Policy IO2.10: Institutional Review Board

Policy Type: Institutional Organization Initial Policy Approved: Current Revision Approved: Procedure Effective Date:

I. Requirements

The Institutional Review Board (IRB) is authorized to review and approve all research involving human subjects conducted under the University's auspices, regardless of funding source, including student research projects that utilize human subjects drawn from outside the class room. Dissemination of information concerning proposals will be limited to those who submit applications and to Federal regulators.

The IRB will enforce and comply with any additional requirements of federal regulation outlined by the federal Office for Human Research Protections in 45 CFR 46 but not explicitly addressed in this policy, including the enforcement of additional reporting requirements and approval conditions on researchers or other institutional staff. No requirements of this policy will be found to be abrogated or nullified due the fact that they impose additional requirements or responsibilities beyond those required by federal regulation.

II. Background and Guidelines

A. Principles and Purposes

East-West University acknowledges the value of conducting research using human subjects for the purposes of advancing basic knowledge and furthering undergraduate education. To assure adherence to state and federal regulations governing human subjects research, as well as to applicable standards of professional ethical conduct, the University accepts its responsibility to oversee the rights and welfare of human subjects involved in research conducted under its auspices. However, the primary responsibility for protecting human subjects remains with each individual who initiates, directs, or engages in this type of research.

The review of human subjects research at the University is a collaborative process intended to result in mutually acceptable research procedures which accomplish the investigator's scientific objectives while protecting the rights and welfare of research subjects. The IRB tries to be as flexible as possible and reviews each project as a separate case rather than imposing rigid requirements. Every attempt is made to take full account of all relevant factors that can affect the outcome of the review. The IRB understands its role as being primarily educational and encourages consultation at all stages of the research process.

B. Identifying Applicable Research

In-class "teaching" activities in which students are active joint investigators creating and utilizing their own research protocols, designs, and instruments are not properly labeled "research." To be classified as research, activities must meet the definition of research provided in 45 CFR 46:

> "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

(see https://www.hhs.gov/ohrp/). Certain courses that teach research techniques (e.g., Experimental Psychology or Methods of Social Research) involve procedures that approximate research but do not meet the definition of research.

"Human Subjects Research" involves the collection of data from or about living human beings. It does not include research utilizing published or publicly available documents or data sets or research on elected or appointed public officials or candidates for public office.

> NOTE: In-class activities teaching students how to create research instruments are not research, although the instruments the students create could possibly be used for future research. Designing and creating practice questionnaires, interview schedules, and experimental protocols are part of a process of learning how to do research as defined above and are not activities subject to committee oversight. However, if student investigators wish to try tools created on respondents or subjects who are not part of the research-tool-creating teams, then their activity may qualify as research, and require review. When this "research" activity moves outside a classroom setting it becomes necessary to determine whether the activity falls inside or outside of the range of activities qualifying for exemption from committee oversight.

C. Student Research

All student investigators must have a supervisor (usually a faculty member) who is responsible for insuring that the student investigators comply with all procedures of the approval process. Students' faculty supervisors must sign their proposals, certifying that the projects are under their supervision.

Class projects that require the collection of data from sources outside of the classroom setting may be reviewed as one proposal, at the discretion of the instructor. If the entire class is not using the same procedure, each student or group of students using a different procedure must submit the required information for their phases of the project, but the class project will still be considered as one proposal.

Students should design research projects, which are eligible for expedited review. Approval for such projects take very little time. Students are not, however, prohibited from conducting research in the full review category. They are advised that additional time may be required to obtain approval from the full IRB. In all cases of student research, it is the instructor's responsibility to ensure that student's use only approved ethical research procedures.

To expedite the approval of external class projects, instructors can obtain approval before the semester begins under two circumstances:

1. if all of the students are using the same procedures (e.g., a class survey) and the instructor has established the research procedures before the term starts, or
2. if the instructor submits a list of alternative procedures for approval, and the students will choose one from the list.

Projects conducted as instructional demonstrations where research subjects are not solicited from outside the classroom generally do not need to be reviewed. Care should be taken, however, to protect the rights and welfare of students who act as classroom research subjects.

