

**EASTERN ILLINOIS UNIVERSITY**

**POLICIES AND PROCEDURES**

**FOR THE**

**REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS**

This manual is believed to be in full compliance with all applicable Federal and state laws and regulations. This manual supersedes all previous versions. Revisions will be issued from time to time that reflect changes in federal and state laws and regulations and changes in University procedures, which experience shows to be needed or desirable. Comments from users of this manual are welcome and will be given full consideration in the preparation of revisions and changes in procedures for the review of research involving human subjects. Please forward your comments to the IRB administrator, care of the Office of Research and Sponsored Programs.

Acknowledgement: This policy is largely based on the policy at Indiana State University. Eastern Illinois University thanks Indiana State University for written permission to use this material. Thanks is also due to the University of Wisconsin-Eau Claire and Penn State University for permission to adapt their materials for use at Eastern Illinois.

---

# TABLE OF CONTENTS

<b>A. INTRODUCTION.....</b>	<b>6</b>
<i>A.1 General Distribution of Responsibility.....</i>	<i>6</i>
<i>A.2 Abbreviations and Definitions Used in Policy and Procedures.....</i>	<i>6</i>
A.2.1 Definitions Used by the Department of Health and Human Services.....	7
A.2.2 Definitions Used by Eastern Illinois University.....	8
<i>A.3 General Information on Submitting Materials to the IRB.....</i>	<i>9</i>
<b>B. RESPONSIBILITIES AND ACTIONS OF THE INSTITUTIONAL REVIEW BOARD.....</b>	<b>9</b>
<i>B.1 Composition of the IRB and Appointment of Members.....</i>	<i>9</i>
<i>B.2 Responsibilities and Actions of the IRB Chairperson.....</i>	<i>10</i>
<i>B.3 Meetings and Quorums.....</i>	<i>11</i>
<i>B.4 Functions and Operations of the IRB.....</i>	<i>11</i>
<i>B.5 Review of Research.....</i>	<i>12</i>
<i>B.6 Approval of Research.....</i>	<i>12</i>
<i>B.7 Actions and Authority of the IRB.....</i>	<i>12</i>
B.7.1 Actions Regarding Approval of Applications.....	12
B.7.2 Additional Actions and Authority of the IRB.....	12
<b>C. RESPONSIBILITIES AND ACTIONS OF THE CHIEF RESEARCH OFFICER.....</b>	<b>13</b>
<i>C.1 Administrative Responsibilities of the CRO.....</i>	<i>13</i>
<i>C.2 Actions of the Chief Research Officer Upon Receipt of Notice of IRB Action from the Chairperson.....</i>	<i>13</i>
<i>C.3 Revisions of Policies and Procedures.....</i>	<i>13</i>
<b>D. RESPONSIBILITIES AND ACTIONS OF THE IRB ADMINISTRATOR.....</b>	<b>14</b>
<b>E. RESPONSIBILITIES AND RIGHTS OF THE PRINCIPAL INVESTIGATOR.....</b>	<b>15</b>
<i>E.1 Responsibilities.....</i>	<i>15</i>
<i>E.2 Rights.....</i>	<i>15</i>
<i>E.3 Responsibilities of the PI Upon Leaving EIU.....</i>	<i>16</i>
<b>F. PROCESS FOR IRB REVIEW AND APPROVAL OF RESEARCH.....</b>	<b>16</b>
<i>F.1 Levels of Review.....</i>	<i>16</i>
F.1.1 Exemption Certification Review.....	16
F.1.1.1 New Application.....	16
F.1.1.2 Modification Request.....	17
F.1.1.3 Continuation Request.....	17
F.1.2 Expedited Review.....	17
F.1.2.1 New application.....	17
F.1.2.2 Modification Request.....	18
F.1.2.3 Continuation Request.....	18

F.1.2.4	Completion of Research .....	18
F.1.2.5	Informing IRB members of Expedited Reviews .....	19
F.1.3	Full Review .....	19
F.1.3.1	New application .....	19
F.1.3.2	Modification Request .....	20
F.1.3.3	Continuation Request .....	21
F.2	Length of IRB Approval .....	21
F.3	Verification of Sources other than the PI .....	21
F.4	Preparation of Public Use Data Files .....	21
<b>G.</b>	<b>PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, AND NONCOMPLIANCE .....</b>	<b>22</b>
G.1	Guidelines for Defining Problems to be Reported.....	22
G.2	Guidelines for Defining Noncompliance .....	23
G.3	Reporting of Problems or Noncompliance by the PI.....	23
G.4	Investigations of Problems and Noncompliance <b>Reported by Others</b> .....	24
G.5	Suspension or Termination of Approval of Research Activities .....	24
G.6	Reporting by EIU of Problems or Noncompliance .....	25
<b>H.</b>	<b>Conflicting Interests.....</b>	<b>25</b>
H.1	Financial Conflict of Interest.....	25
H.2	Intellectual Property.....	25
H.3	Conflicts of Commitment.....	25
H.4	Dual Relationships.....	25
<b>I.</b>	<b>COOPERATIVE RESEARCH .....</b>	<b>26</b>
<b>J.</b>	<b>INFORMED CONSENT .....</b>	<b>26</b>
J.1	Informed Consent Requirements.....	26
J.2	Alterations to the Informed Consent Procedure .....	27
J.3	Alterations in the Documentation of Informed Consent .....	27
J.4	Research Involving Children .....	27
<b>K.</b>	<b>PROTECTION OF CONFIDENTIAL INFORMATION .....</b>	<b>28</b>
K.1	Storage and Retention of Confidential Records.....	28
K.2	Certificate of Confidentiality .....	28
K.3	Access to Confidential Records .....	29
K.4	Other Regulations Related to Privacy, Confidentiality, and Consent .....	29
K.4.1	Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) .....	29
K.4.2	Family Education Rights and Privacy Act .....	29
K.4.3	Protection of Pupil Rights Amendment .....	30
<b>L.</b>	<b>INTERNET RESEARCH.....</b>	<b>30</b>

<b>M. HUMAN SUBJECTS PROTECTION IN FIELD RESEARCH .....</b>	<b>31</b>
<b>N. OTHER STUDIES INVOLVING HUMAN SUBJECTS .....</b>	<b>32</b>
<i>N.1 Student Working with Human Subjects.....</i>	<i>32</i>
N.1.1 Student Research.....	32
N.1.2 Student Class Projects.....	33
N.1.3 Certification of Courses .....	33
<i>N.2 Institutional Research.....</i>	<i>34</i>
<i>N.3 Other Projects.....</i>	<i>34</i>
<i>N.4 Publicly Available Data.....</i>	<i>34</i>
<b>O. TRAINING .....</b>	<b>35</b>
<i>O.1 Who Must Be Trained? .....</i>	<i>35</i>
O.1.1 Training for Conventional Research.....	35
O.1.2 Training for Student Class Projects .....	35
O.1.3 Training for Institutional Research.....	35
O.1.4 Training for Other Projects.....	35
O.1.5 Training for Projects Based Solely on Publicly Available Data .....	36
<i>O.2 When Training Must Occur .....</i>	<i>36</i>
<i>O.3 Training Procedures and Certification.....</i>	<i>36</i>
<b>P. STUDENTS AS RESEARCH SUBJECTS .....</b>	<b>36</b>
<i>P.1 Types of Activities Covered by this Section .....</i>	<i>36</i>
<i>P.2 Recruitment of Students for Research Studies .....</i>	<i>37</i>
<i>P.3 Awarding Credit for Participation in Research Studies .....</i>	<i>37</i>
<b>Appendices .....</b>	<b>38</b>
<b>Appendix 1—Instructions for Submissions and Forms.....</b>	<b>39</b>
<i>Instructions for Submitting Materials for Review by the Institutional Review Board .....</i>	<i>40</i>
<i>Form A – New Application to the IRB for Review of Research Involving Human Subjects .....</i>	<i>41</i>
<i>Form B – Exempt Research Categories .....</i>	<i>46</i>
<i>Form C – Expedited Review Research Categories .....</i>	<i>47</i>
<i>Form D – Proposed Modifications to Protocol or Informed Consent/Assent Form(s) After IRB Approval .....</i>	<i>49</i>
<i>Form E – Continuation Request.....</i>	<i>51</i>
<i>Form F – PI Report of Problems Involving Risk, Adverse Effects, or Noncompliance .....</i>	<i>54</i>
<i>Form G – Completion of Research Activities.....</i>	<i>56</i>
<i>Form H – Certification of Courses .....</i>	<i>57</i>
<i>Form I – Request for Waivers of Informed Consent .....</i>	<i>59</i>
<b>Appendix 2—Reviewer Checklist .....</b>	<b>62</b>

<b>Appendix 3—Informed Consent</b> .....	<b>65</b>
<i>Informed Consent Form Checklist</i> .....	66
<i>Informed Consent Form Template</i> .....	67
<i>Conditions for Waiver of Requirement to Obtain Signed Informed Consent</i> .....	71
<b>Appendix 4—HIPAA Information</b> .....	<b>72</b>
4.a <i>Definitions used in the Privacy Rule</i> .....	73
4.b <i>Authorizations</i> .....	74
4.b.1    Authorization Document.....	74
4.b.2    Waiver or Alteration of Authorization .....	74
4.c <i>Exceptions</i> .....	75
4.c.1    Limited Data Set .....	75
4.d <i>Disclosure of PHI</i> .....	76
4.e <i>Existing Protocols</i> .....	76
4.f <i>HIPAA Defined Personal Identifiers</i> .....	76
<b>Appendix 5—Training Procedures for Human Subjects Protection</b> .....	<b>78</b>

## A. INTRODUCTION

Pursuant to the National Research Act (P.L. 93-348§212a) and 45 CFR 46.103, Eastern Illinois University (EIU) maintains an Institutional Review Board (IRB) and has created the written policy of this document to govern its actions. At EIU, the IRB is charged with assuring the protection of the rights and welfare of human subjects participating in research. Therefore, the IRB is required to review all research involving human subjects prior to the conducting of any research. This manual has been prepared to assist all members of the university community in complying with the stated policy and procedures of the institution regarding research involving human subjects. Appendixes contain forms, instructions, and other guidelines to assist the researcher, the various academic departments and other units of EIU, and the IRB in carrying out the review process.

### A.1 General Distribution of Responsibility

Any undertaking in which an EIU faculty member, staff member, or student investigates or collects information on living humans for research or related activities may be considered as “involving human subjects.” It is the responsibility of each investigator to seek review by the IRB for any study involving human subjects prior to beginning the project.

EIU’s IRB is responsible for the review of research or related activities involving human subjects. The respective authorities and duties of the IRB are described in this policy manual.

Consistent with federal regulations, the chief research officer (CRO) appoints members to the IRB. At EIU, the CRO is the Dean of the Graduate School.

The IRB administrator and Compliance Coordinator, as designated, are responsible for managing the application review process, assisting in liaison with funding agencies, record keeping and reporting, managing human subjects research training, and assisting with assurance of compliance with federal regulations. At EIU, the IRB administrator is the Director of Research and Sponsored Programs. The Compliance Coordinator reports to the Director of Research and Sponsored Programs.

### A.2 Abbreviations and Definitions Used in Policy and Procedures

Federal regulations and university policy use the following abbreviations:

CFR	Code of Federal Regulations
FDA	Food and Drug Administration
DHHS	Department of Health and Human Services
OHRP	Office for Human Research Protection
EIU	Eastern Illinois University
IRB	Institutional Review Board
CRO	Chief Research Officer (who is the Dean of the Graduate School)
PI	Principal Investigator
OGR	Office of Research and Sponsored Programs
EAP	Executive, Administrative, and Professional staff

Federal regulations and university policy define various terms in regard to protection of human research subjects. 45 CFR 46 is the body of regulations promulgated by DHHS. Most projects at EIU fall under these regulations. 45 CFR 46 includes the following definitions:

## **A.2.1 Definitions Used by the Department of Health and Human Services**

(1) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the DHHS to whom authority has been delegated.

(2) *Department or Agency* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(3) *Research* means a systematic investigation—including research, development, testing, and evaluation—designed to develop or contribute to generalizable knowledge. Dissemination of findings to a scientific audience is a sufficient (but not necessary) criterion for identifying generalizable knowledge. Dissemination includes, but is not limited to, honor's, master's, and doctoral theses; presentation at a scientific meeting or conference; submission to or publication in a scientific journal (paper or electronic); and Internet postings. Activities that meet this definition constitute research for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(4) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

- *Intervention* includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., cognitive experiment).
- *Interaction* includes communication or interpersonal contact between investigator and human subject (e.g., a telephone interview).
- *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which he or she can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(5) *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.

(6) *Vulnerable population* means children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers).

(7) *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. Prisoners receive additional protections under 45 CFR 46, Subpart C.

(8) *Child* means a person who has not yet attained the age of consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. Children receive additional protections under 45 CFR 46, Subpart D.

(9) *Parent* means a child's biological or adoptive parent.

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

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

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

(13) *Adverse effect* means an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., subject becomes upset following completion of a depression questionnaire, subject experiences intestinal bleeding associated with aspirin therapy) that is directly or indirectly due to participation in a research study.

Some studies may fall under the regulations promulgated by the FDA (21 CFR 50). These will generally be studies that involve the testing of an investigational medication or a medical device. Refer to 21 CFR 50 for specific definitions regarding these studies. Some FDA definitions differ from the above DHHS definitions.

### **A.2.2 Definitions Used by Eastern Illinois University**

In addition to definitions promulgated by federal agencies, EIU policy uses the following definitions:

(1) *IRB Administrator* is the individual who serves as OHRP's primary institutional contact person and provides oversight of the administrative responsibilities for the IRB. The IRB administrator is the Director of Research and Sponsored Programs, and is also designated as the Human Protections Administrator in EIU's Federalwide Assurance (FWA).

(2) *Compliance Coordinator* is the individual who provides administrative support to the IRB and facilitates the procedures outlined in this policy. The compliance coordinator reports to the Director of Research and Sponsored Programs.

(3) *Principal Investigator* is the person who leads the project and is ultimately responsible for all aspects of it. On most projects, the term has the same meaning as "project director."

(4) *Key Personnel* include the PI, the faculty sponsor of a student conducting research, and any student conducting research that is not considered a "student project" as defined in Item 4 below.

(5) *Student project* means a study in which a student investigator (individually or as part of a group) gathers or analyzes information in a systematic manner, primarily for pedagogical purposes. It is not intended to contribute to generalizable knowledge and is not to be published

(including publication on the Internet), presented, or archived. Research conducted for a master's thesis or doctoral dissertation does not fall under this definition.

(6) *Institutional research* is a study conducted by EIU staff that is designed to obtain information to assist in the administration of the university. Institutional research provides information for administrative planning, policy making, decision making, and includes examinations of institutional effectiveness. It is not intended to produce generalizable knowledge.

(7) *Training* refers to a process approved by EIU, and required by federal regulations, to instruct investigators in the conduct of research involving human subjects.

### **A.3 General Information on Submitting Materials to the IRB**

PIs should submit their application packet directly to the **compliance coordinator**, care of OGR, for review by the IRB. A new application consists of Form A, including answers to all research description questions; Form B (exempt research checklist) or Form C (expedited review research categories), if applicable; and the research grant proposal, if the PI is seeking funding or has received funding. Similarly, any submissions after IRB approval, including modification requests (Form D), continuation requests (Form E), adverse event written reports (Form F) and completion of research activities (Form G) should be submitted to the IRB administrator, care of ORSP. Refer to Appendix 1 for more information on submission materials and for copies of the forms. The compliance coordinator will forward the materials to the IRB chairperson, vice chairperson, or designated IRB member who will determine the level of review required. The IRB chairperson, vice chairperson, designated IRB member, **or compliance coordinator** will correspond directly with the PI regarding the submission. Correspondence of the PI regarding revisions to the submission materials or questions may be directed to the IRB chairperson, vice chairperson, designated IRB member, **or compliance coordinator** and may be conducted through e-mail.

Reports of adverse events must be reported immediately via phone, e-mail, or in person to the IRB chairperson or vice chairperson. A written report of the adverse event, using Form F, must then be submitted to the **compliance coordinator**, care of the OGR, within 5 working days after first awareness of the problem. Refer to Section G for more information.

## **B. RESPONSIBILITIES AND ACTIONS OF THE INSTITUTIONAL REVIEW BOARD**

### **B.1 Composition of the IRB and Appointment of Members**

Federal regulations require that the IRB must be composed of at least five members (45 CFR 46.107). At EIU, the IRB shall be composed of nine (9) members plus three or four (3 - 4) alternates. The IRB administrator may serve as an ex-officio member without vote. Representation will include: (a) at least two members whose primary concerns are in scientific areas, such that both social and behavioral research are represented; both the Psychology Department and the Department of Communication Studies are guaranteed one representative on the IRB. (b) at least one member from each of the four colleges at EIU; (c) at least one member whose primary concerns are in non-scientific areas; and (d) both a community representative and a community alternate who are neither affiliated with EIU nor a member of the immediate family of an EIU employee. Special consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with vulnerable categories of subjects, (such as children, prisoners, pregnant women, or handicapped or mentally disabled persons) if the IRB regularly reviews such research.

