business days
- **Full Board** reviews will be conducted at the next meeting of the IRB, provided that the completed application has been received by the IRB at least 10 working days prior to the scheduled meeting date. The IRB meets on a monthly basis during the fall/spring academic semesters.
- **(June-August Exempt, Expedited and Full Board Reviews):** Please note that the IRB board does not review applications regularly during the summer months, so review times may take longer (approximately 3-4 weeks). Applicants should plan appropriately for such potential delays.

Contact Information

Website: <http://www.eastern.edu/offices-and-centers/institutional-review-board>
 Mailing address: IRB, Eastern University Phone: 610-341-4379
 1300 Eagle Road Email: irb@eastern.edu
 St. Davids, PA 19087

PART I: Project Description

Principal Investigator(s) (PI): (please list all names)		
PI: Please attach an electronic copy of your (PI) NIH human subjects training certificate (NIH training link: https://phrp.nihtraining.com/users/login.php) NOTE: THIS POLICY WILL NOT BE IMPLEMENTED UNTIL JULY 1, 2015.		
Department:	Campus:	
Status: <input type="checkbox"/> Faculty <input type="checkbox"/> Adjunct faculty <input type="checkbox"/> Staff <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate student		
Faculty Mentor (if PI is a student):		Course Number:
Faculty Mentor: Please attach an electronic copy of your Faculty Mentor's NIH human subjects training certificate (NIH training link: https://phrp.nihtraining.com/users/login.php) NOTE: THIS POLICY WILL NOT BE IMPLEMENTED UNTIL JULY 1, 2015.		
E-mail:	Phone:	Fax:
Mail correspondence to:		
Project Title:		
Estimated Project Start Date: (mm / dd / yyyy)	Estimated Data Collection Completion Date (Note: IRB approval cannot exceed one year): (mm / dd / yyyy)	
Is there, or will there be, extramural funding that directly supports this research? YES <input type="checkbox"/> NO <input type="checkbox"/>	Funding agency: If yes: PI on grant:	
Are you conducting your study with Eastern University students? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, and you plan to contact/use more than 100 students in your research, please seek permission from the Vice President for Student Development and the Department of Institutional Review (please attach a document of approval from the departments to this application).		
Are you conducting your study off the premises of Eastern University such as an agency or school? If yes, assurance of oversight by that entity must be provided to the IRB in the form of (please attach to application): A letter of permission from the lead administrator (or his/her designee) to conduct the study, which shows evidence that the administrator or official oversight group has reviewed the protocol and accepted its use at that institution		
IRB #:		(For Administrative Use Only)

ABSTRACT:

Briefly describe the purpose, research design, and procedures. Specify what the subjects will do:

Are there published articles/books/materials that affirm the safety and appropriateness of your methods? If so, list them below (please use professional form when listing citations):

PART II: What level of IRB review is needed for your project?

1. To determine whether your project is *exempt* from a full or expedited review by the IRB, please answer the following questions. *If you answered YES to any of these questions, then your project is NOT exempt, and you should answer the questions in this section to determine whether your project qualifies for expedited review.*

- Yes No 1. Are the subjects' data directly or indirectly identifiable, and could these data place subjects at risk (criminal or civil liability), or might they be damaging to the subjects' financial standing, employability, or reputation?
- Yes No 2. Will subjects be asked to report their own or others' sexual experiences, alcohol or drug use, and will you know their identities?
- Yes No 3. Are subjects used who may not be legally competent (under 18 years old, or subjects with certain conditions of intellectual, emotional or developmental disability?)
- Yes No 4. Are personal records (medical, academic, etc.) used with identifiers and without written consent?
- Yes No 5. Are any subjects confined in a correctional or detention facility?
- Yes No 6. Will alcohol or drugs be administered?
- Yes No 7. Will blood/body fluids be drawn?
- Yes No 8. Will specimens obtained from an autopsy be used?
- Yes No 9. Will you be including pregnant women by design?
- Yes No 10. Are live fetuses subjects in this research?
- Yes No 11. Will Non-English speakers be included?
- Yes No 12. Will economically or educationally disadvantaged populations be targeted?
- Yes No 13. Will members from minority groups be included?