III. Procedures

A. Institutional Review Board Membership

The IRB consists of 5 members appointed by the Chancellor with the advice of the Faculty Council as follows:

- 2-3 faculty members, selected from different programs and serving staggered 3-year terms.
- 1 non-University member for a 1-year term.
- 1-2 representatives of an administrative department other than the faculty

The IRB shall follow the guidelines set forth in federal policy 45 CFR 46. The IRB shall include IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. A majority of the committee's members must have had prior experience conducting

research with human subjects. The IRB shall not consist entirely of one gender. No committee member may participate in the review of research for which he or she is either a principal investigator or faculty supervisor.

The IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

The committee shall select one member to serve as its Chair for a one-year term. The chair's term may be renewed for up to three consecutive terms.

B. Planning Consultation

A person who plans to conduct research involving human subjects should consult with the IRB or its designee as early in the research design phase as is reasonably possible before formal approval is requested. A project's potentially problematic aspects can be identified early and various design alternatives considered. At this time, disposition can also be made regarding the proposed project's eligibility for exempt status. Suggestions can be offered which will help facilitate project approval.

C. Review Process

The principal investigator initiates the review process by completing a formal application (See attached sample). If the PI is a student, the application must be signed by a supervising faculty member. The applicant should respond to all questions in the form of a brief (2-3 pages), typed statement. Copies of all research instruments including survey forms, observation protocols, consent forms, etc., should be attached to the application. It is essential to attend closely to the following issues: informed consent, voluntary participation, confidentiality and/or anonymity of data sources, and debriefing, when required. Rationales explaining each should be included.

1. Determining IRB Jurisdiction

Initial determination as to whether a research project should be considered human subjects research should be made by the project investigator (PI). The PI should consult with the IRB for advice concerning this question. Final authority for making this determination rests with the IRB or its designee.

As a rule, research utilizing local campus data gathered solely for internal institutional consumption does not require review (e.g., course evaluations, routine institutional research projects, or personnel evaluations conducted for administrative purposes). If, however, there exists any probability that the results of such research will be disseminated in any way to any external group, organization, government body, or communications medium, then the research must receive prior committee approval.

2. IRB Review

The review of human subjects research applications is confined solely to questions concerning procedures affecting the rights and welfare of the subjects. The review of such applications does not imply evaluations of the content or scientific merit of the project, unless subjects are found to be "at risk."

Full review normally takes two weeks. Expedited review normally takes three class days. The committee will provide written responses to all applications, and they must be received by the PI before data collection can begin.

If an investigator is unhappy with the outcome of the review, he or she may appeal the decision to the full IRB, after consulting with the chair of that committee.

D. Standard of Review

Certain categories of research activity involving minimal or no risk to human subjects do not require full committee review and approval. With the exception of projects excluded under the definition of human subjects research, such projects must be reported to the committee to enable it to meet its federally mandated obligations.

Once determination has been made that a proposed activity constitutes human subjects research subject to review, it will be reviewed under one of two categories, Expedited Review or Full Review. The relevant procedures are described below. Each researcher makes an initial determination regarding the appropriate review category, although the IRB or its designee may require review under the other category. The researcher may request a higher level of review than that required.

1. Exempt Category

Determination of exempt classes of research is based on the following:

Some research is explicitly exempt from the regulations requiring IRB review. Examples include educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation; and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.

Student and faculty research activities which meet the criteria outlined above are exempted from IRB committee oversight beyond the need to certify to the committee that:

- The research involves the use of existing data, documents, or specimens, where no identifying information will be (or has been) recorded that can link subjects to the data. (It is not necessary to report to the committee the use of published documents or data sets that meet this criterion.)
- Their activities produce and/or record no identifying information that can link subjects to the data. (Investigators certify to the committee that their research design meets this criterion and submit an abstract of their design substantiating this fact.)
- Disclosure of the data will not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation. (Investigators certify to the committee that their research design meets this criterion and submit an abstract of their design substantiating this fact.)

In addition, the investigators must certify that they have taken measures sufficient to assure that they have met the three essential criteria of informed consent, voluntary participation, and minimal risk.

Investigators who conduct exempt classes of research must provide the IRB completed applications for their records certifying that the research qualifies for exemption according to the preceding criteria. This information enables the IRB to maintain required documentation.