In addition, the membership shall include men and women, as well as representation of racial and ethnic minority groups to the fullest extent possible.

In meeting the IRB composition requirements set forth in the previous paragraph, EIU uses the following methods: IRB members are appointed by the CRO after consultation with deans or others. The faculty senate will nominate one representative from each of the four colleges for appointment by the CRO; the nominees must be confirmed by appointment by the CRO.

All IRB members and alternates shall serve three-year terms, which are staggered, and they may be reappointed for consecutive terms. The current membership list is kept on file by the compliance coordinator, and is open to inspection by any employee or student of EIU. Additionally, a current membership list is posted on the IRB website.

The IRB chairperson will be appointed by the CRO. He or she will serve a three-year term with each year being a renewable contract between the individual and the CRO, and he or she may be reappointed for consecutive terms. Similarly, the IRB vice chairperson will be appointed by the CRO with input from the chairperson. He or she will serve a three-year term with each year being a renewable contract between the individual and the CRO, and he or she may be reappointed for consecutive terms.

If a member goes on sabbatical or other leave for a semester, then an alternate will take his or her place. If a member or alternate leaves the university or goes on leave for one year or more, then the CRO will appoint a replacement for the period of leave or for the remainder of the member or alternate's term, whichever is applicable. If either the IRB chairperson or vice chairperson takes a sabbatical, other leave of absence, or leaves the university, the CRO may appoint a replacement for the period of leave or for the remainder of the chairperson's or vice chairperson's term, or appoint a new chairperson or vice chairperson for a three-year term.

## **B.2 Responsibilities and Actions of the IRB Chairperson**

The following actions are the responsibility of the chairperson of the IRB. He or she shall have the administrative and clerical assistance of the IRB administrator, the compliance coordinator, or an individual designated by the IRB administrator in carrying out these duties.

- Call each regular meeting of the IRB and provide copies of review materials and other items of business to each board member at least 5 working days before the meeting.
- Maintain records of all IRB proceedings, applications, and approved projects. Approved project files will be maintained for the period required by the funding agency, if applicable. In any case, records shall be maintained for at least three years from the date of termination of the project. Records will be maintained in a secure location with access limited to the IRB administrator and associated staff, the CRO, and IRB members and alternates.
- Provide advice and counsel on behalf of the IRB to those requesting assistance with the preparation of applications; those requesting information about the protection of human research subjects; and to those inquiring about the policies, procedures, and actions of the IRB.
- Notify each PI informing him or her of the IRB's decision and actions after initial, continuation, modification, adverse event review, or upon any other action taken by the IRB. Notification may be made by e-mail. Notification will also be sent to the compliance coordinator in the Office of Research and Sponsored Programs (institution) for inclusion in the project file.
- Notify the CRO of IRB approved research activities. The notification will be provided each semester and in writing, with a copy to the IRB administrator. Notification will include: IRB

action, the IRB file number, PI name, department, application title, the funding agency (if applicable), and the level of review (e.g., exempt, expedited, or full committee).

- Notify the IRB, IRB administrator, and CRO of any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research.
- Notify the IRB at its regularly scheduled meetings of all findings of expedited review procedures, and granting of exemptions.
- Monitor changes in federal guidelines and alert the CRO if written policies and procedures need to be revised.
- Delegate to the vice chairperson or another IRB member or alternate any new applications, continuation requests, modification requests, or adverse event reports that are submitted by members of the chairperson's department or are projects in which the chairperson is involved.
- Delegate to the vice chairperson other duties and responsibilities as appropriate.
- When the chairperson is unavailable, the vice chairperson assumes the responsibilities of the chairperson.

### **B.3 Meetings and Quorums**

A quorum is required to convene a meeting of the IRB. A quorum consists of at least a majority of members (or their alternates) present at the meeting, either in person or via a conference call. At least one member or alternate who is a nonscientist must be present at the meeting. When members or alternates are associated with a project being reviewed, they are ineligible to vote on the project. However, such members may provide information about the project or they may excuse themselves from the meeting during the review. Conflicts of interest should be noted in the IRB meeting minutes. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early departures, absence of a nonscientist member or alternate), the IRB may not take further actions or votes until the quorum is restored. Alternate members of the board may be invited to each meeting and may participate in the discussion of agenda items, including reviews, although if they are not serving in a member's place, they are not eligible to vote.

The chairperson will convene meetings of the board for review of new applications, modification requests, continuation requests, suspension or termination of IRB approval, and to conduct other IRB business as necessary. The meeting schedule shall be posted on the IRB website.

### **B.4 Functions and Operations of the IRB**

- Conduct initial and continuing review of research with human subjects and report the findings and actions to the PI in writing;
- Determine which projects require more than an annual review and which projects require verification (from sources other than the investigators) that no material changes have occurred since the previous IRB review. Considerations used to make these determinations include the absolute risk to the subject, whether the risks outweigh the benefits, and prior conduct of the investigator(s) regarding the protection of human research subjects.
- Review proposed changes in research activities to insure that the protection of human research subjects is maintained.
- Investigate any actual or suspected adverse event or incident of noncompliance.
- Observe project activities at any point to ascertain whether human subject protections are implemented so as to reduce the likelihood of an adverse event or noncompliance. Before observing a project activity, a majority of the IRB must vote that such observation is justified.

The IRB chairperson must also notify the PI of the date and time of the observation, as well as the reason for the observation.

## **B.5 Review of Research**

In conducting the review of research, the IRB shall follow the regulations stated in 45 CFR 46.109.

## **B.6 Approval of Research**

Requirements to be met for approval are listed in Appendix 2. These requirements are described in 45 CFR 46.111. In order to approve research covered by stated regulations, the IRB shall determine that all of these requirements have been met.

## **B.7 Actions and Authority of the IRB**

Action on any of the options listed below requires a majority vote of the quorum. Action to require revision of an application includes the option of empowering the chairperson, vice chairperson, or designated IRB member to accept revisions on behalf of the IRB or to require reconsideration of the application as revised at a subsequent meeting.

### ***B.7.1 Actions Regarding Approval of Applications***

The IRB may reach any of the following determinations with respect to any proposed project:

- Approve application as submitted.
- Approve pending changes. The IRB determines the changes that are required for approval and these are communicated in writing to the PI. The PI submits the changes to the IRB chairperson. The chairperson, vice chairperson, or designated IRB member may approve the application on behalf of the IRB if the changes meet the requirements described in the written communication with the PI.
- Require modifications and resubmission to the IRB.
- Request consultant review. At any point, the IRB chairperson, vice chairperson, or the IRB may determine that someone not on the IRB with relevant expertise needs to be consulted to address research issues, as they relate to the protection of human research subjects. The consultant shall not be involved in the proposed project. In some cases, the identity of the consultant may need to remain confidential if there is any question that there could be problems should the PI know the identity of the consultant.
- Disapprove the application as submitted: When a project is disapproved, the PI may revise the proposal in accordance with IRB recommendations; discuss the project with the IRB chairperson or respond in writing; or withdraw the proposal application.

### ***B.7.2 Additional Actions and Authority of the IRB***

- Consult with the CRO concerning matters of development and implementation of policies and procedures regarding the protection of human subjects and the training of EIU employees and students regarding the conduct of research involving human subjects.
- Suspend or terminate approval of research that is not being conducted in accordance with the requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a written statement of the reasons for the IRB's action and shall be reported promptly to the CRO and the funding agency (if applicable).

## **C. RESPONSIBILITIES AND ACTIONS OF THE CHIEF RESEARCH OFFICER**

### **C.1 Administrative Responsibilities of the CRO**

The CRO is administratively responsible for the implementation of the assurance to the Secretary of Health and Human Services. Procedures and actions of the CRO with respect to implementation of the assurance include, but are not limited to the following:

- Designate one or more IRBs for which sufficient provision has been made for staff and space needs in order to support the IRB's functions;
- Appoint members and alternates to the IRB;
- Appoint the IRB chairperson and vice chairperson;
- Monitor changes in federal guidelines and revise written policies and procedures in consultation with the IRB;
- Oversee initial training and continuing instruction of IRB members, the IRB administrator, university administrators, and any other personnel for whom federal regulations and EIU policy requires training regarding policies and procedures;
- Review research approved by the IRB in accordance with 45 CFR 46.112;
- Provide that research covered by the regulations will be reviewed, approved, and subjected to continuing review by the IRB;
- Ensure prompt reporting to the IRB, IRB administrator, appropriate university officials, OHRP, if applicable, and any sponsoring federal department or agency head of any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research;
- Provide a statement of principles governing the institution in the discharging of its responsibilities in protection of the rights and welfare of human research subjects;
- Provide of a list of IRB members to DHHS, identified by the requirements contained in 45 CFR 46.103(b)(3); and
- Provide satisfactory written assurance to the Secretary of Health and Human Services that the institution will comply with the requirements as set forth in the applicable federal regulations.

### **C.2 Actions of the Chief Research Officer Upon Receipt of Notice of IRB Action from the Chairperson**

- For externally funded projects approved by the IRB, the CRO, if he or she also approves the project for submission, will complete any documentation required by the funding agency, and send the documentation to the proper agency.
- The CRO may review, approve, or disapprove research that has been reviewed and approved by the IRB. The CRO may not approve research covered by these regulations that has not been approved by the IRB (45 CFR 46.112).
- If the CRO does not also approve projects approved by the IRB, he or she will notify the IRB and the PI in writing of his or her action and of necessary subsequent action by the PI.
- Records of these actions will become part of the project file maintained by the IRB.

### **C.3 Revisions of Policies and Procedures**

The CRO, in consultation with the IRB, may institute any changes of policy and procedure for the review of research involving human subjects as may be consistent with currently applicable regulations,

institutional requirements, and IRB experience. As changes occur in 45 CFR 46 and applicable portions of 21 CFR 50, they will be included in EIU policy and procedures by reference, without requiring separate action by the CRO. When DHHS issues new or revised policies or procedures, the IRB chairperson will consult with the IRB and draft a recommendation to the CRO regarding adoption. The IRB administrator will maintain a current master copy of EIU policy, will provide a copy of any changes in EIU policy to all IRB members and alternates, and will update the IRB website. Additionally, the CRO shall determine the appropriate method of dissemination of policy and procedural changes to the EIU community.

#### **D. RESPONSIBILITIES AND ACTIONS OF THE IRB ADMINISTRATOR**

The IRB administrator will be designated by the CRO. The following actions are the oversight responsibility of the IRB administrator:

- Retain EIU's federalwide assurance, copies of pertinent federal regulations, policies and guidelines related to the involvement of human subjects, as well as EIU's policies and procedures;
- Serve as an ex-officio member, without vote, on the IRB;
- Provide regulatory and ethical advice to PIs in preparation of application for research proposals involving human subjects and consent documents;
- Coordinate with grant and contract services regarding compliance on new, continuing, and competing proposals with human subjects regulations and policy;
- Arrange and oversee the training program for IRB members, IRB alternates, PIs, faculty, staff, and students on the ethical conduct of research involving human subjects;
- Educate members of the EIU community about changes to the IRB policy and procedures;
- Update the IRB website;
- Prepare and distribute meeting packets and agendas;
- Maintain records of IRB proceedings and decisions;
- Receive submissions from PIs and forward the submissions to the IRB chairperson, vice chairperson, or designated IRB member;
- Maintain filing system of submissions to the IRB;
- Maintain a log containing new applications, modification requests, adverse event reports, continuation requests, and completion reports;
- Send each PI a reminder that a continuation request (Form E) is needed, approximately 6 weeks before the expiration of IRB approval of the protocol;
- Send each PI a reminder that a completion (Form G) is needed, at the time the PI stated that the research would be completed;
- Ensure that IRB records are being maintained appropriately and that records are accessible upon request, to authorized federal officials;
- Ensure all cooperating research sites in federally supported research have appropriate OHRP-assurances and provide certification of IRB approval of proposed research to the appropriate federal department or agency;
- Report to the IRB, CRO, and appropriate institutional officials any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research;
- Assist PI's who request assistance in determining whether an event qualifies as sufficiently adverse to be reported; and
- Delegate responsibilities to the compliance coordinator, as appropriate.

## **E. RESPONSIBILITIES AND RIGHTS OF THE PRINCIPAL INVESTIGATOR**

### **E.1 Responsibilities**

The PI has primary responsibility for all aspects of the protection of human subjects on a given project, including:

- Consult with the IRB chairperson or the IRB administrator if unsure whether a study meets the definition of research with human subjects.
- Submit applications for review and approval prior to initiating research, and in accordance with Section F of EIU policy.
- When a full review is required, attend the IRB meeting at which the application is reviewed, in accordance with Section F of EIU policy.
- Conduct the study in accordance with the ethical standards described in the Belmont Report, federal regulations, EIU policy, and the protocol as approved by the IRB.
- Begin research activities only after written approval by the IRB. If the research is administered to an individual in an emergency or other situation before the study begins, the individual may not be considered a subject in the research. If the project involves new drugs or devices, FDA requirements must be satisfied.
- If changes are needed in an approved protocol, submit the proper application to modify the protocol and wait to receive written approval before implementing any changes.
- Submit requests for continuing review in accordance with the timeframe established by the IRB at the time of approval of the protocol.
- Report any unanticipated risks, physical or psychological harm, or other problems to the IRB chairperson or vice chairperson immediately upon becoming aware of them. Section G of this policy provides definitions and examples of problems that should be reported.
- Report to the IRB when the research project is completed (see Section F of EIU Policy). Retain signed informed consent forms and research materials for at least three years after the completion of the research project. Some funding agencies may have different retention requirements, and the PI is responsible for understanding and complying with those policies.
- Make accessible all records for inspection and copying by a designated IRB member or the department or agency supporting the research.
- Ensure that all investigators have certification of current training to conduct research with human subjects, as required in Section N of EIU's policy.

### **E.2 Rights**

- Applications shall be reviewed by the IRB in accordance with the ethical principles described in the Belmont Report, federal regulations, and EIU policy.
- When protocols are submitted, the IRB shall review the application in a timely manner as specified in the policy, barring any unforeseen and insurmountable problems.
- All decisions of the IRB shall be conveyed to the PI in writing.
- The PI may consult with the IRB chairperson or vice chairperson if he or she is unclear about the rationale for its decisions or if any questions arise at any time.

### **E.3 Responsibilities of the PI Upon Leaving EIU**

When a PI plans to leave EIU and continue the research activities at another institution, he or she must notify the IRB in writing. This will allow the IRB to close the active research file. The PI is responsible for obtaining IRB approval at the new institution. If the research project will continue at EIU under another investigator, the PI must submit Form D, and the IRB will follow the review guidelines set forth in this policy.

## **F. PROCESS FOR IRB REVIEW AND APPROVAL OF RESEARCH**

### **F.1 Levels of Review**

This section describes the three possible levels of IRB review for studies that involve human research subjects.

#### ***F.1.1 Exemption Certification Review***

##### **F.1.1.1 New Application**

Research activities in which the involvement of human subjects constitutes no more than minimal risk and falls within one or more of the exemption categories described in 45 CFR 46.101 (see Form B) may be eligible for exemption certification. The PI may request that the research application receive exemption certification by submitting Form B with his or her application. Only the IRB may certify that the proposed research meets the exemption criteria. Exempt review is conducted by the IRB chairperson or vice chairperson, or a designated IRB member who will verify level of review through the categories listed in form B (exempt research checklist) and consider the issues delineated in the reviewer checklist (Appendix 2), the informed consent information (Appendix 3), and local context issues.

If the IRB chairperson is involved with the study or if the PI and IRB chairperson are from the same department or program, the IRB chairperson will designate the vice chairperson or another IRB member, who is not involved with the project or from the same department, to review the study for exemption certification. Similarly, if the IRB vice chairperson is unable to review the study because he or she is involved in the project or from the same department as the PI, the IRB chairperson or another IRB member will review the study for exemption certification.

The PI may expect written notification of the status of the project (i.e., certified, additional information or modifications needed, or denial of exemption certification) within 10 working days of receipt of the research application by the IRB administrator (care of OGR).

The IRB chairperson, IRB vice chairperson, or designated IRB member may take one of the following actions:

- Certify the research project as exempt and requiring no further IRB review, unless modifications are proposed which are outside the exemption categories. The PI is sent an exemption certification letter.
- Require additional information or modification(s). The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI in writing to request the required additional information or modification(s). If the IRB chairperson, IRB vice chairperson, or designated IRB

member is satisfied that the protocol meets the exemption criteria, the research project is certified as exempt and an exemption certification letter is sent to the PI.

- Deny exemption certification. If the protocol does not fall within one or more of the exemption categories, as deemed by the IRB chairperson, IRB vice chairperson, or designated IRB member, the PI is contacted in writing or via e-mail and the application is considered for expedited or full review.