2. If you answered YES to any of the questions above, please do not check anything here and proceed to the Expedited Review Criteria Section (p. 6). If you answered NO to all of the questions above, then your research qualifies for exempt review IF it fits into at least one of the following categories. *Please check all that apply:*

- Educational Research**
Research in established or commonly accepted educational settings, involving normal educational practices. This is for research that is concerned with improving educational practice.
- Surveys, Questionnaires, Interviews, or Observation of Public Behavior**
The subject matter must not involve "sensitive" topics, such as criminal or sexual behavior, alcohol or drug use on the part of the subjects, unless they are conducted in a manner that guarantees anonymity for the subjects
- Surveys, Questionnaires, Interviews or Observation of Public Behavior**
Surveys that involve sensitive information and subjects' identities are known to the researcher may still be exempt if: (1) the subjects are elected to appointed candidates for public office; or (2) federal statute(s) specify without exception that confidentiality will be maintained throughout the research and thereafter.
- Archival Research**
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. These data/samples must be preexisting, which means they were collected prior to the current project.
- Research Examining Public Benefit or Public Service Programs**
To qualify for this exemption, the research must also be conducted by (or subject to review by) an authorized

representative of the program in question. Studies in this category are still exempt if they include pregnant women by design and their purpose is to examine benefit programs specifically for pregnant women.

Taste Evaluation Research

Studies of taste and food quality evaluation. Studies of taste evaluation qualify for this exemption only if (1) wholesome foods without additives are consumed; or (2) a food is consumed that contains a food additive present at or below the level that has been found to be safe.

Noneducational/Other Research involving Special Consideration Populations (e.g., persons who are not legally competent, emotionally, cognitively or developmentally disabled populations, non-English speakers, economically or educationally disadvantaged populations, members from minority groups)

To qualify for exemption, the research must pose no more than minimal risk to subjects. The federal definition of minimal risk is: *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.*

If you determined that your project is *exempt* from expedited or full board review, then please proceed to page 7, Part III. Data Collection Procedures. Otherwise, please answer the following questions to determine whether your project qualifies for expedited review.

Expedited Review Criteria

1. To meet expedited review criteria, your project must meet the following conditions:

- No more than minimal risk to the subjects
 - i. The federal definition of minimal risk is: *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.*
- Subjects must not be confined in a correctional or detention facility
- Subjects must be participating in one or more of the ways described in the following section (see #2).

2. Your project qualifies for expedited review IF subjects are participating in one or more of the following ways. Please check all that apply.

- Collection of excreta and external secretions**
This includes sweat, saliva, placenta, and/or amniotic fluid. None of these may be collected by "invasive" procedures, such as those that use cannulae or hypodermic needles, such as amniocentesis.
- Recording of data using noninvasive procedures routinely employed in clinical practice.**
This includes but is not limited to the use of 'contact' recording electrodes, weighing, tests of sensory acuity, electrocardiography and electroencephalography, and measure of naturally occurring radioactivity.
IMPORTANT EXCLUSIONS: This does NOT include procedures which: (a) impart matter or significant amounts of energy to the subjects; (b) invade the subjects' privacy; or (c) expose subjects to significant amounts of energy outside the visible range (e.g. ultraviolet light from tanning beds).
- Collection of hair or nail clippings, or teeth from patients whose care requires the extraction or collection of plaque and/or calculus**
Collection of dental material must use routine procedures for the cleaning of teeth.
- Voice recordings**
Recordings made for research purposes such as the investigation of speech defects and speech pathology.
- Moderate exercise**
Moderate exercise performed by healthy volunteers.
- Experimental procedures (i.e., manipulation of an independent variable)**
Research performed to investigate individual or group behavior or the characteristics of individuals, such as studies of perception, cognition, game theory, or test development.
IMPORTANT EXCLUSIONS: This does NOT include studies that (a) involve significant stress to the subjects or (b) that are intended to produce a relatively lasting change in behavior.
- Educational research with subjects under 18 years of age**
Research in established or commonly accepted educational settings, involving normal educational practices and involving subjects are under 18 years of age. This is for research that is concerned with improving educational practice.
- Studies of archived data, records or diagnostic specimens**
This category would include studies of these specimens that do not qualify for exempt review.
- Collection of blood samples**
Studies involving the collection of blood samples by venipuncture, in amounts not exceeding 550 mL (about one pint) in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

If your study fits into one or more of the nine types of participation and meets the required criteria, then your project can receive EXPEDITED REVIEW from the IRB. If your study does not meet expedited review criteria, then it qualifies for FULL BOARD review. *The IRB will determine which level of review is appropriate for your project, based upon the information you provide in this form.*

Full Board Reviews

Research projects that require full board review have the potential for more than minimal risks (physical, psychological, or social) to subjects and/or include populations with special considerations (including research on prisoners, persons who are not legally competent, emotionally, cognitively or developmentally disabled populations).