2. Expedited Review Category

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after Full Review in accordance with this policy.

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

1. Some or all of the research found by the reviewer(s) to involve no more than minimal risk, and appearing on appearing on the list of categories of research designated by the Secretary of Health and Human Services and available at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html
2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Research in this category generally does not require written documentation of informed consent, but oral consent is required for all research involving direct interaction with subjects. The investigator must be familiar with Informed Consent procedures. All research in schools requires written permission from the school district.

3. Full Review Category

All other proposed research requires a Full Review. The designated reviewer of an Expedited Review may require full review of any research as an alternative to approval. Even if a proposal might otherwise qualify for another category of review, a full review is required if it involves:

- Research that could put subjects at more than minimal risk.
- Research involving psychological or physiological intervention.
- Non-curricular, interactive research in schools.
- Research involving deception.
- Research on vulnerable populations, e.g., minors, prisoners, and the mentally incompetent.
- Research conducted outside the United States, regardless of the procedures involved.

E. Full Review Conditions of Approval

IRB project approval signifies only that the committee agrees that the proposed research procedures adequately protect the rights and welfare of the research subjects. It should not be taken to indicate University approval to conduct the research.

IRB approval applies only to the procedures described in the research proposal. Investigators must secure prior approval from the IRB for any procedural changes that will materially affect the welfare of a project's human subjects. Investigators must also report to the IRB any problems that arise regarding the use of human subjects.

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

3. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
4. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
5. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
6. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
7. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
8. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

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

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

In addition to the basic requirements for conducting human subjects research, specific research topics often present additional concerns relating to the rights and welfare of research subjects. The IRB reserves the right to delay approval of protocols in these topics until additional information addressing those concerns is received.

Project approval is valid for one year only. Investigators must request a continuation for the approval yearly if the research activity lasts more than one calendar year. No more than two (2) continuations will be granted for a given project. After three years, the project must be resubmitted for reapproval.

F. Subsequent Reviews

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

G. Suspension or Termination of IRB Approval

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

IV. Policy Owners

- Provost

V. Related Documents

- IO2.10 Appendix A: IRB Application for Research with Human Subjects
- IO2.10 Appendix B: Guidelines for Informed Consent
- IO2.10 Appendix C: Informed Consent Checklist
- IO2.10 Appendix D: Informed Consent Agreement Template
- IO2.10 Appendix E: Socially Sensitive Research
- IO2.10 Appendix F: Questionnaires
- IO2.10 Appendix G: Deception
- IO2.10 Appendix H: International Research

VI. Definitions

VII. Revision History

IO2.10 Appendix A: IRB Application for Research with Human Subjects

Be sure to attach any questionnaires and consent forms and other supplemental information to ensure your application gets processed in a timely manner.

This application is for (check one):

☐ **EXEMPT f**rom Review (see required documentation on page 4, POLICY booklet)	☐ **EXPEDITED** Review	☐ **FULL** Review

Principal investigator (student name if student- led research):

Name: _____ Email address: _____

Telephone: _____

Project Title: _____

This project is being concluded as (check one):

This project is being funded by (if applicable): _____

DIRECTIONS

In considering applications, the IRB committee will want to see the following issues addressed in a brief (e.g., 1-2 page) statement attached to this Application. The Committee's general concern is the safety and well-being (both physical and psychological) of human subjects in research. Failure to answer all questions can result in the proposal being returned to you for further information. Please allow at least two weeks for review. A member of the Review Committee will contact you with a decision in writing. Do no collect data prior to this time. The application number you will be given must appear on all documents such as survey forms, reports, and summaries related to this research project. Please type/computer print your responses.

1.) What is the purpose of the study? Please provide a brief description of the hypothesis and issues under consideration

2.) What subject group(s) will you work with, and how will you recruit them?

3.) What information will you offer subjects about your study before they participate? (E.g., how will the study be described, what incentives will be offered?) Except in special circumstances (which you must describe and justify), potential subjects should be given enough information about the project to make an informed decision about whether to participate. Subjects should not be coerced or pressured, and should be told that they are free to withdraw from participation at any time.