#### **F.1.1.2 Modification Request**

If a study is certified as exempt, the PI must request approval for any proposed modifications (see Form D) to the research project's protocol or informed consent or assent forms that do not fall within the exemption categories. The modifications must be approved by the IRB prior to implementation.

#### **F.1.1.3 Continuation Request**

Once a study is certified as exempt, continuation reviews are not required.

### ***F.1.2 Expedited Review***

#### **F.1.2.1 New application**

Research activities in which the involvement of human subjects involves no more than minimal risk and falls within one or more of the expedited review categories (see Form C) may be eligible for expedited review. The PI may request that the research application receive expedited review by submitting Form C with his or her application. Only the IRB may decide whether the proposed research meets the expedited review criteria requirements. Expedited review is conducted by the IRB chairperson or vice chairperson, and a designated IRB member who will verify level of review through the categories listed in form C (expedited review research checklist) and evaluate for consistency with the issues delineated in the reviewer checklist (Appendix 2), the informed consent information (Appendix 3), and local context issues. If there is a conflict of interest for both the chairperson and vice chairperson, two designated IRB members will conduct the review. Prior to sending the application for review by the second IRB member, the IRB chairperson, IRB vice chairperson, or designated IRB member may ask the PI to make revisions to the protocol or informed consent procedures. The PI should expect notification that revisions are required prior to the second review, the application has been sent to a second reviewer, or the application needs full review within 10 working days of receipt of the new application by the IRB. Once the revisions, if needed, are received, the revised application will be sent to the second reviewer, and the PI may expect notification of the status of his or her project within 10 working days. The reviewers may exercise all of the authorities of the IRB, except they may not disapprove the research application.

Under the expedited review process, the reviewers may take one of the following actions:

- Approve the research application.
- Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or a designated IRB member will contact the PI in writing to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less and a letter of approval is sent to the PI.
- Require a full review of the application. If the protocol does not fall within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the subjects, or the additional information or modifications are extensive, the reviewers will forward the application for a full review. The PI will be notified in writing that a full review is required

and will be informed of the reasons for this decision. Additionally, the PI may be asked to revise the application prior to distribution of the application to the full IRB committee.

#### **F.1.2.2 Modification Request**

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

Modification requests to the protocol or informed consent or assent forms for research projects that were previously approved through the expedited review process may be reviewed under the expedited review process. The PI will submit Form D for review. For minor modifications that do not change the substance of the project, the level of risk to the subjects, or the level of review required, the IRB chairperson, vice chairperson, or a designated IRB member may conduct the review. For more than minor modifications, the review process is the same as for a new application. The timeline is the same as for a new application. The reviewers may take one of the following actions:

- Approve the requested modifications. The PI is sent a letter of approval of the requested modifications.
- Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI in writing to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the requested modifications meet the IRB review criteria, the modifications are approved and a letter of approval is sent to the PI.
- Require a full review of the modification request. If the modifications change the study protocol such that the study no longer falls within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the subjects, or the additional information or modifications are extensive, the reviewers will forward the modification request for a full review. The PI will be notified in writing that a full review by the IRB is required and will be informed of the reasons for this decision. Additionally, the PI may be asked to revise the modification request prior to distribution of the modification request to the full IRB.

#### **F.1.2.3 Continuation Request**

Research projects which are approved under the expedited review process will require continuation review at a specified interval, which will not exceed one year.

A continuation request for a research project that was approved under expedited review procedures may be reviewed under the expedited review process. The PI will submit Form E. The IRB chairperson or a designated IRB member will verify the appropriate level of review for the continuation request, and will inform the PI in writing or via e-mail if a full review is needed. The expedited review process, timeline, and review actions are the same as for a new application.

If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the approval expiration date. All research activities, including data analysis, must cease, unless the IRB finds it is in the best interest of the individual subjects to continue participating in the research interventions or interactions. A notification letter will be sent by the IRB chairperson or vice chairperson to the PI and, if appropriate, the funding agency.

#### **F.1.2.4 Completion of Research**

For a completed research project that has undergone expedited review, the PI must submit Form G **as soon as possible upon completion or termination of the project.** This will allow the IRB to close the

active file. The compliance coordinator will send a reminder approximately 6 weeks prior to the estimated project completion date.

#### **F.1.2.5 Informing IRB members of Expedited Reviews**

At each regular IRB meeting, the IRB chairperson will provide the IRB with a list of new research applications, modification requests, and continuation requests that have been submitted or approved through the expedited review process.

### **F.1.3 Full Review**

#### **F.1.3.1 New application**

Research activities in which the involvement of human subjects involves more than minimal risk does not fall within one or more of the exemption categories (Form B) or expedited review categories (see Form C), or involves certain vulnerable populations (e.g., prisoners) must undergo a full IRB review. Prior to distribution to the IRB members, the IRB chairperson, IRB vice chairperson, or a designated IRB member will review the application and may ask the PI to make revisions to the protocol or informed consent procedures. Once revisions, if needed, are received, a full review will be scheduled for the next regular IRB meeting or a special meeting may be called. The application materials will be distributed to the IRB members at least 5 working days before the meeting. By invitation of the IRB, the PI may attend the meeting in which his or her application will be reviewed. If the PI is a student, the faculty sponsor must attend, and the IRB strongly recommends that the student attend, as well.

A schedule of the IRB meetings, along with submission deadlines for new applications, modification requests, and continuation requests requiring full review, is posted on the IRB website. The PI is responsible for submitting the required materials to the IRB administrator, care of OGR, by the deadline, typically 10 working days prior to a scheduled meeting. Submission of materials by the deadline does not guarantee the full review will be conducted at the next meeting. Reasons for delaying review until the next meeting may include an already full agenda or the protocol requires revisions prior to review. Therefore, the IRB recommends that the PI submit the materials as early as possible.

Under the full review process, the IRB will discuss issues delineated in the reviewer checklist (Appendix 2) and the informed consent form information (Appendix 3), as well as issues related to the local context. The IRB may take one of the following three actions:

- Approve the research application and decide on the length of time the study is approved (one year or less from the date of the convened meeting at which the IRB reviewed and approved the proposal).
- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information available at the meeting, the PI will forward this information, in writing, to the IRB chairperson or IRB vice chairperson, as soon as possible. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
  - The IRB chairperson, IRB vice chairperson, or designated member may review the additional information or modifications to ensure that they meet the IRB requirements and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB chairperson, IRB vice chairperson, or designated IRB member may continue to work individually with the PI until the IRB requirements are met or request that the IRB continue its review at the next meeting, or
  - The IRB may require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.

- Disapprove the research application. The PI is sent a letter describing the reasons the research application was not approved. The PI may revise the research application in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB chairperson or a designated IRB member; or withdraw the research application.

### **F.1.3.2 Modification Request**

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

Modification requests to the protocol or informed consent or assent forms for research projects that were previously approved through the full review process may be reviewed under the expedited review process if the requested modifications are minor (see Modification Request under the discussion of Expedited Reviews, above), otherwise, a full review process will be used. The PI will submit Form D and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the modification request. The PI will be informed of the level of review required. For modification requests, which can be reviewed under the expedited review process, see the modification request section (Section F.1.2.1) under expedited review process (Section F.1.2). For modification requests that require a full review, prior to distribution to the IRB members the IRB chairperson or a designated IRB member will review the application and may ask the PI to make revisions to the protocol or informed consent procedures. Once revisions, if needed, are received, a full review will be scheduled for the next regular IRB meeting or a special meeting may be called. The modification request will be distributed to the IRB members at least 5 working days before the meeting. By invitation of the IRB, the PI may attend the meeting in which his or her modification request will be reviewed. If the PI is a student, the faculty sponsor must attend, and the IRB strongly recommends that the student attend, as well.

The IRB may take one of the following actions:

- Approve the requested modifications. The PI is sent a letter of approval of the requested modifications.
- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information, the PI will forward this information, in writing, to the IRB chairperson or IRB vice chairperson. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
  - The IRB chairperson, IRB vice chairperson, or designated IRB member may review the additional information or modifications to ensure they meet the IRB requirements and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB chairperson, IRB vice chairperson, or designated IRB member may continue to work individually with the PI until the IRB requirements are met or request that the IRB continue its review at the next meeting, or
  - The IRB should require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.
- Disapprove the modification request. The PI is sent a letter describing the reasons the modification request was not approved. The PI may revise the modification request in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB chairperson, IRB vice chairperson, or designated IRB member; or withdraw the modification request.

### **F.1.3.3 Continuation Request**

Research projects that are approved under the full review process will require continuation review at a specified interval, which will not exceed one year.

A continuation request for a research project that was approved under the full review procedures may be reviewed under the expedited review process if the research project meets the requirements listed in Form C; otherwise a full review will be required. The PI will submit Form E and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the continuation request. The PI will be informed of the level of review required. For expedited reviews, see Continuation Review in Section F.1.2.2 under Expedited Review (Section F.1.2). For full reviews, the review process and review actions are the same as for a new application.

If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the approval expiration date. All research activities involving human participants must cease. A notification letter will be sent to the PI and, if appropriate, the funding agency.

## **F.2 Length of IRB Approval**

Typically, the IRB approves a research study or continuation request for one year. However, approval may be granted for less than one year in some circumstances, which may include, but are not limited to, high-risk protocols, projects involving unusual types of risk to subjects, projects involving vulnerable subjects (e.g., prisoners), and projects conducted by a PI who has previously failed to comply with IRB requirements.

## **F.3 Verification of Sources other than the PI**

Some projects may require verification from sources other than the PIs that no material changes have occurred since previous IRB review. The criteria for determining which studies may need outside verification include, but are not limited to complex projects involving unusual levels or types of risk to subjects; projects conducted by PIs who previously failed to comply with 45 CFR 46 or the requirements or determinations of the IRB; and projects where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

## **F.4 Preparation of Public Use Data Files**

Many funding agencies require or recommend that projects produce public use data files. If the PI knows that a public use data file will be created, he or she must indicate this on the initial application (Form A). Once the project is completed, the PI shall submit the proposed public use data file to the IRB for inspection. The funding agency may provide guidance in creation of public use files. The PI should provide this information to the IRB when submitting the protocol to prepare a public use data file. If the PI does not initially plan to develop a public use data file, once the determination to develop a public use data file is made, he or she will need to submit a modification request to the IRB.

For the IRB to classify the file as a public use data file, one of the two following situations must apply:

- The data were anonymous when originally collected or data were collected from unknown persons.
- The data were collected from identified persons, but the file has been stripped of individual identifiers and any other information that may risk disclosure of any subject's identity.

When data have been collected from identified persons, the PI must consider the following elements in determining whether he or she has properly addressed the risk of disclosure of subjects' identity:

- All individual identifiers of each human research subject or any person named by any human research subject must be removed
- All variables that can be surrogates for individual identifiers (e.g., street address of subject) must be removed.
- To remove the possibility of identification when a human research subject is in a small subgroup within the sample, it may be necessary to collapse or combine categories of a variable. For example, detailed breakdowns of religious denomination in a survey question, ICD-9 codes, or medical procedure codes may need to be collapsed into fewer categories.
- Delete or mask, as described above, any variable that a secondary user may employ to identify any research subject. For example, the PI may need to assign a new subject ID to each individual if the original subject ID contained identifying information, such as letters from the last name or part of the date of birth.
- Use statistical methods to add random variation to variables that cannot otherwise be masked. For example, a data file may contain a combination of public and private information on a relatively small sample, perhaps demographic characteristics and salary of a public official, along with attitudinal information. The income variable may need to be altered so that it cannot be combined with the demographic characteristics to enable identifying the individual and thereby risking disclosure of private information. This option should be used only if other techniques do not work, because it may compromise the integrity of the data.

EIU may post on the ORSP website information regarding two types of public use data files: (1) a list of all data files created by EIU investigators that have been certified for public use, and (2) a list of approved sources of publicly available data. The purpose of the first list is to allow investigators at other universities or organizations to be informed that the EIU IRB has certified that a specific data file is a public use data file, even if it is available from another source (e.g., ICPSR). The primary purpose of the second list is to inform EIU investigators that any data file obtained from these sources is certified as a public use data file and thus does not require IRB review.

## **G. PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, AND NONCOMPLIANCE**

### **G.1 Guidelines for Defining Problems to be Reported**

Unanticipated problems involving risks to subjects or others and adverse effects need to be reported to the IRB. Adverse effects may be directly or indirectly related to the research and may be expected or unexpected.

The following examples illustrate what needs to be reported:

Unanticipated problem involving risk to subjects: The laptop computer which has identifying information about research subjects is stolen.

Unanticipated problem involving risk to others: The research assistant involved in the project is inadvertently exposed to a low level of radiation.

Expected adverse effect: Subject A becomes upset when asked about feelings regarding prior sexual abuse. The subject is referred for counseling.

Unexpected adverse effect: Subject B becomes agitated and angry when asked general non-invasive questions about the appropriateness of corporal punishment of children. The subject is referred for counseling.

The last two scenarios are examples of direct effects. An example of an indirect effect is if Subject A or B misses class or work due to the psychological conditions described.

In general, the PI must report the following events to the IRB chairperson or IRB vice chairperson:

- Situations related to the protection of study data, such that there is an inadvertent breach of confidentiality
- Negative outcomes from unintentional or intentional deviations from research protocol or informed consent process (e.g., loss of privacy, loss of rights, damage to reputation, legal problems, academic failure)
- Unforeseeable events that occur during or after a research intervention, even if it is unclear whether they were actually caused by the intervention
- Known side effects of an intervention
- Allergic reactions (or other adverse reactions to medications, devices, or procedures)
- Complications from procedures (e.g., infection, abnormal EEG, psychological change)
- Complications from research-related tests (medical and psychological)
- Increase in seriousness of a primary condition or situation

## **G.2 Guidelines for Defining Noncompliance**

Noncompliance includes, but is not limited to:

- Misuse or nonuse of approved informed consent forms or procedures
- Failure to submit protocols in a timely manner
- Breaking confidentiality, unless required by law (e.g., child abuse)
- Unapproved subject recruitment activities
- Failure to secure confidential records in the required manner
- Failure to report problems involving physical or psychological injury to subjects or others
- Failure to report risks to subjects or others that exceed the protocol as approved
- Report from a subject of abuse by the PI or research staff
- Conducting research involving human subjects that has never been approved by the IRB
- Initiating changes to research protocols involving human subjects without prior IRB approval
- Continuing research activities beyond the IRB approval expiration date

Even though these types of events must be reported, the PI is encouraged to contact the IRB chairperson or IRB vice chairperson if anything occurs that causes concern regarding the protection of human subjects.

## **G.3 Reporting of Problems or Noncompliance by the PI**

The PI must contact the IRB chairperson or vice chairperson via phone or e-mail immediately following an incident of injury, increase in risk, unanticipated risk, other adverse effects experienced by subjects or others involved in research, or incident(s) of noncompliance. Additionally, the PI must submit Form F to the IRB administrator, care of OGR, as soon as possible thereafter, but no later than 20 working days

after first awareness of the problem. The report will be reviewed by the IRB chairperson, IRB vice chairperson, designated IRB member(s), or the full IRB. If the incident is severe or increases the risk to subjects or others, the PI may be asked to suspend research activities pending further review by the IRB or CRO.

#### **G.4 Investigations of Problems and Noncompliance Reported by Others**

If any member of the IRB receives information about injuries to subjects, unanticipated problems involving risk to subjects or others, or serious noncompliance, through a source other than the PI or co-PI, he or she will immediately inform the IRB chairperson or vice chairperson. The IRB chairperson or vice chairperson may temporarily suspend IRB approval for a study, pending investigation, after learning of the problem, adverse effect, or noncompliance.

A subcommittee of the IRB consisting of the IRB chairperson or vice chairperson, an IRB member or alternate who is the community representative, and another IRB member, who holds tenure and is outside the PI's department, will investigate the allegation of a problem involving risk to subjects or others, an adverse effect, or noncompliance. The IRB chairperson or vice chairperson will request an interview with the individual(s) alleging the problem, adverse effect, or noncompliance, unless the allegation was received in writing. The IRB chairperson or vice chairperson will share the results of this interview or written correspondence with the other members of the ad hoc committee, and they will decide how to proceed. The IRB chairperson or vice chairperson will notify the PI in writing within 5 working days that an allegation of problem, adverse effect, or noncompliance was received. Following the interview or upon receipt of a written allegation, the IRB chairperson or vice chairperson will request an interview with the PI and any other researchers involved, in order to assess the situation, require changes in the protocol, if necessary, and resolve the issues without further official action. The ad hoc committee members will decide if both need to be present at the interview with the PI and other researchers involved. If the ad hoc committee members are not satisfied with the results of the initial interview with the PI, they may expand the investigation. The ad hoc committee members may interview the research staff and any other persons who have relevant information, including research subjects. The ad hoc committee will produce written summaries to the interviewed parties for comments, and written comments received will be included in the record of the investigation.