The IRB will determine which level of review is appropriate for your project, based upon the information you provide in this form.

PART III: Data Collection Procedures

1. Please indicate the method(s) to be used: *(check all that apply)*

<input type="checkbox"/> Survey administered by:	<input type="checkbox"/> Investigator <input type="checkbox"/> Subject <input type="checkbox"/> Mail <input type="checkbox"/> Phone <input type="checkbox"/> In Person <input type="checkbox"/> Internet / E-mail
<i>Please submit a copy of the survey that you will use.</i>	
<input type="checkbox"/> Interview	<input type="checkbox"/> One-on-one <input type="checkbox"/> Focus Group <input type="checkbox"/> Oral History <input type="checkbox"/> Other (specify):
<i>Please submit a copy of the interview questions that you will use.</i>	
<input type="checkbox"/> Observation of Public Behavior	<input type="checkbox"/> Classroom <input type="checkbox"/> Public Setting <input type="checkbox"/> Other (specify):
<input type="checkbox"/> Archived Data or Records	<input type="checkbox"/> Academic <input type="checkbox"/> Medical <input type="checkbox"/> Legal <input type="checkbox"/> Other (specify):
<input type="checkbox"/> Taste or Sensory Evaluation	<input type="checkbox"/> Food Tasting <input type="checkbox"/> Olfactory
<input type="checkbox"/> Therapeutic Evaluation	<input type="checkbox"/> Biomedical <input type="checkbox"/> Psychological <input type="checkbox"/> Physical Therapy
<input type="checkbox"/> Experimental Procedures	<input type="checkbox"/> Biomedical <input type="checkbox"/> Psychological <input type="checkbox"/> Other (specify):
<input type="checkbox"/> Examination of Pathological or Diagnostic Tissue Specimens	
<input type="checkbox"/> Other (briefly describe):	

2. Please indicate how the data will be handled: (see the IRB manual, p. 45)

- Anonymous Confidential Intentionally identified

1. What form of consent will be obtained? (refer to the "Informed Consent Form Guidelines" document)

- Written (please attach consent form). If you are not using written consent please provide rationale and then select the type of consent below:

Implied (please attach cover letter or describe terms on a separate page)

Verbal (please attach consent script)

Seeking Waiver of Consent (please contact IRB for further information)

Consent Not Applicable (please explain reasons on a separate page)

2. If the data will be handled in an anonymous or confidential manner, how will confidentiality be maintained? (please check all that apply)

Anonymous is defined as: data are recorded such that no identifier whatsoever exists to link a subject's identity to that subject's response. No one can link an individual person to the response of that person, including the investigator(s). Face-to-face interviews and data collection are never anonymous.

Confidential is defined as: there exists a documented linkage between a subject's identify and her/his response in the research. The investigator provides assurance in the protocol and in the informed consent that the identity of any individual subject will not be revealed in any report of the study. Confidentiality means that the investigator can (or could) identify individuals who participated in a study, perhaps through a code.

- Coded to a master list and separated from the data
 Stored in a locked cabinet
 Stored in a locked office
 Stored in a restricted (password-protected) computer
 Other (specify):

3. Who will have access to the data?

4. Will any of the following be collected? Please check yes or no for each of these 3 categories below

- Yes No Video recordings (either tape or digital)
 Yes No Audio recordings (either tape or digital)
 Yes No Photographs

5. If you answered YES to any of the above in Question 4, then please provide the following information:

Where will the recordings or photographs be stored?

When (approximate date) will this material be destroyed? *This should also be included in the consent form.*

How will confidentiality be maintained?

PART IV: Description of the Population

1. Approximate number of subjects: _____ Approximate age range: _____
2. How will subjects be selected or recruited, and how will subjects be approached (or contacted)?