4.) Does the study involve children or others for whom additional consent will be necessary? If so, how will you obtain this consent? (Note: Research involving children normally requires written permission from parents or guardians, in addition to written permission from a school principal or other institutional director, if applicable. Describe how you will seek this permission, attaching copies of proposed permission/consent forms where appropriate.)

5.) How will you plan to protect the privacy and/or anonymity of your subjects, and the anonymity of the data after the study? Please specify how you will destroy the data. If you do not intend to destroy the data, how will it be stored and protected?

6.) Does the study involve deception? If so, explain why deception is necessary and how you will address any potentially harmful consequences.

7.) What are your experimental procedures? Are there any potentially harmful effects that might occur in your study? If so, what are they, and how will you guard against them or seek to minimize them?

8.) If appropriate, how will you debrief your subjects after their work is completed?

9.) Please attach a copy of any survey, questionnaire and/or consent form(s) you plan to use.

IO2.10 Appendix B: Guidelines for Informed Consent

Unless otherwise authorized by the IRB, no investigator may involve a human being as a research subject under the auspices of the University unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative.

"Informed consent" means each individual asked to participate as a subject in a research project must be able to choose freely whether to participate. When appropriate, the subject's legally authorized representative must be asked, and must be able to choose freely. Free power of choice means the investigator must not coerce or constrain the potential subject via any form of force, fraud, deceit, or duress. Properly informing the participant consists of the following:

1. Making certain the subject has the legal and mental capacity to give consent. Should the subject not have this capacity, the subject's representative must give consent.
2. Giving the subject or the representative sufficient opportunity to consider whether to participate.
3. Providing language understandable by the prospective subject or representative the information necessary to consider whether to participate.
4. Ensuring via points 2 and 3, that no possibility of coercion or undue influence exists.
5. Ensuring the prospective subject or representative that none of the subject's legal rights have been waived or appear to have been waived.
6. Ensuring that the investigator, the sponsor, or the institution or its agents have not been released nor appear to have been released from liability for negligence.

In projects where subjects are determined to be at risk:

- The actual procedure utilized in obtaining "legally effective informed consent" must be fully documented. This is accomplished by using a written consent form embodying all of the elements of information required for the project.
- The consent form must be read by or to the person signing the form and the signed form must be maintained in the investigator's files for an indefinite period of time following completion of the study.

In projects where subjects are determined to be at no more than minimal risk:

- Provision may be made for oral or written presentation and consent. Under this procedure, the subject is informed of those basic elements of consent which are applicable to low risk procedures and no signed document is necessary on the part of the subject.
- A sample copy of the presentation must be approved by the IRB.

A major exception to this policy occurs when research involves minors as subjects, in which case, written parental consent is usually required.

In seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. 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;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. 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.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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; and
6. The approximate number of subjects involved in the study.

In some cases, 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 entirely waive the requirement to obtain informed consent, provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

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

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; and

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

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

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

IO2.10 Appendix C: Informed Consent Checklist

As a researcher develops the consent form or procedure, the following information should be included.

- State that the study involves research.
- Explain the purposes of the research and the expected duration of the participants' participation.
- Describe the procedures that directly involve human participants, and identify any procedures that are experimental.
- Describe any foreseeable risks or discomforts to participants.
- Describe any benefits to participants or to others that may reasonably be expected from the research.
- Disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.
- Describe the extent to which confidentiality of records identifying participants will be maintained, where the records will be stored, how long they will be stored, and who will have access to the records.
- For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs. If compensation or treatments are available, they should be described. The procedures for obtaining additional compensation/treatment information should be stated.
- Identify who participants can contact for answers to pertinent questions about the research, and participants' rights including the faculty supervisor (for student=led research), the IRB chair, and a resource in case of discomfort (e.g., SGA).
- State that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.
- If you intend to audio- or videotape an interview, include a separate signature lines for consent to the audiotaping or videotaping in addition to the signature line for general consent to participating in the project.