The ad hoc committee will prepare a report which includes a description of the investigative activities, how and from whom information was obtained about the problem(s), a list of those interviewed, a summary of records obtained, finding, basis of findings, and actions taken. Before the report is shared with the IRB and CRO, identifying information which may put the individual making the allegation at risk may be removed. The final report, which contains all identifying information, will be filled with confidential project records.

Appropriate institutional officials, and, if applicable, OHRP and funding agency officials will be notified if problems are confirmed by the ad hoc committee.

#### **G.5 Suspension or Termination of Approval of Research Activities**

At any point, the IRB may vote to suspend a study under either of two conditions: (1) The IRB finds that unacceptable and uncorrectable levels of risk or harm to the subjects or others exist; or (2) serious disregard on the part of the researcher to the policies and directives of the IRB has occurred. The chairperson or vice chairperson will promptly notify the PI(s), as well as the IRB administrator and CRO, in writing of this decision and the reason(s) for suspension of approval. The CRO will notify OHRP and funding agency (if applicable) of the suspension or termination of approval.

## **G.6 Reporting by EIU of Problems or Noncompliance**

The IRB chairperson or vice chairperson will keep the CRO informed of reports by PIs or others of unanticipated problems involving risk to subjects or others, adverse effects, serious or continuing noncompliance, and suspension or termination of IRB approval. The CRO will notify appropriate institutional officials, and, if applicable, OHRP, and the Department or Agency head of the funding agency (if the study is funded) of unanticipated problems involving risk to subjects or others, unanticipated adverse effects, serious adverse effects that may have been expected, serious or continuing noncompliance, and the IRB suspension or termination of approval for research activities.

## **H. Conflicting Interests**

Several types of conflicting interests may arise in conducting research. Project personnel must report all such real or potential conflicts to the PI. The PI is responsible for making certain that no project personnel perform research tasks if there is likely to be a conflicting interest.

Conflicting interests apply to both funded and non-funded research. 45 CFR 46 does not directly address conflicts of interest, but the IRB is required to determine that information provided to potential and actual subjects regarding the research is objective regarding the risks and benefits. It is also required to determine whether risks of the research have been properly addressed in the protocol. If conflicting interests exist, then such objectivity and handling of risks can be compromised.

Such potential conflicting interests include, but are not necessarily limited to those discussed below.

### **H.1 Financial Conflict of Interest**

Illinois state law describes financial conflicts of interest on the part of public employees. Disclosure of any such conflicts must be made in writing. Federal policy covers Financial Conflicts of Interest in Research that is funded by DHHS, FDA, and NSF, among others.

The CRO has final responsibility to assure compliance with university policy and state and federal law regarding financial conflicts of interest.

### **H.2 Intellectual Property**

All investigators must adhere to EIU's policy regarding intellectual property claims.

### **H.3 Conflicts of Commitment**

Conflicts of commitment arise when an investigator's time or other commitments to a project cannot be honored because of existing commitments to the university. All investigators must avoid such conflicts that may arise due to the conduct of a research project.

### **H.4 Dual Relationships**

Dual relationships exist whenever one role of the investigator calls into question his or her ability to be objective about fulfillment of another role. While such dual relationships may involve financial conflicts of interest, many do not. At EIU, the most common situations are likely to be those in which faculty recruit students for research projects. See Section P of this policy for a detailed discussion of students as research subjects.

## **I. COOPERATIVE RESEARCH**

Cooperative research projects are those projects which involve more than one institution. The official relationship between the two institutions is not relevant. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal and institutional policies. See 45 CFR 46.114 for more information.

EIU faculty, staff, and students who are conducting research at another institution are required to abide by EIU requirements, as well as the requirements of the other institution. If the other institution has an IRB, the PI may be required to seek its approval as well, or file a request to designate one of the institutions' IRB to review the research (e.g., IRB authorization agreement). For studies funded by DHHS the PI is responsible for ensuring all data collection sites within the cooperative research protocol have an approved DHHS assurance (e.g., federalwide assurance), and each will review the research separately or designate one of the institutions' IRB to review the research (e.g., IRB authorization agreement).

When EIU is considered to be "engaged in research" (see OHRP guidance document "Engagement of Institutions in Research," January 26, 1999) but the PI is not associated with EIU, the PI must submit the following for review by the IRB: an application (Form A, and Forms B or C, if applicable). The IRB will then complete the appropriate review process, based on the nature of the research project. EIU may choose to rely on the review of the PI's IRB, in which case both institutions would need to complete the IRB authorization agreement. When EIU is not "engaged in the research," the unaffiliated PI needs to obtain IRB approval at his or her institution and secure permission from the IRB at EIU to conduct the study at EIU.

## **J. INFORMED CONSENT**

### **J.1 Informed Consent Requirements**

Informed consent is an ongoing process, not just a form that is signed. Informed consent assures that potential subjects understand the nature of the research project and their participation and can make an informed, voluntary decision about participating or not participating in a research study. The language used to present the information needs to be appropriate for the targeted subject population. Researchers should keep in mind that individuals have the right to participate or not participate in a study and those who decide to participate may withdraw their consent from the study at any time for any reason, without incurring negative consequences.

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. Documentation of informed consent must comply with 45 CFR 46.117. Unless changes to the informed consent process are approved by the IRB, the PI is responsible for ensuring that informed consent is obtained in writing from the subject or the subject's legally authorized representative (e.g., parent), is understandable to the subject (or representative), is obtained in circumstances that are not coercive and that offer the subject (or representative) sufficient opportunity to decide whether he or she will participate. If any subjects are members of certain vulnerable populations, 45 CFR 46 Subpart B, Subpart C, and Subpart D describe additional informed consent requirements.

The informed consent form checklist in Appendix 3 delineates the basic elements that must be included in an informed consent form. The checklist also provides additional elements that may need to be included in the informed consent form, depending on the nature of the research study. The informed

consent process and documents in research studies that involve health information may need to include statements that meet the requirements of Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Section K.4 and Appendix 4). Informed consent forms should be written in second person (e.g., “You are invited to participate...”), with the exception of the signature section, which may be written in first person. Use of first person in the body of the informed consent may be interpreted as suggestive or coercive. The informed consent form may not include exculpatory language in which the subject or representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the PI, sponsor, or institution (or its agents) from liability for negligence. The person who signs the informed consent form must be given a copy as a reference.

Informed consent procedures must be delineated in the research description portion of the application to the IRB (Form A). Any waivers to the procedure or documentation must be requested by the PI using Form I. For studies in which the documentation of informed consent is waived, a letter of invitation to participate, which includes the elements of informed consent, may be appropriate. Additionally, informed consent forms and assent forms, if applicable, must be submitted to the IRB for review.

A sample informed consent form is included in Appendix 3. This document should be edited so that its content is specific to the project for which IRB approval is sought.

The IRB number should appear on the informed consent document that is presented to the research subjects.

## **J.2 Alterations to the Informed Consent Procedure**

Federal regulations on informed consent do allow for modifications in the consent procedures and, under certain circumstances, informed consent may be waived entirely if the research meets certain conditions [see 45 CFR 46.116(c)(d)]. Note that such modifications and waivers are not allowed under FDA regulations. See 45 CFR 46.116(c)(d) and Appendix 3 for more information.

## **J.3 Alterations in the Documentation of Informed Consent**

Typically, informed consent must be documented through the use of a written informed consent form that has been approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy should be given to the individual signing the form. However, documentation of informed consent may be waived in some circumstances. See 45 CFR 46.117(c) and Appendix 3 for more information.

## **J.4 Research Involving Children**

Research projects involving children as subjects typically require the written permission of one or both parents [see 45 CFR 46.408(b)] or guardian in accordance with the informed consent procedures delineated in the informed consent requirements (Section J.1). In addition to parental or guardian permission for a child to participate in a research study, the assent of the child may be solicited, assuming the child is capable of providing assent. To make this judgment, the IRB will consider the age, maturity, and psychological state of the targeted child population. Even if the children are capable of providing assent, the IRB may waive the assent requirement when consent requirements are waived (see CFR 46.116).

Typically, parental or guardian permission must be documented. However, a PI may request a waiver of the documentation of informed consent based on 45 CFR 46.117(c) (see Appendix 3 for information).

Additionally, the IRB may determine that parental or guardian permission is not a reasonable requirement to protect subjects (e.g., neglected or abused children) and it may waive the consent requirements, provided that an appropriate mechanism for protecting the children who participate as subjects in the research is substituted and the waiver is not inconsistent with federal, state, or local law [45 CFR 46.408(c)].

## **K. PROTECTION OF CONFIDENTIAL INFORMATION**

The PI is responsible for ensuring the privacy and confidentiality of all personally identifiable information from research subjects, except as required by law (e.g., child abuse) or allowed with written permission of the research subject. This information may be contained in either electronic or hard copy formats. When appropriate, the informed consent document should outline those conditions under which data are not considered confidential (e.g., child abuse). Data collection and storage, and safeguards to ensure confidentiality must be delineated by the PI in the research description portion of the application to the IRB.

### **K.1 Storage and Retention of Confidential Records**

The PI must store confidential hard copy information gathered from or about any research subject in a secure (locked) facility to which only the PI and authorized project staff have access. Electronic data shall be password-protected at the workstation or file level. If this level of protection is not feasible, electronic data should be stored on removable media. Records (e.g., signed informed consent forms, data) relating to the research project must be retained for at least three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner [45 CFR 46.115(b)].

### **K.2 Certificate of Confidentiality**

For studies, whether funded or not funded, in which data are being collected about sensitive issues, the PI may obtain from the appropriate Federal agency an advance grant of confidentiality, known as a Certificate of Confidentiality that will provide protection of research data against subpoena. Sensitive issues include, but are not limited to, the collection of information falling into one or more of the following categories:

- information relating to sexual attitudes, preferences, or practices;
- information relating to the use of alcohol, drugs, or other addictive products;
- information pertaining to illegal conduct;
- information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
- information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- information pertaining to an individual's well-being or mental health;
- other information that is not listed here may also be considered sensitive, given specific cultural or other factors.

Sensitive information may exist in a number of forms, including, but not limited to, survey responses, medical or other records, results of medical or psychological tests, or responses to experiments.

For information on how to apply for a Certificate of Confidentiality, contact the IRB administrator.

### **K.3 Access to Confidential Records**

The university has the right of access to the supporting records for all research at the university or supported by university-sponsored funds, provided such access to the records shall be for reasonable cause, at reasonable times, and after reasonable notice. The university's right of access to the data shall continue regardless of the location of the responsible investigator. Information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed. Extramural sponsors providing support for research at EIU may also have the right to review the data and records resulting from that extramural support. Co-investigators and trainees who are an integral part of a research project have the right to review all records and data which are part of that project.

### **K.4 Other Regulations Related to Privacy, Confidentiality, and Consent**

In addition to 45 CFR 46 and FDA regulations (21 CFR 50), other federal regulations may apply to research involving human subjects.

#### **K.4.1 Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)**

The Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, regulates the way covered entities handle individually identifiable health information known as protected health information (PHI). The Privacy Rule itself applies only to covered entities, not to research itself; however, the Privacy Rule may affect researchers because it establishes the conditions under which covered entities can use or disclose PHI for research. EIU is a hybrid entity, which means that some units are covered under HIPAA, while other units are not. The Privacy Rule does not directly regulate researchers who are engaged in research within units that are not part of the covered entities, even though they may gather, generate, access, and share personal health information. The Privacy Rule is in 45 CFR Part 160 and Subparts A and E of Part 164. Appendix 4 contains more detailed information related to the Privacy Rule. PIs planning to engage in physical or medical health related research that is covered under the Privacy Rule are advised to begin consultation with the covered entity early in the research design process.

#### **K.4.2 Family Education Rights and Privacy Act**

The Family Education Rights and Privacy Act (FERPA) is a federal law (20 U.S.C. § 1232g; 34 CFR Part 99) that applies to educational agencies and institutions that receive federal funds under any program administered by the Secretary of Education. FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches age 18 or attends a postsecondary school. Students to whom the rights have been transferred are "eligible students." Generally, schools must have written permission from the parent or eligible student before releasing any identifiable information from a student's education record. The consent must specify the records that may be disclosed, state the purpose of the disclosure, and identify the party to whom the disclosure may be made. FERPA does, however, allow schools to disclose records to organizations conducting studies for, or on behalf of the school, in order to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction. Additionally, schools may disclose, without consent, "directory" information, unless specifically directed by parents or eligible students not to disclose directory information about them. PIs are encouraged to consult with the school early in the research design process regarding the need to obtain consent for educational records.

### **K.4.3 Protection of Pupil Rights Amendment**

The Protection of Pupil Rights Amendment (PPRA) is a federal regulation (20 U.S.C. § 1232g; 34 CFR Part 99) that was amended by Congress in 2001 by the No Child Left Behind Act regulates survey research in schools. Schools and contractors must obtain prior written parental consent before minor students are required to participate in any U.S. Department of Education funded survey, analysis, or evaluation that reveals information concerning the following: political affiliations or beliefs of the student or the student's parent; mental and psychological problems of the student or the student's family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisals of other individuals with whom respondents have close family relationships; legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; religious practices, affiliations, or beliefs of the student or student's parent; or income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program). Additionally, local educational agencies or institutions that receive funds under any program administered by the U.S. Department of Education are required to develop and adopt policies concerning parents' rights to inspect, upon request, any survey created by a third party before the survey is administered or distributed by a school to students and provide parents the opportunity to ask that their child not participate. PIs are encouraged to consult with the school early in the research design process regarding how PPRA may impact the research protocol.

## **L. INTERNET RESEARCH**

Research using the Internet has unique characteristics that are not directly addressed by the Federal regulations. Currently, the Internet is used primarily for two research activities – recruitment of subjects and survey administration. Most human subjects protection issues that arise in conducting research activities on the Internet concern privacy and consent. For a thorough discussion of the pertinent issues, refer to “Ethical and Legal Aspects of Human Subjects Research on the Internet,” prepared for DHHS by The American Association for the Advancement of Science (<http://www.aaas.org/spp/dspp/sfrr/projects/intres/main.htm>)

The ability to consent is difficult to ascertain over the Internet. Generally, this ability is related to age, but may be relevant to other vulnerable populations (e.g., decisionally impaired, incarcerated). Also, email-based activities are far less secure than website-based activities. Software exists to enhance the privacy of both types of activities. EIU strongly recommends that researchers work with a vendor that specializes in Internet-based research to minimize risks in these areas.

Internet-based studies may not include minors as subjects unless the IRB waives written parental permission and informed consent.

Whether the purpose is recruitment, survey administration, or some other purpose, Internet-based materials must include the following items, to the extent applicable. These items are to be included in addition to all information that is normally required for informed consent:

1. email addresses of the investigator and IRB
2. no claim about the superiority, safety, or effectiveness of procedures, interventions, devices, or any other materials used in research;

3. a description of the process for completing the on-line research activity
4. information on subsequent contacts that will be made if the individual agrees to participate
5. no promise of anonymity
6. information regarding procedures for protection of information that the subject provides over the Internet
7. a statement that there will be no future email contacts or an opt-out message that permits individuals to have their names removed from any future mailings. If future contacts are planned, the information must state the number and frequency of such contacts.
8. instructions to delete the email message that originated the contact

After reading information about the study, the individual must be required click a button either to indicate his or her wish to continue or to leave the site and opt out of participation. After clicking the button, the subject will be taken via a link to the study task. If the individual opts out, clicking the button will exit the site.

Generally, Internet-based surveys do not require written documentation of consent, but the IRB reserves the right to require such documentation.

In all Internet-based surveys, individuals must be able to easily print a readable copy of information about the study and the informed consent documentation (if required) for their own records.

## **M. HUMAN SUBJECTS PROTECTION IN FIELD RESEARCH**

Field research typically involves observation of and interaction with individuals and groups in their own environment, often over long periods of time. It also includes other types of generally qualitative activities that fall under the definition of research, such as interviews conducted for historical or biographical research and archival research on identifiable living individuals. Interviews by journalists conducted solely for the purpose of writing an article in a newspaper, magazine, or other media outlet are not considered research and do not require IRB review.

It may not be possible to specify in an informed consent statement the detailed description of the research protocol, as the research itself may involve interactions between the researcher and subjects that evolve over time. Likewise, differences in language, culture, or the nature of the subjects or topic may preclude the use of a written informed consent document. If appropriate justification is given, the IRB may waive the requirement for some or all of the informed consent requirements or the requirement to obtain signed informed consent in certain situations; 45 CFR 46.116(c) and (d) describes the circumstances in which waiver is possible (also see Appendix 3 of this policy for more information). The investigator should request such a waiver if he or she determines that it is appropriate. The IRB will make the final determination. In addition, the sensitive nature of some field research may make it advisable for the investigator to consider obtaining a Certificate of Confidentiality (see Section K.2 of this policy for more information).