3. Will subjects be compensated (including extra credit*)? Yes No
If yes, then please explain how much, when, and how they will be compensated, and explain whether they must complete the project in order to be paid.

**If extra credit is to be given, please explain how students who do not participate may earn extra credit through alternative means.*

4. Are any subjects under 18 years of age? Yes No

If yes, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Please provide a copy of the parental consent form with the IRB application.

If yes, does the proposed research include children between the ages of 8 and 17 years old? An assent form should be used for subjects who are 8 to 17 years old. Please provide a copy of the minor assent form with the IRB application.

5. Are any subjects not legally competent to give consent? Yes No
If yes, then please explain how consent will be obtained. Who will give consent on their behalf? What procedures will be followed? Please attach consent form.

6. Will any minority groups be excluded from the study pool? Yes No
If yes, then please justify the exclusion.

7. Will any minority groups be included/targeted in this study? Yes No
If yes, please provide justification for including/targeting minority groups.

Specify how risks are minimized for this population.

8. Is this study likely to involve any subjects who are not fluent in English? Yes No
If yes, please submit both English and translated versions of consent forms and surveys, if applicable. Please ensure that the translations are accurate.

9. Does this study involve subjects located outside of the United States? Yes No
If yes, please explain on an attached page exactly who the subjects are and the identities (if possible) and responsibilities of any additional investigators.

10. Does this study involve economically or educationally disadvantaged populations? Yes No
If yes, please provide justification for including/targeting economically or educationally disadvantaged populations.

Specify how risks are minimized for this population.

4. Describe the expected benefits to the individual subjects and those for society. *This is required information.*

5. If blood or other biological specimens will be collected, then please address the following:

- a. Brief description of sampled tissues:
- b. Describe the personnel involved and procedure(s) for obtaining the specimen(s). *Please note that IRB requires that only trained certified or licensed persons may draw blood. Contact IRB for more information.*

PART VII: Use of Collected Data

Please check all that apply:

- Thesis / Dissertation
- Journal Article / Publication
- Grant Activities
- Other (*briefly describe*):

PART VIII: Drug or Alcohol Consumption

Note: If your project is exempt from expedited or full board review, then you may skip this section and proceed to Part IX on the next page.

1. Will any *Investigational New Drug* (IND) or any other substance regulated by the Food and Drug Administration (FDA) be used? Yes

No

If yes, then please note that the Eastern University IRB is not able to provide approval or oversight for your project. In order to conduct research involving Investigational New Drugs (INDs) or other substances subject to FDA regulation, you will need to work with a collaborator affiliated with another institution whose IRB is able to provide the review and oversight required by federal regulations.

2. Will alcohol be ingested by the subjects? Yes

No

If yes, then please describe what type and how it will be administered.

PART X: Assurances – signatures needed only if submitting hard copy

This investigation involves the use of human subjects. I understand Eastern University’s policy concerning research involving human subjects and I agree to:

1. Obtain voluntary and informed consent of persons who will participate in this study, as a required by the Eastern University Institutional Review Board (IRB).
2. Report to the Eastern University IRB any adverse effects on subjects which become apparent during the course of, or as a result of, the activities of the investigators.
3. Cooperate with members of the IRB who are responsible to review this project, and to give project reports as required by the IRB.
4. Obtain prior approval from the IRB before amending or altering the project or before implementing changes to the approved consent form.
5. Maintain documentation of IRB approval, consent forms and/or procedures, together with the data, for at least three years after the project has been completed.
6. Treat human subjects in the manner specified on this form.

Principal Investigator: <i>The information provided in this form is accurate, and the project will be conducted in accordance with the above assurances.</i>		
Signature _____	Print Name _____	Date _____
Principal Investigator		
Signature _____	Print Name _____	Date _____
Principal Investigator		
Signature _____	Print Name _____	Date _____
Principal Investigator		
Faculty Sponsor (if PI is a student): <i>The information provided in this form is accurate, and the project will be conducted in accordance with the above assurances.</i>		
Signature _____	Print Name _____	Date _____
Faculty Sponsor (if P.I. is a student)		
Chair, Director, or Dean: <i>This project will be conducted in accordance with the above assurances.</i>		
Signature _____	Print Name _____	Date _____
Chair, Director, or Dean		