IO2.10 Appendix D: Informed Consent Agreement Template

Header on Template:

Informed Consent	**Template for Creating an Informed Consent Letter**

Footer on Template:

Page 13 of 20	**Participant's Initials: _____**

Note to Investigators:

Consent to participate must be obtained from the subjects if possible: Attach a copy of your written Informed Consent form to your IRB request. If it is not possible to obtain a written consent form, describe, in written form and full detail, the explanation which will be given to the subjects and through what means you will provide this explanation: orally, use of an interpreter, other. In this case, a shortened written consent form may be appropriate. If written consent is completely anonymous or impossible to gain without maintaining confidentiality, please consider a waiver of consent.

When creating Informed Consent forms, investigators are encouraged to keep language and vocabulary as basic and straightforward as possible. Investigators are also encouraged to use this template when creating informed consent letters. Use of alternative wording or format is permitted, but doing so may slow down the review process. All sections of the consent form, except the "Consent" section, should be written in second person ("You are invited...").

Headers should include "Informed Consent" followed by the title of the study (e.g., the header in this document). Footers should include page numbers. If your consent letter is more than one page, the footer should also include a space for the participant's initials (e.g., the footer in this document).

Be sure to include any basic components of informed consent that are appropriate to your study. If components apply to your study, they must be included. If you have any further questions, contact a member of the EWU IRB.

***Information in italics is for your information and should be deleted from your actual consent form. Material in brackets should be replaced with relevant information. ***

TITLE OF STUDY

[Insert title]

PRINCIPAL INVESTIGATOR

[Name]

[Program]

[Address]

[Phone]

[Email]

PURPOSE OF STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to [Briefly describe purpose of study.]

STUDY PROCEDURES

List all procedures, preferably in chronological order, which will be employed in the study. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using non-technical language. Explain all procedures using language that is appropriate for the expected reading level of participants.

State the amount of time required of participants per session, if applicable, and for the total duration of the study.

If audio taping, videotaping, or film procedures are going to be used, provide information about the use of these products.

RISKS

List all reasonably foreseeable risks, if any, of each of the procedures to be used in the study, and any measures that will be used to minimize the risks.

You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

BENEFITS

List the benefits you anticipate will be achieved from this research. Include benefits to participants, others, or the body of knowledge. If there is no direct benefit to the participant, state so. For example, "There will be no direct benefit to you for your participation in this study. However, we hope that the information obtained from this study may…."

When applicable, disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.

CONFIDENTIALITY

Your responses to this [survey] will be anonymous. Please do not write any identifying information on your [survey]. OR For the purposes of this research study, your comments will not be anonymous. Every effort will be made by the researcher to preserve your confidentiality including the following:

[State measures taken to ensure confidentiality, such as those listed below:

- Assigning code names/numbers for participants that will be used on all research notes and documents
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.]

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

COMPENSATION *If there is no compensation, delete this section.*

Indicate what participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of credit or compensation. State whether participants will be eligible for compensation if they withdraw from the study prior to its completion. If compensation is pro-rated over the period of the participant's involvement, indicate the points/stages at which compensation changes during the study.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, please contact the Institutional Review Board at (865) 354-3000, ext. 4822.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the

relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

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*Note**:** Please delineate the "Consent" section of the Informed Consent Form by drawing a line across the page (like the one above this paragraph). This delineation is important because the consent form grammar shifts from second person to first person, as shown in this example.*

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

IO2.10 Appendix E: Socially Sensitive Research

I. Risks.

A first planning step for any researcher doing "greater than minimal social risk" research is to outline fully all the potential social and physical risks. In this kind of research, risks often include:

- Loss of confidentiality about the identity of the volunteers.
- Loss of confidentiality about the information given by the volunteers.
- Triggering internal conflicts within volunteer-respondents, e.g., emotional reactions or needs.
- Triggering external conflicts of social, stigmatizing, or physical damage against volunteers, e.g., assault by abusing partners or legal action by authorities, if study participation in the study became known.

In some research (e.g., about fetal alcohol syndrome), the people at risk include not only the subjects of the research, but third parties (e.g., the mothers) as well.

The next step is to ensure that the research methods minimize the risks to the volunteers and any others.