Investigators conducting field research should consider guidelines developed by a relevant professional association, such as the American Anthropological Association, the American Historical Association, or the American Sociological Association, when designing their protocols.

## **N. OTHER STUDIES INVOLVING HUMAN SUBJECTS**

This section sets out policy for conducting other types of studies that include human subjects, but do not meet the Federal definition of research.

### **N.1 Student Working with Human Subjects**

Student involvement with human subjects typically occurs in one of two broad categories of activities: Faculty-supervised independent research projects (including theses), or class projects whose function is principally training.

#### ***N.1.1 Student Research***

When graduate or undergraduate students design a research project under the supervision of a faculty or EAP staff member, the review and approval of a human subjects research protocol by the IRB is required if:

- The outcome of the proposed research could potentially contribute to generalizable knowledge, and/or
- The results of the project will be disseminated to a scientific audience. Such dissemination is a sufficient (but not necessary) criterion for identifying generalizable knowledge. Dissemination includes (but is not limited to) Honor's, Master's, Specialist and Doctoral theses, presentation at a scientific meeting or conference, including conferences whose presenters are solely or primarily students, submission to or publication in a scientific journal (paper or electronic), and electronic posting on the Web.

These are the principal criteria to be used in determining if a student project qualifies as research, and therefore falls under the purview of IRB review. Whether or not the student receives academic credit for the activity, and/or whether or not the activity is a requirement for any type of degree are not in and of themselves criteria to be used in making the determination of research.

All student research projects must have an EIU faculty or EAP staff sponsor. The faculty/staff member is responsible for determining whether the proposed study is subject to IRB review. If so, the faculty/staff member (i.e. sponsor) must assist the student in preparing the application for review. The sponsor should supervise the student researcher sufficiently to assure the protection of human research subjects in accordance with EIU policy.

Students conducting research and their faculty/staff sponsor must be trained in the ethics of conducting research with human subjects in accordance with EIU policy, Section O.

In their own research, student researchers assume all of the responsibilities of becoming a PI. All activities must be conducted in accordance with the principles and procedures set forth in EIU policy. Students must report to their sponsor any problems that may arise in the conduct of the research, including adverse incidents. If any harm to a subject has or may occur, the student researcher must inform the faculty sponsor and the IRB immediately, in accordance with EIU policy, Section G. While a decision about continuing the project is pending, the student should cease research activities on that project.

### ***N.1.2 Student Class Projects***

Students may be required in particular courses to conduct projects involving human subjects. The purpose of such projects is not intended to contribute to advances in generalizable knowledge, nor are the results of such activities to be published, presented, or archived. Rather, the function of these class projects is to contribute to the students' individual knowledge and training in a particular academic discipline. Consequently, such projects are not research subject to IRB review as defined by this policy, unless the project places the subjects at more than minimal risk, usually evidenced by one or more of the following:

- Subjects are members of a vulnerable population (see A.2.1, Definitions).
- The study asks identifiable subjects about illegal activities (e.g., underage drinking), which may place the data at risk of subpoena.
- The study places identifiable subjects at risk of a breach of confidentiality that may lead to criminal or civil liability, or damage the subject's financial standing, employability, or reputation [45 CFR 46.109(b)(3)].
- The study places subjects at more than minimal risk due to psychologically sensitive subject matter (e.g., interviews covering traumatic events).

Instructors are advised to discuss protection of human subjects with students before the instructional assignment or project begins so that informed decisions can be made about whether IRB review is needed. If even the slimmest likelihood exists that an instructional assignment or project may fall under the definition of research outlined in this document, students should submit a human subjects research protocol to the IRB for review and approval. Please note that IRB approval of a research protocol cannot be granted retroactively under any circumstances.

Even though IRB review may not be required for most class projects, they are subject to faculty oversight as outlined in the following section.

### ***N.1.3 Certification of Courses***

When instruction-related research projects involving human subjects are being performed as part of normal course activities, and such projects are not intended to contribute to generalizable knowledge or place the subjects at more than minimal risk (see N.1.2, Student Class Projects), then the instructor must request course certification. This course approval mechanism ensures that human subjects in class projects are nevertheless protected in activities that are not under direct oversight by the IRB.

Instructors who teach such courses must file Form H, Certification of Courses (See Appendix 1), and the requested additional materials listed on Form H with the Office of Research and Sponsored Programs prior to the initiation of any data collection by students, even though said data is intended for instructional purposes only. Further, an instructor shall not allow student research projects to begin until course certification approval has been received. This form must be submitted every year by the instructor for each course in which instruction-related research is performed. If more than one instructor teaches a section of the same course, each instructor must submit the Certification of Courses Form. Completion and submission by the instructor of Form H and all required materials will designate certification of a course.

The submission of this form will certify to the IRB that the instructor is fully cognizant of the policies of EIU regarding the utilization of human subjects in research. Furthermore, the instructor will hereby certify to the IRB that she/he will exercise reasonable and customary instructional supervision in an

attempt to ensure that all class research projects will be conducted in compliance with these policies. Students must conduct only the activities approved by the instructor.

Instructional-related research projects must communicate applicable elements of informed consent (e.g., institutional affiliation of researcher, risk, benefit, voluntary participation, permission to withdraw, etc., see Appendix 3) and include appropriate anonymity and confidentiality protections.

Instructors incorporating human subject research projects in their instruction must be trained in accordance with EIU policy, Section O. In addition, instructors are required to provide training to students in the ethics of conducting research with human subjects in accordance with this same section. This will ensure that students conducting class projects involving human subjects understand, and can apply, ethical principles in human research.

Students must report to their instructor any problems that may arise regarding human subjects as a result of project activities. The instructor must investigate reported problems, and if any harm to a subject has or may occur, the instructor should inform the IRB immediately. The students should cease project activities until it is determined whether or not the project may continue.

## **N.2 Institutional Research**

Data collected or studies conducted for purposes of providing information to the university, any unit within the university, or any other organization (e.g., accrediting agency), with the purpose of addressing issues deemed important to university operations is considered to be institutional research. Studies of this nature do not require IRB review. If information collected is intended for further dissemination, publication (including Internet), or involves more than minimal risk, it requires IRB review.

When IRB review is not required, institutional research projects or other activities must still communicate applicable elements of informed consent (e.g., purpose, risk, benefit, voluntary participation, permission to withdraw) and include appropriate anonymity and confidentiality protections.

## **N.3 Other Projects**

Projects such as program evaluation, policy analysis, or quality assurance studies conducted for the purpose of providing information only to the organization studied do not require IRB review, provided they meet the following conditions: (1) They are not intended to produce knowledge that is generalizable or publishable; (2) They involve no more than minimal risk as defined in Federal regulations and EIU policy; (3) They do not involve vulnerable populations.

When IRB review is not required, such projects must still communicate applicable elements of informed consent and include appropriate anonymity or confidentiality protections.

## **N.4 Publicly Available Data**

Many private organizations and public agencies make individual level data available to the public. Such files fall outside the federal regulations for the protection of human subjects, once they have been classified as public use data files. Not all publicly available data, however, has been classified as public use.

To classify files as public use, producers and suppliers of such files are responsible for having the data reviewed by the appropriate IRB before making them available to the public. Information to this effect should be indicated on the documentation supplied with the file.

PIs do not need to obtain IRB approval to use public use data files nor do they need to seek IRB review of the exemption status of the data. Where applicable, such information has already been reviewed for the protection of human subjects and the files produced have been certified not to violate confidentiality.

If an EIU PI plans to obtain individually identifiable data (from the sponsor of the public use data file or any other source) and merge with the public use data file, the EIU investigator must seek IRB approval.

## O. TRAINING

### O.1 Who Must Be Trained?

The training requirements discussed herein cover all funded and non-funded projects that include human subjects. This policy covers all proposed and ongoing projects submitted to the IRB for approval, regardless of the level of review required (i.e., full, expedited, exempt).

#### O.1.1 Training for Conventional Research

EIU's assurance with the OHRP requires training for all IRB members and alternates, PIs, co-PIs, and faculty and staff sponsors who conduct research involving human subjects. Students conducting research for a thesis or independent study project must receive the same training as their faculty supervisor(s). The training program consists of an on-line program found at <http://www.eiu.edu/~grants/ConsentTraining/index.html>. Certification of completion of training must be verified before the IRB will approve the research.

If any new investigator is added after the submission of the initial application or a continuation request, the PI must submit these names to the IRB administrator, care of ORSP. These investigators must be trained before working with human research subjects. The IRB strongly recommends that the PI and co-PI provide the opportunity for all staff working on the research project to successfully complete the training.

#### O.1.2 Training for Student Class Projects

Students conducting research involving human subjects that is not intended to contribute to generalizable knowledge, such as that found in a research methods class, must complete one of the student training options described in Appendix 5. The training should be completed before the students conduct their projects.

Course instructors should complete the same on-line training program found in O.1.1 above.

#### O.1.3 Training for Institutional Research

Staff who conduct institutional research that may be publicized should complete the same on-line training program found in O.1.1.

#### O.1.4 Training for Other Projects

Students and staff conducting other projects, as defined in section N.3, are not required to complete training.

### ***O.1.5 Training for Projects Based Solely on Publicly Available Data***

Students and staff conducting projects based solely on publicly available data, as defined in section N.4, are not required to complete training.

## **O.2 When Training Must Occur**

Training of all PIs and co-PIs must be completed before the project or renewal is approved. In addition, funding agencies may require completion of training before funds are approved or released, and may have training requirements that exceed EIU's. The PI is responsible for adhering to both EIU's and the funding agency's training policies.

## **O.3 Training Procedures and Certification**

Follow the training procedures described in Appendix 5.

## **P. STUDENTS AS RESEARCH SUBJECTS**

Students are often used as subjects in research studies, both by EIU student, faculty, and staff researchers as well as researchers from other universities and organizations. Because of their unique position, EIU policy addresses several issues pertaining to the use of students in research projects.

### **P.1 Types of Activities Covered by this Section**

Some course work involves research-type activities that serve an entirely pedagogical purpose. For example, professors may have students administer surveys or psychological instruments to each other in class so that they can practice interviewing techniques. These activities are not considered research, as defined by Federal regulations or this policy, do not require IRB review, and are not covered by this section. Projects in which students include other students in studies that are not designed for use beyond a course are not considered research as defined by federal regulations or this policy (e.g, administering a brief survey to students in the dining hall regarding food service). Although they are not covered in this section, these studies may require review as set forth in Section N of this policy.

Research involving normal educational practices typically falls under an exempt review category (see Form B) under 45 CFR 46.101(b)(1) and must be submitted to the IRB for exemption certification. For example, instructors may administer standard surveys in classes and use the resulting data as the basis for publishable research. Informed consent procedures must be followed, though. In many such cases, students cannot opt out of participation in the instructor's research, since the research activities may be the pedagogical techniques routinely used in the class. In such studies, the instructor should provide information on the research at the beginning of the course. This information should offer the student the option to refuse to have his or her information (e.g, grades) included in the study. If the study is conducted at another school (e.g., student teaching assignment), informed consent must be obtained in accordance with the rules of that school, as well. In these studies, the informed consent must include a contact person to address questions regarding the study who is not the instructor or graduate assistant assigned to the course. The contact person may be the IRB chairperson or vice chairperson or the IRB administrator.

Research that is exempt under 45 CFR 46.101(b)(2) and (3) and all non-exempt research must follow the recruitment and protection policies set forth in this section.

## **P.2 Recruitment of Students for Research Studies**

Faculty should think very carefully about the implications of using students as participants in research. Although students often provide a ready source of potential participants, they are not always as representative or appropriate to the research as other subject pools, and many research proposals and manuscripts have been rejected for funding or publications, respectively, on those grounds. If students are determined to be appropriate participants, then several key issues need to be considered.

1. Coercion : If the instructor of the course is also the PI on the project, recruitment of students into the project by the instructor could be viewed as coercive. Students may fear that their grades would be jeopardized by their non-participation in the research, especially since the instructor could identify who has participated and who has not. Therefore, it is important that measures are built into the research to ensure students that their participation is strictly voluntary and that they may withdraw their participation at anytime without penalty.

2. Consent : Even though potential participants are enrolled in the PI's class, informed consent is still required. The PI must explain the procedures; disclose all the risks and benefits, and any other information, which may influence the potential participant's decision to willingly participate. Signed informed consent is required, except under the following conditions:

- a. Anonymous (no means of identifying participants) mailed questionnaires or telephone interviews; and
- b. The only record linking the subject and the research would be the signed consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Please note: Although signed informed consent may be waived, participants must still receive the standard consent information.

3. Use of Class Assignments in Research: Instructors should not use their students' class assignments (e.g., journals, term papers, etc.) in research without the signed consent of the students.

## **P.3 Awarding Credit for Participation in Research Studies**

If extra credit is offered in exchange for participation, an alternate means of earning equivalent extra credit for an equivalent commitment of time and effort should be made available to the entire student pool. (Please note that extra credit should be awarded only in addition to the base amount of points to be earned for the course, rather than being figured in to the base amount of points to be earned.)

# Appendices

## Appendix 1—Instructions for submissions and forms

Instructions for Submitting Materials for Review by the University Institutional Review Board

Form A—Initial Application to the Institutional Review Board for Review of Research Involving Human Subjects

Form B—Exempt Research Checklist

Form C—Expedited Review Research Categories

Form D—Proposed Modifications to Study Protocol or Informed Consent/Assent Form(s) after IRB Approval

Form E—Continuation Request

Form F—Adverse Incident Report

Form G—Completion of Research Activities

Form H—Form for Certification of Courses

Form I—Request for Waivers of Informed Consent

## Appendix 2—Reviewer Checklist

## Appendix 3—Informed Consent

Informed Consent Form Checklist

Informed Consent Form Template

Conditions for waiver of some or all informed consent requirements

Conditions for waiver of requirement to obtain signed informed consent

## Appendix 4—HIPAA Information

Authorization document

Waiver of alteration of authorization

HIPAA defined personal identifiers

Limited data set

## Appendix 5—Training Procedures for Human Subjects Protection

## Appendix 1—Instructions for Submissions and Forms

Instructions for Submitting Materials for Review by the University Institutional Review Board

Form A—Initial Application to the Institutional Review Board for Review of Research Involving Human Subjects

Form B—Exempt Research Checklist

Form C—Expedited Review Research Categories

Form D—Proposed Modifications to Study Protocol or Informed Consent/Assent Form(s) after IRB Approval

Form E—Continuation Request

Form F—Adverse Incident Report

Form G—Completion of Research Activities

Form H—Form for Certification of Courses

Form I—Request for Waivers of Informed Consent

## **Instructions for Submitting Materials for Review by the Institutional Review Board**

**Submit 1 unstapled copy of all required materials to the Office of Research and Sponsored Programs(ORSP) .**

### **New Application**

- \_\_\_\_\_ Form A, including answers to all Research Description items
  - Students: do not submit dissertation or thesis proposals
- \_\_\_\_\_ Form B or Form C, if applicable
- \_\_\_\_\_ Informed consent/assent forms or Request for Waivers of Informed Consent (Form I)
- \_\_\_\_\_ Questionnaires, surveys, tests, or other materials that will be administered to subjects
- \_\_\_\_\_ Written permission from other institutions or agencies involved in the research (e.g., school district, hospital, agency, prison)
  - If permission letters are not available at the time of submission, they must be obtained and submitted to ORSP prior to IRB approval.
- \_\_\_\_\_ HIPAA Authorization or waiver of Authorization if your proposed study involves protected health information
- \_\_\_\_\_ Advertisements, letters, or flyers that will be used, if any

**Reminder: All PI's, Co-PI's and sponsors must complete the "[On-line Training Tutorial for Certification](#)" prior to IRB approval.**

### **Modification Request**

- \_\_\_\_\_ Form D and documentation requested on the form

### **Continuation Request**

- \_\_\_\_\_ Form E and documentation requested on the form
- \_\_\_\_\_ Protocol summary, including approved modifications since last review and/or proposed changes
- \_\_\_\_\_ Informed consent forms, permission forms, and assent forms, if applicable

### **Adverse Incident Report**

Call or e-mail the IRB Chairperson immediately and complete and submit Form F and documentation requested on the form to ORSP within 20 working days

- \_\_\_\_\_ Form F and documentation requested on the form

### **Completion of Research Activities**

- \_\_\_\_\_ Form G and documentation requested on the form

### **Certification of Courses**

- \_\_\_\_\_ Form H and documentation requested on the form

For IRB use only  
IRB File No.: \_\_\_\_\_  
Date received: \_\_\_\_\_  
Approval expires: \_\_\_\_\_

**Form A**

Eastern Illinois University  
Institutional Review Board

NEW APPLICATION FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

Federal regulations and Eastern Illinois University's IRB policy require that all research involving humans as subjects be reviewed and approved by the University's Institutional Review Board (IRB) prior to the commencement of the data collection. Approval of this project by the IRB only signifies that the procedures adequately protect the rights and welfare of the subjects.