Please Note: *The IRB approval is effective for only one year. After that, an extension request must be submitted before you can continue your project.*

Institutional Review Board Approval: *These assurances are acceptable, and this project has adequate protections for the subjects. This project has been properly documented and reviewed and is in compliance with federal, state, and university regulations.*

Signature _____ Print Name _____ Date _____
 Signature _____ Print Name _____ Date _____

Eastern University IRB use ONLY:

Review Status of Protocol: Exempt Expedited Full Board

Adverse Events Guidelines and Form

Investigators must report all UNEXPECTED adverse events of MODERATE OR GREATER SEVERITY **associated with the study intervention** for subjects at Eastern University.

For research conducted at external sites, only UNEXPECTED SERIOUS adverse events that occur and are **associated with the study intervention** (i.e., sponsor-generated reports) are required to be reported.

- An adverse reaction is considered serious if it is fatal or life-threatening; requires or prolongs hospitalization; produces a disability; or results in a congenital anomaly/birth defect.
- An adverse reaction is considered to be of moderate or greater severity if it requires medical evaluation (such as additional laboratory testing) and/or medical treatment; or if it is a serious adverse reaction.
- An adverse reaction is considered to be unexpected if it is not identified in nature, severity or frequency in the current IRB-approved research protocol or informed consent document.
- An adverse reaction is considered to be associated with the research intervention if there is a reasonable possibility that the reaction may have been caused by the research intervention (i.e., a causal relationship between the reaction and research intervention cannot be ruled out by the investigator(s)).

DECLARATION: I certify that I have reviewed the attached report and conclude that the risk-benefit ratio of the research continues to be acceptable, and that the risks are minimized to the greatest extent possible. By signing below, I certify that the information contained in this report is correct.

Principal Investigator:

Signature _____ Print Name

Date

Faculty Sponsor: (if P.I. is a student)

Signature _____ Print Name

Date

The EU-Institutional Review Board:

IRB Chair

Date

Request for Extension

(To be completed by the Principal Investigator)

Instructions: Inform the IRB via e-mail of your intent to submit an Adverse/Effect Report before completing this form. Once it is completed, submit a digital version of the form with electronic signatures on the IRB website. You should also mail a hard copy to the IRB.

Type or print:

Extension Request date:

Principal Investigator:

Contact Person:

Phone:

Fax:

E-mail:

Sponsor:

Title of Protocol:

Has this project been completed; i.e., have you finished gathering data and have all individual identifiers been removed from the data? Or, have you archived individually identifiable data that you plan to use for future studies?

Yes No

If **yes**, please sign below and return this form to the Institutional Review Board (IRB).

If **no**, you may request an extension by completing this form and submitting any required materials to the IRB **prior to the expiration date**.

ATTENTION: If you continue your research without an approved extension, you are in non-compliance of federal regulations. You risk having your research halted and the loss of any data collected while IRB approval has lapsed.

Will the research protocol or the consent form be modified in any way?

Yes No

If **yes**, please attach a description of the modifications and a new consent form. **All changes must be approved by the IRB prior to implementing the changes.**

Have any subjects complained about the research or reported any injury?

Yes No

If **yes**, please attach an explanation of the complaint or injury.

By signing below, I certify that the information contained in this extension request is correct.

Principal Investigator:

Signature _____ Print Name _____ Date _____

Faculty Sponsor: (if P.I. is a student)

Signature _____ Print Name _____ Date _____

The EU-Institutional Review Board Action:

Approved through _____

New protocol is needed. See attached explanation.

IRB Chair

Date

Protocol Amendment Form

(To be completed by the Principal Investigator)

Instructions: Inform the IRB via e-mail of your intent to submit an Adverse/Effect Report before completing this form. Once it is completed, submit a digital version of the form with electronic signatures on the IRB website. You should also mail a hard copy to the IRB.

Type or print:

Amendment date:

Principal Investigator:

Contact Person:

Phone:

Fax:

E-mail:

Sponsor:

Title of Protocol:

Material revised/amended includes: (Check all that apply)

Protocol

Consent form

Drug Information Sheets

Other - Identify

Briefly summarize changes:

Principal Investigator:

Signature _____ Print Name _____ Date _____

Faculty Sponsor: (if P.I. is a student)

Signature _____ Print Name _____ Date _____

Chair, Director or Dean:

Signature _____ Print Name _____ Date _____

Exempt Protocols: Signed original amendment form and one copy of all attachments that help explain the changes (e.g., revised consent form).

Expedited Protocols: Signed original amendment form and two copies of all attachments.

Full Board Protocols: Signed original amendment form and five copies of all attachments.

The EU-Institutional Review Board approved this amendment on this date

Chair

Date

IRB

CONSENT FORMS

A. FREQUENTLY ASKED QUESTIONS CONCERNING CONSENT PROCEDURES

1. Do I need to get consent? Can I get a waiver from the consent requirements?

Written consent is used with any face-to-face research activity whether minimal risk or greater than minimal risk studies in both Biomedical and Social Behavioral research. Obtaining a signature on a consent form is standard. If you are using archived data, consent may not be necessary or even possible. Some data do not meet the definition of “archived data,” but researchers may still seek a waiver of consent requirements. Only studies with a restricted set of conditions may use this option and each waiver request is separately reviewed and considered by EUIRB.

2. What if I want to give my subjects anonymity?

You should not use a written consent form. Instead you can use a consent script (e.g., phone surveys) or a cover letter (e.g., mail surveys). These documents do the same basic job as a written consent form, informing subjects about the study and their rights. The only difference is that subjects do not sign their name.

3. Do I need to get consent if my project is exempt?

The requirement for some form of consent applies to ALL research, although most exempt projects (particularly mail or phone surveys) can use a consent script or cover letter (for implied consent).

4. What if I audio or video tape or take pictures of my subjects?

You will need to get a written consent. The consent procedure needs to specify WHEN the tapes or photographs will be destroyed, WHERE they will be stored, and WHO will have access to the tapes or photographs. Use a version of the WRITTEN CONSENT FORM.

5. What if I want to intentionally identify individuals in my research report(s) (i.e., quote individuals who I have interviewed and give their identities)?

Then you will be required to get their written consent.

6. What if my project is BIOMEDICAL in nature?

Use the sample for written consent forms and the BIOMEDICAL CONSENT FORM CHECKLIST.

7. What are the special consent considerations for children?

If a child is between the ages of 8 and 17, you should seek both written parental and child assent. One parent must give permission if the research is minimal risk or greater than minimal risk but holds prospect of direct benefit. If the research is greater than minimal risk and holds no prospect of direct benefit, both parents must give permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. The assent form language should be written at about the same grade level as the child. If the child is between the ages of 3 and 7, then you should use a VERBAL ASSENT, which is a consent script with language appropriate for the child's age. A child younger than age 3 is considered incapable of participating in the consent process. At all age levels, the final power of consent is usually left to the parents or guardians.

8. Are there laws that affect the consent process?

In the course of your research, if you become aware that any specific individual is in imminent danger of harming him/herself or others (e.g., due to acute depression, etc.) or is currently suffering mental or physical abuse, or is/has been abused by others, or is abusing another individual, you are required by Pennsylvania state law to inform the appropriate authorities. If there is a reasonable chance that you may discover such information about your subjects, you must tell them of this requirement when you ask for their consent, because the law requires you to break confidentiality in these circumstances. Contact IRB for more information on this topic, including specific language to be used.

B. CONSENT FORM TEMPLATES

[CONSENT FORM]
[Insert Title of Study]

[Your name]
[Contact information]

I am a [graduate/undergraduate] student pursuing a [Your Degree] in the [Program] at Eastern University.

You are invited to be in a research study of [general statement about study]. You were selected as a possible participant because [explain how the subject was identified]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Background Information:

Currently, I am working on a research study for a [course/thesis]. The study is designed to [describe the study briefly].

Procedures:

If you agree to be in the study, I/we will ask you to do the following things: [describe tasks and

procedures: subjects should be told about video or audio recording, photographs that may be taken, length of time for participation, frequency of procedures and make assurances about anonymity/confidentiality/etc.].