1. Title of Project: \_\_\_\_\_

2. Principal Investigator\*: \_\_\_\_\_

Status:  Faculty     Student\*     EAP Staff     Other—specify: \_\_\_\_\_

\*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below.

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

Has PI completed training (on-line tutorial for certification)?  Yes     No

**All PI's, Co-PI's and sponsors must complete the "[On-line Training Tutorial for Certification](#)" prior to IRB approval.**

Co-Investigator or Sponsor: \_\_\_\_\_

Status:  Faculty     Student     EAP Staff     Other—specify: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

Has Co-PI or sponsor completed training (on-line tutorial for certification)?  Yes     No

List additional co-investigators, including above information, on a separate sheet.

3. Level of Review Sought:     Exempt (submit Form B)     Expedited (submit form C)     Full

4. Is this research being conducted to meet requirements of a course or to complete an academic degree?  
 Yes (do NOT submit your dissertation or thesis proposal)     No

5. Estimated Project Starting Date: \_\_\_\_\_ Estimated Project Completion Date: \_\_\_\_\_

6. Extramural Funding:  
Principal Investigator of Contract or Grant: \_\_\_\_\_  
Funding Source: \_\_\_\_\_  
Contract or Grant Title: \_\_\_\_\_  
Contract or Grant Number: \_\_\_\_\_

7. Indicate the categories of subjects and controls to be included in the study: Check ALL that apply:

- |  |   |
|--|---|
| <input type="checkbox"/> Abortuses/Fetuses                             | <input type="checkbox"/> Patients       |
| <input type="checkbox"/> Decisionally Impaired                         | <input type="checkbox"/> Prisoners      |
| <input type="checkbox"/> Decisionally Impaired (Institutionalized)     | <input type="checkbox"/> Pregnant Women |
| <input type="checkbox"/> Minors (17 yrs or less)—Give age range: _____ | <input type="checkbox"/> Students       |
| <input type="checkbox"/> Normal Volunteers                             |   |

8. Approximate number of human subjects: \_\_\_\_\_

9. Indicate which of the categories listed below accurately describes this protocol:

- Not greater than minimal risk
- Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition
- Research not otherwise approvable, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of subjects

10. Does this research involve any of the following? (Check all that may apply)

- Past, present, or future physical health of the participants
- Mental health (as defined in DSM-IV TR)
- Provision of health care to the participants
- Past, present, or future payments for the provision of health care to the participants

If any of the above categories are checked, please refer to Appendix 4, HIPAA Information, in the EIU Policy and Procedures for the Review of Research Involving Human Subjects

11. Will a public use data file be created?  Yes  No

**12. Complete all items from the Research Description section, which follows this application form.**

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study’s protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

\_\_\_\_\_  
Principal Investigator’s Signature

\_\_\_\_\_  
Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

\_\_\_\_\_  
Faculty or EAP Staff Sponsor’s Signature

\_\_\_\_\_  
Date

## RESEARCH DESCRIPTION

Provide responses to the following items and submit your responses along with Form A. Each response should be numbered or labeled to correspond to the following items. If an item does not apply to your research project, simply indicate "Not applicable." The research description (answers to all of the items below) should not exceed 5 type-written single-spaced pages. Use a font size of 11 or larger.

### PROJECT DESCRIPTION

1. **DESCRIPTION**—Provide a brief description in layperson's terms of the proposed research. Include the purpose and research questions/hypotheses.
2. **DISSEMINATION**—Describe how the results of the research will be disseminated. Dissemination includes, but is not limited to: honor's, master's or doctoral theses; presentation at a scientific/professional meeting or conference; submission to or publication in a scientific/professional journal (paper or electronic); and internet postings.

### METHODOLOGY

3. **PARTICIPANTS**—Describe the characteristics (e.g., age, gender, ethnicity, health status) of the subject population whom you are targeting and the approximate number of participants. Provide exclusion and inclusion criteria. Will there be any special populations (see 45 CFR 46, subparts B, C, and D), such as children, mentally incapacitated individuals, prisoners, or others whose ability to give voluntary informed consent may be in question included?—If yes, explain the rationale for their inclusion.
4. **RECRUITMENT**—Describe how you will identify and recruit prospective subjects. Attach a draft or final copy of any planned advertisements, flyers, and letters to potential subjects.
5. **LOCATION OF STUDY**—Identify specific sites or agencies to be used. For research conducted at a facility other than one owned and operated by Eastern Illinois University, additional information is required.
  - a. **Non-federally funded research**—If the research project will not receive federal funds, a letter from the appropriate administrator of each facility should be submitted on the facility's letterhead stationary and should contain the following: agreement for the study to be conducted; identification of someone at the site who will provide information about appropriateness for its population; assurance of adequate capabilities to perform the research as approved by the IRB; and if applicable, assurance that facility personnel involved in data collection have appropriate expertise and will follow IRB approved procedures. If the approval letters are not available at the time of IRB review, IRB approval will be contingent upon receipt of the letters.
  - b. **Federally funded research**—If the research project receives federal funds from an agency such as the National Institutes of Health (NIH), each study site must have a Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP). FWAs are a requirement of OHRP or NIH and not EIU's IRB or EIU's Office of Research and Sponsored Programs. EIU has negotiated a FWA. Contact ORSP for the information to enter on the funding agency's application form regarding FWA documentation. If the study is a collaborative project and another organization in addition to EIU is engaged in human subjects research (as defined by DHHS), then the PI must obtain information on the other organization's FWA and provide it in this section of the EIU application. A search for another organization's FWA may be found at OHRP's web site, <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>.
6. **INSTRUMENTS, RESEARCH MATERIALS, RECORDS**—Identify the sources of research material (e.g., specimens, records, data) to be obtained from subjects. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data. If applicable, attach a copy of all questionnaires, tests, surveys, or other materials to be administered to the subjects; describe the setting and mode of administration (e.g., group, telephone, individual); describe the duration of administration, intervals of administration (if multiple administrations), and overall length of participation.

7. PROCEDURES—Describe the study design and research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. If applicable, differentiate between procedures that involve standard or routine procedures for care or treatment from those which will be performed specifically for the conduct of this research project.
8. DATA COLLECTION, STORAGE, AND CONFIDENTIALITY—Describe how data will be collected and recorded. If subjects are identifiable by name or other means, explain special steps that will be taken to ensure confidentiality. Describe how data will be stored during the study and how it will be secured. Delineate who will have access to the data or to subject identifiers. Describe what will happen with data from subjects who formally withdraw from the study. Describe what will happen to the data when the research has been completed. [Note: Records (e.g., signed informed consent forms, data) relating to the research project must be retained for at least three years after completion of the research. See 45 CFR 46.115(b)]

If all or some of the subject(s) of the proposed research will be audio or videotaped, justify why the use of audio or videotaping is necessary to the study. Who will have access to the tapes and for what purposes? Where will the tapes be stored and what security measures will be taken to prevent unauthorized persons from accessing the tapes? What are your plans for the ultimate use and disposal of the tapes?

9. INFORMED CONSENT—Describe the informed consent procedures to be followed, including circumstances under which consent will be sought and obtained, who will seek it, and the method for documenting consent. If minors will be included, refer to 45 CFR 46.408 for information regarding parental consent and minor's assent. Include applicable informed consent and assent forms for review purposes. If the informed consent process is to be waived, or if written consent or a signed informed consent is not to be obtained, specifically point this out and complete and submit Form I, Request for Waivers of Informed Consent [see 45 CFR 46.116(d) and 45 CFR 46.117(c)].

#### RISKS/BENEFITS

10. RISKS—Describe the short-term and long-term potential risks (physical, psychological, social, legal, or other) to subjects and assess their likelihood and seriousness. Where appropriate, describe alternative treatments or procedures that might be advantageous to the subjects.
11. SAFETY PRECAUTIONS—Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subject(s) and attach a referral list. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.
12. BENEFITS—Describe the potential direct benefits subjects may receive as a result of participating in this research. Describe the potential benefits to society that may be expected from this research.
13. BENEFITS VS. RISKS—Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.
14. INCENTIVES AND RESEARCH RELATED COSTS—Describe the incentives, if any, being offered to subjects for their participation in the research study. If monetary compensation is offered, indicate how much subjects will be paid and describe terms of payment. Describe what will be done if subjects withdraw before completion of the research (e.g., will monetary payments be prorated or payment in full?). Also, if applicable, describe any costs which will be accrued by the subjects as a consequence of participating in the research.

#### QUALIFICATIONS OF INVESTIGATORS

15. Briefly describe the qualifications of the investigators(s) conducting this research project.

OTHER (Provide information regarding the following if applicable)

16. DATA SAFETY AND MONITORING FOR NIH SPONSORED RESEARCH—The National Institutes of Health policy requires that grantees have in place procedures for data safety monitoring of clinical trials. The IRB is required to review and approve the data safety monitoring plans. For NIH funded clinical trials, include a description of the Data Safety Monitoring Plan.

17. Describe any requirements imposed by funding agencies that are not already covered in this application.

**Form B**

Exempt Research Categories  
(45 CFR 46.101b)

For IRB use only IRB File No.: _____ Date received: _____ Approval expires: _____
--

Principal Investigator: \_\_\_\_\_

Title of Project: \_\_\_\_\_

ONLY research activities in which involvement of human subjects will be in one or more of the categories specified below are eligible for exemption certification. If the research study involves a vulnerable population, such as children, prisoners, pregnant women, refer to 45 CFR 46 subparts B, C, and D for protections afforded these groups.

Check the appropriate categories that apply to your research project:

\_\_\_\_\_ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

\_\_\_\_\_ 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. *Note: According to 45 CFR 46.401, if the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*

\_\_\_\_\_ 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under #2 (above) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

\_\_\_\_\_ 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

\_\_\_\_\_ 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

\_\_\_\_\_ 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

For IRB use only IRB File No.: _____ Date received: _____ Approval expires: _____
--

**Form C**

Expedited Review Research Categories  
 (63 FR 60364; November 9, 1998)

Principal Investigator: \_\_\_\_\_

Title of Project: \_\_\_\_\_

**Applicability**

- A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- B. The categories in this list apply regardless of the age of the subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risk related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.
- F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

**Research Categories**

Research projects may receive expedited review when the involvement of human subjects falls within one or more of the categories below. Check the appropriate categories that apply to your research project.

- \_\_\_ 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - \_\_\_ (a) Research on drugs for which an investigational new drug application (21CFR Part 312) is not required (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).
  - \_\_\_ (b) Research on medical devices for which (i) an investigational device exemption application(21CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- \_\_\_ 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - \_\_\_ (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; OR
  - \_\_\_ (b) from other adults and children<sup>1</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

---

<sup>1</sup> Children are defined in the HSS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR 46.402(a).

- \_\_\_ 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulation by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time or rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washing; (j) sputum collected after saline mist nebulization.
- \_\_\_ 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
- Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- \_\_\_ 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- \_\_\_ 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
- \_\_\_ 7. Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- \_\_\_ 8. Continuing review of research previously approved by the convened IRB as follows:  
\_\_\_ (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; OR  
\_\_\_ (b) where no subjects have been enrolled and no additional risks have been identified; OR  
\_\_\_ (c) where the remaining research activities are limited to data analysis.
- \_\_\_ 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

For IRB use only  
IRB File No.: \_\_\_\_\_  
Date received: \_\_\_\_\_  
Approval expires: \_\_\_\_\_

**Form D**

Eastern Illinois University  
Institutional Review Board  
for Review of Research Involving Human Subjects  
PROPOSED MODIFICATIONS

TO PROTOCOL OR INFORMED CONSENT/ASSENT FORM(S) AFTER IRB APPROVAL

1. Title of Project: \_\_\_\_\_  
IRB File Number: \_\_\_\_\_

2. Principal Investigator\*: \_\_\_\_\_

Status:  Faculty     Student\*     EAP Staff     Other—specify: \_\_\_\_\_

\*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below.

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

Co-Investigator or Sponsor: \_\_\_\_\_

Status:  Faculty     Student     EAP Staff     Other—specify: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

List additional co-investigators, including above information, on a separate sheet.

3. Are there any proposed changes in the protocol requested?  
 Yes—describe proposed changes to the protocol and submit protocol with revisions incorporated.  
 No

4. Are there any proposed changes to the informed consent/assent form(s)?  
 Yes—describe changes and attach new consent/assent form(s) with changes highlighted.  
 No

5. Are there any additions and/or changes in sites where data are being collected?  
 Yes—list additional sites or changes. Attach approval letters (See location of study in Research Description of the New Application packet—Form A).  
 No

6. Are there changes in key personnel assisting in the research project?  
 Yes—list changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, and responsibility in project.  
 No

7. Describe any proposed changes, not listed above.

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study's protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)

This is to certify that I have reviewed this proposed modification request and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

\_\_\_\_\_  
Faculty or EAP Staff Sponsor's Signature

\_\_\_\_\_  
Date

For IRB use only  
IRB File No.: \_\_\_\_\_  
Date received: \_\_\_\_\_  
Approval expires: \_\_\_\_\_

**Form E**

Eastern Illinois University  
Institutional Review Board  
for Review of Research Involving Human Subjects  
CONTINUATION REQUEST

Federal guidelines (45 CRF 46.109e) require that Institutional Review Boards (IRB) “conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.” In conducting the continuation review, the IRB will review, at a minimum, a protocol summary and informed consent/assent forms, as well as a status report on the progress of the research.

1. Title of Project: \_\_\_\_\_  
IRB File Number: \_\_\_\_\_

2. Principal Investigator\*: \_\_\_\_\_

Status:  Faculty     Student\*     EAP Staff     Other—specify: \_\_\_\_\_

\*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below.

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

Co-Investigator or Sponsor: \_\_\_\_\_

Status:  Faculty     Student     EAP Staff     Other—specify: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

List additional co-investigators, including above information, on a separate sheet.

3. Project begin date: \_\_\_\_\_ Estimated project end date: \_\_\_\_\_

4. Approximate total number of subjects who will be enrolled: \_\_\_\_\_

Number of subjects actually enrolled as of this date: \_\_\_\_\_

Number of subjects who have dropped out: \_\_\_\_\_

Number of subjects who have formally withdrawn: \_\_\_\_\_ (If subjects have withdrawn, please summarize reason(s) for withdrawal)

5. Since the last IRB review, have any injuries or adverse events occurred?

Yes—summarize injuries or events

No

6. Since the last IRB review, have any unanticipated problems involving risks to subjects or others occurred?
- Yes—summarize problems
- No
7. Since the last IRB review, have any complaints about the research been received?
- Yes—summarize complaints
- No
8. Are there any changes in the protocol requested?
- Yes—describe proposed changes to the protocol and attach a protocol summary. Include amendments or modifications to the research since the last review.
- No—attach a protocol summary. Include amendments or modifications to the research since the last review.
9. Are there any changes to the informed consent/assent form(s)?
- Yes—describe changes and attach new consent/assent form(s) with changes highlighted.
- No—attach informed consent/assent forms
10. Are there any additions and/or changes in sites where data are being collected?
- Yes—list additional sites or changes. Attach approval letters (See location of study in Research Description of the New Application packet—Form A).
- No
11. Are there changes in key personnel assisting in the research project?
- Yes—list changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, and responsibility in project.
- No
12. Summarize any relevant recent literature and interim findings.
13. If this is a multi-center trial, summarize any relevant trial reports.
14. Summarize any other relevant information, especially information about risks associated with the research, not requested above.

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study's protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)

This is to certify that I have reviewed this proposed continuation request and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

\_\_\_\_\_  
Faculty or EAP Staff Sponsor's Signature

\_\_\_\_\_  
Date

For IRB use only  
IRB File No.: \_\_\_\_\_  
Date received: \_\_\_\_\_  
Approval expires: \_\_\_\_\_

**Form F**

Eastern Illinois University  
Institutional Review Board  
for Review of Research Involving Human Subjects  
PI REPORT OF PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, OR NONCOMPLIANCE

All problems involving risk to subjects or others, injury or other adverse effects experienced by subjects in research, and incidents of noncompliance must be reported to the IRB immediately. This report should be submitted as soon as possible, but NO LATER THAN 5 WORKING DAYS after first awareness of the problem.

1. Date of Report: \_\_\_\_\_
2. Title of Project: \_\_\_\_\_  
IRB File Number: \_\_\_\_\_
3. Principal Investigator\*: \_\_\_\_\_

Status:  Faculty     Student\*     EAP Staff     Other—specify: \_\_\_\_\_

\*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below.

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

Co-Investigator or Sponsor: \_\_\_\_\_

Status:  Faculty     Student     EAP Staff     Other—specify: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

List additional co-investigators, including above information, on a separate sheet.