Confidentiality:

Participation in this study is voluntary and [confidential/ anonymous – see “Definitions” p. 45 of IRB manual]. Any identifying information will be removed from the final research report. [if the study is conducted at a place of employment, indicate that employer will not have access to the files/surveys/etc. and that participation will not affect their employment in any way] Research records [video or audio recordings/photographs] will be stored securely [indicate where and how] and only researchers will have access to these records. These records will be maintained [confidentially/anonymously] for 3 years and then destroyed on [date of destruction]

In any sort of report I/we might publish, we will not include any information that will make it possible to identify a subject.

Risks and Benefits of participating in the Study:

The risks of this study are [insert risks] (Risk must be explained, including the likelihood of the risk). [If there are risks, please indicate how they will be handled].

The benefits of this study are [insert benefits].

Compensation:

You will receive payment/extra credit [indicate if there is/is not compensation. If so, explain how much, when and how they will be compensated, and explain whether they must complete the study in order to be paid or if they will receive partial compensation for completing a percentage of the study. If subjects receive class points you must explain how students who do not participate may earn extra credit through alternative means].

Voluntary Nature of the Study: Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Eastern University [or with other cooperating institutions, insert names here] and will result in no penalty. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships and without penalty.

Contacts and Questions:

The researcher(s) conducting this study is/are: [name of researcher(s)]. You may ask any questions you have now. If you have questions later, you are encouraged to contact [the researcher(s)] at [phone number and email of researcher(s)]. *(If the researcher is a student, include advisor’s name, telephone number and email address here.)*

This project has been approved by Eastern University’s Institutional Review Board as indicated by the date in the lower right-hand corner of this document. Do not agree to participate in this

study if the date is older than one year. If you have any concerns about the manner in which this study is conducted, you may contact the IRB at email irb@eastern.edu.

You will be given a copy of this information to keep for you records.

CONSENT STATEMENT:

I have read the above information and agree to participate in this research study. I understand that if I have any questions or concerns regarding this project, I can contact the investigator at the above location or the Eastern University Institutional Review Board at IRB@eastern.edu. I consent to participate in the study.

(Participant's Signature)

(Date)

(Parent or Guardian Signature, if a minor)

(Date)

(Investigator Signature)

(Date)

GUIDELINES FOR COMPOSING A BIOMEDICAL PROJECT CONSENT FORM

Determine if the consent form is going to be written using first person (I) or second person (you). The language should avoid technical medical terminology; use uncomplicated and understandable words. If technical terms must be used, clearly explain in simple language. (e.g., Placebo is an inactive medication or “sugar pill” or a placebo contains no medication). Consider attaching a glossary of terms. The name of the investigator and telephone number should appear in the consent form.

BIOMEDICAL CONSENT FORM CHECKLIST

- Title of study
- Investigator name, title and contact information
- Investigator affiliation

HEADINGS FOR CONSENT FORM

Introduction/Background Information:

- Description of the study
- Role of participant

Purpose:

- What is being studied
- Why it is being studied
- Purpose of research

Procedures:

- List of all procedures
- Intervals of procedures
- Length of time participant in study
- What will be given or received and how administered
- Length of hospital stay, if required
- Prior experience with drug or device

Voluntary Participation/ Withdrawal:

- Statement regarding voluntary participation
- Statement regarding voluntary withdrawal by participant
- Statement regarding voluntary withdrawal of participant by physician (in consent form or as attachment)

Confidentiality:

- Indicate records are confidential
- Safeguards used if data published

- Who will have access to records
- Indicate the date records will be destroyed

Risks:

- Describe all risks in detail
- Describe all possible side effects
(in consent form or as attachment)

Benefits to Participant :

- Describe in detail
- State if none

Reimbursement/Compensation for Illness/Injury During Study:

- Name/phone number of treating doctor
- Where will treatment be given
- Other forms of compensation

Alternative Treatment/Procedures:

- Describe in detail

Exclusions for Nonparticipation:

- Describe in detail

Participant Costs/Payment:

- Payment to be received by participant
- Costs to participant, if any
- Insurance coverage, if any

Legal Rights/Patient Consent:

- Statement regarding legal rights
- All questions answered
- Emergency phone number
- Copy of consent form given to participant
- Signature and date line for participant (or guardian)
- Signature and date line for investigator
- Signature and date line for witness

Other:

- Written in first person/second person
- Technical medical terminology explained

Contacts and Questions:

- Name/phone number of investigator
- Listing of EU IRB: irb@eastern.edu