4. Description of problem involving risk to subjects or others, adverse effect, or noncompliance  
Date: \_\_\_\_\_  
The problem, adverse effect, or noncompliance was:  mild     moderate     severe     fatal  
Was the event related to the research procedure?  Yes     No     Maybe     Unknown  
Provide a brief description.
5. Treatment provided to the subject or other  
Was treatment provided to the subject or other?  
 Yes—Date of treatment: \_\_\_\_\_  
Describe the treatment provided to the subject or other.  
 No —Explain why treatment was not provided.

6. Changes necessitated by the problem involving risk to subjects or others, adverse effect, or noncompliance
- A. Change in Protocol: In your judgment is a change in your protocol necessary to reduce or eliminate risk?
- Yes—Provide revised protocol with changes highlighted. Note that data should not be collected until the revised protocol is approved by the IRB.
- No —Provide a brief rationale.
- B. Change in Informed Consent/Assent Document(s): Are any changes required in the informed consent/assent document(s) to better inform and protect the rights and welfare of the subjects?
- Yes—Attach the revised consent/assent form with changes highlighted. Note: No new subjects may be enrolled in the study until the revised consent/assent form(s) is approved by the IRB.
- No —Provide a brief rationale.
- C. Enrolled Subjects: Is it necessary to inform presently enrolled subjects or legal representatives of the adverse event?
- Yes—Describe how subjects or legal representatives will be informed and if necessary, attach a revised consent or assent form.
- No—Provide a brief rationale.

7. Additional Comments:

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Faculty or EAP Staff Sponsor's Signature  
(required when a student is the PI)

\_\_\_\_\_  
Date

For IRB use only  
IRB File No.: \_\_\_\_\_  
Date received: \_\_\_\_\_  
Approval expires: \_\_\_\_\_

**Form G**

Eastern Illinois University  
Institutional Review Board  
for Review of Research Involving Human Subjects  
COMPLETION OF RESEARCH ACTIVITIES

1. Title of Project: \_\_\_\_\_  
IRB File Number: \_\_\_\_\_

2. Principal Investigator\*: \_\_\_\_\_

Status:  Faculty  Student\*  EAP Staff  Other—specify: \_\_\_\_\_

\*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below.

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

Co-Investigator or Sponsor: \_\_\_\_\_

Status:  Faculty  Student  EAP Staff  Other—specify: \_\_\_\_\_

Mailing address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department or Unit \_\_\_\_\_

List additional co-investigators, including above information, on a separate sheet.

Project Begin Date: \_\_\_\_\_ Project End Date: \_\_\_\_\_

**Subject Recruitment**

Total number of subjects enrolled in study: \_\_\_\_\_

Number of subjects who formally voluntarily withdrew from study at their own request: \_\_\_\_\_

Number of subjects who dropped out or did not finish the study: \_\_\_\_\_

Please identify any problems the participants may have encountered during the research study. How were the problems handled?

Attach a summary of the completed research (an abstract is sufficient)

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Faculty or EAP Staff Sponsor's Signature  
(required when a student is the PI)

\_\_\_\_\_  
Date

For IRB use only IRB File No.: _____ Date received: _____ Approval expires: _____
--

**Form H**

Eastern Illinois University  
Institutional Review Board  
**CERTIFICATION OF COURSES**

This request must be made to the IRB administrator prior to the initiation of any data collection by students conducting an instruction-related research project involving human subjects. A course certification is valid only for the instructor actually making the request and only for a period of one year. If another instructor is teaching the same course, he or she must apply for and receive separate certification for the course.

**NOTE: Please see second page for important information.**

1. Name of Instructor (printed) \_\_\_\_\_
2. Department \_\_\_\_\_ Phone \_\_\_\_\_ E-mail \_\_\_\_\_
3. Course Number \_\_\_\_\_ Section Numbers \_\_\_\_\_
4. Course Title \_\_\_\_\_
5. Semester: Fall 20\_\_\_\_ Spring 20\_\_\_\_ Summer 20\_\_\_\_
6. I am familiar with the published policies of the Institutional Review Board at Eastern Illinois University and have completed the on-line tutorial at <http://www.eiu.edu/~grants/ConsentTraining/index.html>. (Check one.)  
YES \_\_\_ NO \_\_\_
7. Prior to the beginning of all research projects, all students enrolled in this course will receive training by one of the following three options (Check one):
  - \_\_\_ (1) Complete the on-line tutorial at <http://www.eiu.edu/~grants/ConsentTraining/index.html>.  
**The instructor is responsible for collecting from the class the certificates generated by the tutorial and submitting them to the Office of Research and Sponsored Programs (ORSP) .**
  - \_\_\_ (2) Read the “Protecting Human Subjects in Research” document found at <http://www.eiu.edu/~grants/IRB.htm>. These instructions may also be printed out and incorporated into the course syllabus. In either case, the course syllabus should explicitly mention the training as part of course requirements, and questions about the material should be included on at least one quiz or exam.  
**The instructor is responsible for submitting a copy of the course syllabus to ORSP.**
  - \_\_\_ (3) Trained by a method of the instructor’s choice, provided the essentials of proper protection of human subjects are conveyed. The course syllabus should explicitly mention the training as part of course requirements, and questions about the material should be included on at least one quiz or exam.  
**The instructor is responsible for submitting to ORSP (1) a written description of the training and (2) a course syllabus.**

I will exercise reasonable and customary instructional supervision in an attempt to ensure student compliance with the policies for the protection of human subjects at Eastern Illinois University.

\_\_\_\_\_  
Instructor’s Signature

\_\_\_\_\_  
Date

**NOTE:**

Course certifications can only be used for instruction-related research and class projects that place the subjects at no more than minimal risk.

If the project falls into one or more of the following categories, then IRB review and approval may be required:

- Subjects are members of a vulnerable population. Vulnerable population means children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers).
- The study asks identifiable subjects about illegal activities (e.g., underage drinking), which may place the data at risk of subpoena.
- The study places identifiable subjects at risk of a breach of confidentiality that may lead to criminal or civil liability, or damage the subject's financial standing, employability, or reputation.
- The study places subjects at more than minimal risk due to psychologically sensitive subject matter (e.g., interviews covering traumatic events).

For IRB use only  
IRB File No.: \_\_\_\_\_  
Date received: \_\_\_\_\_  
Approval expires: \_\_\_\_\_

**Form I**

Eastern Illinois University  
Institutional Review Board  
**REQUEST FOR WAIVERS OF INFORMED CONSENT**

“Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate” (*IRB Guidebook*). Informed consent is also mandated by Federal regulations (45 CFR 46) and EIU Policy and Procedures for the Review of Research Involving Human Subjects.

Federal regulations do allow the IRB to approve, under limited circumstances, two types of waivers to the usual consent requirements:

- 1) Waiver of Informed Consent – waives the requirement to obtain informed consent OR waives or alters some or all of the elements of informed consent
- 2) Waiver of Documentation of Informed Consent – waives the requirement for written documentation of consent

An investigator should request a waiver of informed consent or a waiver of documentation of informed consent only under compelling circumstances. The IRB will not grant a waiver without written justification.

---

Principal Investigator: \_\_\_\_\_

Title of Project: \_\_\_\_\_

Type of Waiver Requested:

- \_\_\_ Waiver of Informed Consent (Complete Section A)
- \_\_\_ Waiver of Documentation of Informed Consent (Complete Section B)

**FOR IRB USE ONLY**

Waiver of Informed Consent:            Approved \_\_\_            Not Approved \_\_\_

Waiver of Documentation of Consent:    Approved \_\_\_            Not Approved \_\_\_

Comments:

**SECTION A - Waiver of Informed Consent**

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or may waive the requirement to obtain informed consent provided that **all four** of the criteria listed below are met. Provide justification for each criterion.

Note: Even if the waiver is granted, the IRB may require other conditions, including but not limited to providing subjects with an information sheet (written summary) about the research.  
If a waiver of informed consent is granted, documentation of informed consent is also waived.

1. The research involves no more than minimal risk\* to the subjects.
  
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
  
3. The research could not practicably be carried out without the waiver or alteration.
  
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If not all of the elements of informed consent are being waived, list the elements of informed consent for which the waiver is being requested and a justification for each.

\* *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 (45 CFR 46.102(i)).

<b>SECTION B - Waiver of Documentation of Informed Consent</b>
--

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all potential subjects if **one** of the following two criteria is met. Select the appropriate criteria and provide justification.

NOTE: Even if written documentation of informed consent is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research which contains all of the required elements of informed consent.

\_\_\_\_ 1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

\_\_\_\_ 2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

## **Appendix 2—Reviewer Checklist**

Eastern Illinois University  
Institutional Review Board  
for Review of Research Involving Human Subjects

**REVIEWER CHECKLIST**

<u>Minimal regulatory requirements for IRB review, discussion, and documentation in the meeting minutes from IRB Protocol Review Guidelines (<a href="http://www.nihtraining.com/ohsrsite/irb/protocol.html">http://www.nihtraining.com/ohsrsite/irb/protocol.html</a>)</u>	
<u>Regulatory review requirement</u>	<u>Suggested questions for IRB discussion</u>
1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.	(a) Is the hypothesis clear? Is it clearly stated? (b) Is the study design appropriate to test the hypothesis? (c) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?
2. Risks to subjects are <b>reasonable</b> in relation to anticipated benefits, if any, to subjects, <b>and</b> the importance of knowledge that may reasonably be expected to result.	(a) What does the IRB consider the level of risk to be? (See risk assessment guide on back of form.) (b) What does the PI consider the level of risk/discomfort/inconvenience to be? (c) Is there prospect of direct benefit to subjects? (See benefit assessment guide on back of form.)
3. Subject selection is equitable.	(a) Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill persons? Healthy volunteers? (b) Are these subjects appropriate for the protocol?
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.	(a) Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired?
5. Informed consent is obtained from research subjects or their legally authorized representative(s).	(a) Does the informed consent document include the eight required elements? (b) Is the consent document understandable to subjects? (c) Who will obtain informed consent (PI, nurse, other?) & in what setting? (d) If appropriate, is there a children's assent? (e) Is the IRB requested to waive or alter any informed consent requirement?
6. Subject safety is maximized.	(a) Does the research design minimize risks to subjects? (b) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?
7. Subject privacy & confidentiality are maximized.	(a) Will personally-identifiable research data be protected to the extent possible from access or use? (b) Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?

<b><u>Additional considerations</u></b>	
1. Ionizing radiation.	If ionizing radiation is used in this protocol is it medically indicated or for research use only?
2. Collaborative research.	Is this domestic/international collaborative research? If so, are SPAs or other assurances required for the sites involved?
3. FDA-regulated research	Is an investigational new drug (IND) or investigational device exemption (IDE) involved in this protocol?
4. Other	

### **Risk/Benefit Assessment**

#### **RISK**

Regulatory definition of minimal risk: 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 ([45 CFR 46.102\(h\)\(i\)](#)).

Risk categories

1. The research involves no more than minimal risk to subjects.
2. The research involves more than minimal risk to subjects.
  - a. The risk(s) represents a minor increase over minimal risk, **or**
  - b. The risk(s) represents more than a minor increase over minimal risk.

#### **BENEFIT**

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Benefit categories:

1. The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.
2. The research involves the prospect of direct benefit to individual subjects.

## **Appendix 3—Informed Consent**

Informed Consent Form Checklist

Informed Consent Form Template

Conditions of waiver of some or all informed consent requirements

Conditions for waiver of requirement to obtain signed informed consent

Eastern Illinois University  
 Institutional Review Board  
 for Review of Research Involving Human Subjects  
**Informed Consent Form Checklist**

Informed consent/assent forms should be written in second person (e.g., You are being asked to participate...).

Basic elements to include

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them
	A description of any benefits to the subject or to others which may reasonably be expected from the research. Monetary compensation is not a benefit. If compensation is to be provided to research subjects or healthy volunteers, the amount should be stated in the consent document
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Include a description of whom may have access to research records
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional elements, as appropriate

	An explanation as to why subject is eligible to participate
	The approximate number of subjects involved in the study
	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
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	Payment for participation—give amount and if/how it will be prorated if subject does not complete study
	A statement that the collection of data will be audiotaped or videotaped
	A 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
	When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study
	If the subject is or may become pregnant, a statement that the particular treatment may involve risks, which are currently unforeseeable, to the subject or to the embryo or fetus

## Informed Consent Form Template

### CONSENT TO PARTICIPATE IN RESEARCH

*Title or paraphrased title of the study*

You are invited to participate in a research study conducted by *name of PI (and faculty sponsor if the PI is a student)*, from the *departmental affiliation* at Eastern Illinois University.

Your participation in this study is entirely voluntary. Please ask questions about anything you do not understand, before deciding whether or not to participate. *Generally, the investigator and potential subject(s) read through and discuss the informed consent information together.*

**OPTIONAL:** You have been asked to participate in this study because *explain succinctly and simply why the prospective subject is eligible to participate. If appropriate, state the approximate number of subjects involved in the study. State whether there are inclusion or exclusion criteria for participation (e.g., a medical condition or a demographic that would include or exclude a person).*

#### • PURPOSE OF THE STUDY

*Briefly state what the study is designed to examine, assess, or establish.*

#### • PROCEDURES

If you volunteer to participate in this study, you will be asked to:

*Describe the procedures chronologically using simple language, short sentences, and short paragraphs. If there are several procedures or if they are complex, the use of subheadings may help organize this section and increase readability.*

*Define and explain scientific or discipline-specific terms. Use language appropriate to the population.*

*If applicable, specify the subject's assignment to study groups, length of time for participation in each procedure or study activity, the total length of time for participation, frequency of procedures and location of the procedures to be done.*

*If subjects will be recorded (audiotaped, videotaped, digitally), describe the procedures to be used.*

*If any study procedures are experimental, clearly identify which ones.*

*If applicable, describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that might be advantageous to the subjects and should be considered before the subjects decide whether to participate in the study.*

#### • POTENTIAL RISKS AND DISCOMFORTS

*Describe any reasonable foreseeable risks or discomforts, including physical inconveniences and their likelihood, and explain how these will be managed. In addition to physiological risks/discomforts, describe any reasonably foreseeable psychological, social, legal, or financial risks or harms that might result from participating in the research.*

*If there are circumstances in which the researcher may terminate the study, describe them. (This refers to situations in which the study itself may be terminated. It is not the same thing as circumstances in which a specific subject may be withdrawn; this issue is to be discussed below, if relevant.)*

*Explain whether any compensation/treatments are available if injury occurs and, if so, describe the extent and nature of the compensation. If there are any foreseeable risks of physical or psychological harm, explain how subjects will receive a referral for medical or psychological help if the subject needs or requests it.*

- **POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY**

*Describe benefits to subjects expected from the research. If the subject will not benefit directly from participation, clearly state this fact.*

*State the potential benefits, if any, to science or society expected from the research.*

*Note: Payment or other incentives for participation (e.g., a gift certificate, extra credit) are **not** a benefit and is not to be discussed in this section.*

- **INCENTIVES FOR PARTICIPATION (Optional)**

*State whether the subject will receive incentives to participate. If not, delete this section. If subject will receive incentives, describe type and amount, and when incentives (e.g., money, extra credit, gift certificate) are scheduled for distribution.*

- **CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of *describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.*

*If information will be released to any other party for any reason, state the person or agency to whom the information will be furnished, the nature of the information, the purpose of the disclosure, and the conditions under which it will be released.*

*If activities are to be audio- or videotaped or digitally recorded, describe who will have access, if the tapes/files will be used for educational purposes, and when they will be erased or destroyed.*

- **PARTICIPATION AND WITHDRAWAL**

Participation in this research study is voluntary and not a requirement or a condition for being the recipient of benefits or services from Eastern Illinois University or any other organization sponsoring the research project. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits or services to which you are otherwise entitled.

You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled.

***Include the following paragraph in this section only if relevant***

The investigator may withdraw you from this research if circumstances arise which warrant doing so. *Describe the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.*

**• IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about this research, please contact *identify research personnel: Principal Investigator, Faculty Sponsor (if student is the P.I.), Co-Investigator(s), if any. Include day phone numbers, addresses, and email addresses for all listed individuals. For some studies of greater than minimal risk, it may be necessary to include night/emergency phone numbers.*

**• RIGHTS OF RESEARCH SUBJECTS**

If you have any questions or concerns about the treatment of human participants in this study, you may call or write:

Institutional Review Board  
Eastern Illinois University  
600 Lincoln Ave.  
Charleston, IL 61920  
Telephone: (217) 581-8576  
E-mail: eiuirb@www.eiu.edu

You will be given the opportunity to discuss any questions about your rights as a research subject with a member of the IRB. The IRB is an independent committee composed of members of the University community, as well as lay members of the community not connected with EIU. The IRB has reviewed and approved this study.

---

I voluntarily agree to participate in this study. I understand that I am free to withdraw my consent and discontinue my participation at any time. I have been given a copy of this form.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

***NOTE: Use the following signature line for minor/handicapped subjects only if applicable.***

I hereby consent to the participation of \_\_\_\_\_, a minor/subject in the investigation herein described. I understand that I am free to withdraw my consent and discontinue my child's participation at any time.

\_\_\_\_\_  
Signature of Minor/Handicapped Subject's Parent or Guardian

\_\_\_\_\_  
Date

I, the undersigned, have defined and fully explained the investigation to the above subject.

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

## Conditions for Waiver of Some or All Informed Consent Requirements

The IRB may approve a waiver of some or all of the informed consent requirements provided that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practically be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation. [see 45 CFR 46.116 (d)]

Additionally, for research studies that are designed to evaluate or demonstrate possible changes in (or alternatives to) provision of benefits or services provided under federal, state, or local programs, an IRB may approve alteration or waiver of informed consent requirements providing the research could not be practically carried out without such waiver or alteration. [See 45 CFR 46.116 (c)]

## Conditions for Waiver of Requirement to Obtain Signed Informed Consent

Federal regulations [45 CFR 46.117 (c)] allow the IRB to waive the requirement to obtain a signed informed consent for some or all of the subjects providing that the IRB finds either of the following:

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

Additionally, the IRB may decide to waive written documentation of informed consent (i.e., signature of subjects) for research that falls within one or more exemption categories (see Form B). For example, a PI who is using a survey may include the elements of informed consent in a letter of invitation to participate and by completing the survey subjects are consenting to participate in the research study.

## Appendix 4—HIPAA Information

- 4.a Definitions used in the Privacy Rule
- 4.b Authorizations
  - 4.b.1 Authorization document
  - 4.b.2 Waiver of alteration of authorization
- 4.c Exceptions
  - 4.c.1 Limited data set
- 4.d Disclosure of PHI
- 4.e Existing protocols
- 4.f HIPAA defined personal identifiers

Eastern Illinois University  
Institutional Review Board  
for Review of Research Involving Human Subjects  
ADDITIONAL INFORMATION REGARDING THE PRIVACY RULE UNDER HIPAA

**4.a Definitions used in the Privacy Rule**

(1) *Covered Entity* - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard.

(2) *Health Care Provider* - A provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

(3) *Health Care* - Care, services, or supplies related to the health of an individual, including (1) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual that affects the structure or function of the body; and (2) sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

(4) *Protected Health Information* - PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

(5) *Research (as defined under the Privacy Rule)*- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research.

(5) *Authorization* - An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise permitted by the Rule, a covered entity may not use or disclose PHI for research purposes without a valid Authorization.

(6) *Data Use Agreement*- An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

(7) *Health Information* - Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

(8) *Individually Identifiable Health Information* - Information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(9) *Limited Data Set* - Refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.

(10) *Waiver or Alteration of Authorization* - The documentation that the covered entity obtains from a researcher or an IRB or a Privacy Board that states that the IRB or Privacy Board has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

#### **4.b Authorizations**

The Privacy Rule allows covered entities to use and disclose PHI for research if explicitly authorized to do so by the subject in accordance with the Privacy Rule. The Authorization for use of PHI for research may be combined with informed consent for participation or the Authorization may be a stand alone HIPAA authorization document. The Authorization and informed consent form must be kept for 6 years after the conclusion of the study.

##### **4.b.1 Authorization Document**

The HIPAA authorization document (either a stand-alone document or part of an informed consent form) must contain the following specific core elements and required statements:

###### **Authorization Core Elements:**

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

###### **Authorization Required Statements:**

- A statement of the individual's right to revoke his/her Authorization and how to do so, and, if applicable, the exceptions to the right to revoke his/her Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.
- A statement of the potential risk that PHI will be re-disclosed by the recipient. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

##### **4.b.2 Waiver or Alteration of Authorization**

Waiver or Alteration of Authorization, in whole or in part, needs to satisfy the following criteria:

1. The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
  - a. An adequate plan to protect health information identifiers from improper use and disclosure.
  - b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so).

- c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.
2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to and use of the PHI.

#### **4.c Exceptions**

The Privacy Rule also allows covered entities to use and disclose PHI without Authorization for certain types of research activities, including de-identified PHI; when the covered entity and researcher enter into a data use agreement for sharing a limited data set; and documentation that an IRB or Privacy Board has waived the requirement for Authorization or allowed an alteration of Authorization. Refer to Appendix 4 for more information on identifiers, data use agreement, and Authorization waivers or alteration.

Additionally, covered entities may use or disclose PHI to a researcher without an individual's Authorization, a waiver or alteration of authorization, or a data use agreement, when the researcher's request is solely to review PHI necessary to prepare a research protocol, the PHI will not be removed from the covered entity in the course of review, and the PHI is necessary for the research.

The covered entity may also use or disclose PHI of the deceased for research purposes without obtaining Authorizations from personal representatives or next of kin, a waiver or an alteration of Authorization, or a data use agreement. The covered entity, however, must obtain the following from the researcher who is seeking access to decedents' PHI: (1) oral or written representations that the use and disclosure is sought for research on the PHI decedents, (2) oral or written representations that the PHI for which use or disclosure is sought is necessary for research purposes, and 3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought by the researchers.

##### **4.c.1 Limited Data Set**

The following identifiers must be removed from health information if the data are to qualify as a limited data set:

- |  |  |
|--|--|
| 1. Names.  | 10. Certificate/license numbers  |
| 2. Postal address information, other than town or city, state, and ZIP Code. | 11. Vehicle identifiers and serial numbers, including license plate numbers. |
| 3. Telephone numbers.  | 12. Device identifiers and serial numbers.                                   |
| 4. Fax numbers.  | 13. Web universal resource locators (URLs).                                  |
| 5. Electronic mail addresses.  | 14. Internet protocol (IP) address numbers.                                  |
| 6. Social security numbers.  | 15. Biometric identifiers, including fingerprints and voiceprints.           |
| 7. Medical record numbers.   | 16. Full-face photographic images and any comparable images.                 |
| 8. Health plan beneficiary numbers.  |  |
| 9. Account numbers.  |  |

A data use agreement is the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will use or disclose the PHI in the data set only for specified purposes. Even if the person requesting a limited data set from a covered entity is an employee or otherwise a member of the covered entity's workforce, a written data use agreement meeting the Privacy Rule's requirements must be in place between the covered entity and the limited data set recipient.

The Privacy Rule requires a data use agreement to contain the following provisions:

- Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule).
- Identify who is permitted to use or receive the limited data set.
- Stipulations that the recipient will

- Not use or disclose the information other than permitted by the agreement or otherwise required by law.
- Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.
- Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
- Not identify the information or contact the individuals.

#### **4.d Disclosure of PHI**

Upon receiving a subject's request, a covered entity must account for disclosures of that individual's PHI made on or after the covered entity's compliance date, unless a particular disclosure or type of disclosure (e.g., under Authorization for the disclosure, part of a limited data set under a data use agreement, prior to the compliance date) is excluded from this accounting requirement in 45 CFR 164.528(a). The accounting of disclosures starts with the covered entity's compliance date and goes back 6 years from the date of the request, not including periods prior to the compliance date. Therefore, a covered entity must keep records of disclosures for 6 years. The Privacy Rule allows for three methods for accounting for research-related disclosures that are made without the individual's Authorization or other a limited data set: (1) standard approach, (2) a multiple-disclosures approach, and (3) an alternative for disclosures involving 50 or more individuals. See 45 CFR 164.528 for more information.

#### **4.e Existing Protocols**

For research studies that began before the compliance date (April 14, 2003), a covered entity may use or disclose PHI that was created or received for research either before or after the compliance date, if the covered entity obtained any of the following prior to the compliance date: 1) an Authorization or other express legal permission from an individual to use or disclose PHI for research, 2) the informed consent of the individual to participate in the research, or 3) a waiver of informed consent by the IRB. If a waiver of informed consent was granted initially, but an informed consent is sought from the research subject after the compliance date, the covered entity must obtain the individual's Authorization as required by the Privacy Rule unless use or disclose is permitted without Authorization. Also, if informed consent was obtained after the compliance date, the covered entity must obtain the individual's Authorization to use or disclose PHI.

#### **4.f HIPAA Defined Personal Identifiers**

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
  - a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
  - b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be
  4. Telephone numbers.
  5. Facsimile numbers.
  6. Electronic mail addresses.
  7. Social security numbers.
  8. Medical record numbers.
  9. Health plan beneficiary numbers.
  10. Account numbers.
  11. Certificate/license numbers.
  12. Vehicle identifiers and serial numbers, including license plate numbers.
  13. Device identifiers and serial numbers.
  14. Web universal resource locators (URLs).
  15. Internet protocol (IP) address numbers.
  16. Biometric identifiers, including fingerprints and voiceprints.
  17. Full-face photographic images and any comparable images.
  18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

aggregated into a single category of age 90 or older.

## **Appendix 5—Training Procedures for Human Subjects Protection**

Eastern Illinois University  
Institutional Review Board  
TRAINING PROCEDURES FOR HUMAN SUBJECTS PROTECTION

1. Training for Investigators

Included in this category are faculty, faculty sponsors, staff, students conducting research for a thesis, and students conducting research as part of an independent study project. Instructors filing a course certification (Form H) for research methods courses must also take this training.

Investigators will complete either:

**“On-line Training Tutorial for Certification”** OR **“CITI Training”**

2. Training for Students Conducting Other Research

Students who conduct other research, such as that found in a research methods class, must be trained by one of the following options if their research will contribute to generalizable knowledge or be published:

Option 1: The instructor may require students to complete the online training program described under Section 1 of this Appendix. Documentation of this training option will consist of the certificate generated by the training program. The instructor is responsible for collecting these certificates from the class and submitting them to ORSP along with Form H, Certification of Courses.

Option 2: The instructor may require students to read the document “Protecting Human Subjects in Research” found on the IRB website at [http://www.eiu.edu/~grants/COMP\\_IRB.php](http://www.eiu.edu/~grants/COMP_IRB.php). This document may also be printed out and incorporated into a course syllabus. In either case, the course syllabus should explicitly mention the training as part of course requirements, and questions about the material should be included on at least one quiz or exam. Documentation of this training option will consist of submitting a course syllabus to ORSP. The instructor is responsible for submitting a copy of the course syllabus to ORSP along with Form H, Certification of Courses.

Option 3: Students may be trained by a method of the instructor’s choice, provided the essentials of proper protection of human subjects are conveyed. The course syllabus should explicitly mention the training as part of course requirements, and questions about the material should be included on at least one quiz or exam. Documentation of this training option will consist of submitting to ORSP (1) a written description of the training and (2) a course syllabus. The instructor is responsible for submitting both of these documents to ORSP along with Form H, Certification of Courses.

# PROTECTING HUMAN SUBJECTS IN RESEARCH

## ETHICAL ISSUES

Research involving human subjects poses complex ethical issues. As a researcher, it is your responsibility to educate the participants about risks and benefits, obtain their consent before involving them in your research, and keep them informed. This is called the "informed consent process." To discern the key components of informed consent, you need to understand three ethical issues of research involving human subjects:

**Autonomy** means that each person should be given the respect, time, and opportunity necessary to make his or her own decisions. Prospective participants must be given the information they will need to decide to enter a study or not to participate. There should not be pressure to participate. Special protection must be given to potentially vulnerable populations such as children, the elderly, the mentally ill, or prisoners. If the person is deemed to be incompetent, the investigator must seek the consent of a proxy. A parent or guardian must act as the proxy for the child and complete a parental permission form. Children also need to give their "assent." Assent is the affirmative agreement to participate in the study if the child is able to comprehend aspects of the research. The researcher must use a "consent document" that explains the nature of the research and any risks and benefits to the participant. A copy of the consent document is reviewed by the IRB before it is presented to prospective participants.

**Beneficence** obligates the researcher to secure the well-being of all study participants. It is your responsibility to protect participants from harm, as well as ensure that they experience the possible benefits of involvement.

The ethical considerations of risks versus benefits raise the question of **justice**. Who should bear the risk of a study and who should receive its benefits? Convenience should not be the sole factor in the selection of participants. Keep the following tips in mind when selecting prospective participants: (1) Participants should not be selected due to gender, class, socioeconomic status, or race unless justified by study objectives. (2) Teacher-student relationships always carry a perception of inequality in roles. The informed consent process should reflect the precautions taken to balance the relationship and guard against even the perception of coercion.

## RESEARCH THAT MUST HAVE APPROVAL FROM THE INSTITUTIONAL REVIEW BOARD (IRB)

Nearly all research at EIU that involves humans, human tissue, or records gathered on human subjects requires IRB review. This is true regardless of its funding source or area of research. Even courses in research methods and class assignments involving research with human subjects require IRB approval if the research results will be publicized.

Interviews by journalists conducted solely for the purpose of writing an article in a newspaper, magazine, or other media outlet are not considered research and do not require IRB review.

The IRB conducts both an initial review and continuing review of research. The initial IRB approval is based on the researcher's best estimate of the anticipated risks and benefits to the subjects. It is only after research has begun that the real risk is established and the actual risk/benefit ratio can be calculated. Responsible researchers stay involved in continuous reevaluation of a project since risks and benefits are always better understood after the research has begun.

## IRB REVIEW CRITERIA

The IRB uses the following criteria to review your research: (1) Risks to the subjects are minimized. (2) Risks to the subjects are reasonable in relation to anticipated benefits. (3) Selection of subjects is equitable. (4) Informed consent is sought from each prospective participant or his or her legally authorized representative and is properly documented. (5) Adequate preparation is taken to protect the privacy and confidentiality of subjects. (6) Adequate provisions are made for the ongoing monitoring of the subjects' welfare.

## OBTAINING INFORMED CONSENT

You should use an informed consent document to make your participants aware of the following information: (1) *Research Purpose* (2) *Research Procedures* (including time commitment and why the individual is eligible to participate) (3) *Risks* (including common risks such as inconvenience, pain, and

embarrassment). (4) *Benefits* (such as feeling good, monetary compensation, or free access to an experimental drug. Be careful not to oversell any benefits.) (4) *Alternatives* (State alternative procedures or courses of treatment, if any, that might be advantageous and available to the subject. In nontherapeutic studies, the alternative may simply be nonparticipation.) (5) *Confidentiality* (Describe the steps that will be taken to protect the participant's privacy. Also describe under what circumstances records will be made available and to whom. Include any techniques you may use for identifying data, such as creation of a numeric code. Subjects should be assured that their identity will not be disclosed.) (6) *Disclosure of Potential Conflict of Interest* (Researchers must inform their participants of any conflicts of interest they have in the research, such as a stake in a company that might benefit from the research.) (7) *Contact Information* (Give the names of people who can answer questions about the research; include the principal investigator. If the researcher is a student, also include the name and phone number of the faculty supervisor.) (8) *Withdrawal*: Always stress the fact that participation is voluntary. State that refusing to participate will involve no penalty or decrease in benefits to which the participant is otherwise entitled. Emphasize that the individual may discontinue participation at any time without penalty or loss of benefits.

A consent document must be made readable but without compromising the content. Direct it at an eighth-grade reading level. Use simple, straightforward sentences. Use commonly recognizable terms and measurement amounts. Avoid the use of jargon or technical language, and explain terms that may not be easily understood. When you have finished writing the consent document, ask a lay person to read and explain it to you. If your document is not understandable, a claim could be made that the participant did not understand what was signed

Obtaining informed consent is not merely disclosing information. The process should include time for both discussion and reflection. Participants may need time to think about their decision or to discuss their involvement with family, friends, or religious advisors. In your discussion, use open-ended and nondirective questions. Open-ended questions often begin with words such as "what," "where," "how often," "when," and "please describe." The goal is to foster an open exchange of information, rather than to quiz the participants. A few of the questions you may want to ask are: "Describe in your own words the purpose of the study." "What more would you like to know?" "Would you please explain to me what you think we're going to ask you to do?" "What are your concerns?"

## **EXCEPTIONS**

The IRB may approve a waiver of some or all of the informed consent requirements provided that: (1) the research involves no more than minimal risk; (2) the waiver or alteration will not adversely affect the subjects; (3) the research could not practically be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional information after participation.

The IRB may waive the requirement to obtain a signed informed consent if the IRB finds either of the following: (1) 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; or (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Additionally, the IRB may decide to waive signature of subjects for research that falls within one or more exemption categories.

## **UNEXPECTED FINDINGS, NEW KNOWLEDGE, AND ADVERSE EVENTS**

Unexpected results can affect the research project itself. The researcher is responsible for informing the IRB of unexpected findings (or new knowledge attributable to other research projects) that can affect the risk/benefit ratio. Adverse events are unexpected problems whose nature, severity, or frequency are not described accurately in the study protocol. It is the researcher's responsibility to analyze the impact of an adverse event. Incidents where subjects have been seriously harmed should be reported to the IRB immediately. The IRB should always be informed of any problems or accidents in the study. The death of a participant, whether related to the study or not, should also be reported to the IRB immediately.

New findings, new knowledge, and adverse effects may need to be communicated to the participants to determine whether their effects will change the subjects' willingness to participate. This may require a revised consent document.