II. Confidentiality.

One of the most important risks in socially sensitive research is the unanticipated effect of a breach of confidentiality. The researcher must make every effort to try to ensure confidentiality; it is suggested relying on anonymity whenever possible. Although research data must be kept confidential in all types of research, this is especially true in socially sensitive research. With some research topics, such as sexuality or criminality research, not only is the information sensitive, but the subjects' presence in the study can itself be a sensitive piece of information. It is important to note that demographic variables can sometimes identify subjects as well as names and other obvious identifiers. When anonymity is not feasible, then the researcher must demonstrate to the IRB how confidentiality is being assured. Depending on the sensitivity of the subject matter, extra care should be taken to ensure that subjects cannot be identified. At times, coding schemes should be used to minimize the risk of a confidentiality breach (see section below on Questionnaires).

III. Emotional Risks.

To minimize emotional risks triggered by the research itself, the research must take steps before, during, and after the intervention with the subject to assess the emotional impact of the material, to assess the emotional state of each subject, and to deal with any emotional reaction which might take place. Often this includes pilot testing research materials, extended listening, ventilating discussion, and referral to counseling services. (Cooperation of counseling services must be obtained before approving the research.)

IV. Social Risks.

If the research concerns illegal behavior, e.g., a study of HIV and risk factors among prostitutes, the researcher may need to have the cooperation of local legal authorities or a federal Certificate of Confidentiality. If there is a risk of triggering retribution by others, such as violence by abusing partners, the researcher must insure that nothing given can identify a person as a respondent. Risk to the community must be minimized, often by researchers and community agreeing about publication, e.g., whether to identify the community.

V. Benefits.

Researchers should also attempt to maximize benefits of the research to each volunteer and community. They must ensure availability of services to the volunteers. For a survey of fetal alcohol syndrome, for instance, researchers should link themselves to established, or help establish, real services of prevention and treatment. At the very minimum, subjects should be provided with sources of help and support available in the community.

VI. Coercion.

Research involving emotionally-vulnerable subjects should avoid coercion by caregivers. Many patients who are dependent on caregivers' help may feel that refusing to take part in research will lead to loss of the care they need, in spite of the written "no-coercion disclaimer" in consent forms. One way to avoid the problem is to emphasize repeatedly the freedom to refuse. Another is to have at least the consent, and sometimes the research as well, done by people other than the caregivers.

IO2.10 Appendix F: Questionnaires

Questionnaires are probably the most common research technique used in conducting human subjects research at the University. As a result, some researchers may tend to overlook various of the human subjects' concerns, which can hold up approval of a questionnaire study.

I. Consent.

Although most questionnaire studies do not require a written consent form, researchers must still ensure that subjects are giving informed consent to participating in the study. All questionnaires must include some form of cover sheet containing instructions to subjects, which provides subjects with the same information which would be normally be included in a consent form. In particular, subjects need to be informed:

- About the nature of the questions they are going to be asked (especially any questions pertaining to sensitive topics)
- That they can skip any question they chose not to answer
- About the procedures in place to protect their confidentiality

II. Confidentiality.

In even the most innocuous questionnaire research, all research information must be kept strictly confidential. Complete anonymity is the best protection from breaches of confidentiality. However, researchers must be aware that demographic variables can, in some circumstances, be identifiers. Anything which allows an individual subject to be identified is an identifier, and this kind of information must be protected. The degree of protection required depends upon the sensitivity of the information obtained. Another overlooked point pertains to the procedure used for the collection of completed questionnaires. Sometimes, individuals collecting questionnaires can identify who turned in which forms. For sensitive information, it would be best if forms were returned in sealed envelopes.

III. Subject Coding.

One method commonly used to protect confidentiality is to use subject codes rather than names or other identifiers. Care must be taken, however, to ensure that the code cannot be used as an identifier. For example, a frequently used code is the last four digits of the subject's Social Security number. Unless an extremely large number of subjects are being used, this number can still be used to identify an individual subject. Arbitrary or random codes are much better at protecting confidentiality. On the other hand, when different sets of data for a single subject must be linked, arbitrary codes are usually unsuitable, because subjects will likely forget them. In such cases, the best method is to provide subjects with a formula they can use to generate a unique personal code which will generally result in the same code number each time the subject uses it.

The following is one example of a workable formula:

- First & Second letters of your letters of your mother's first name
- First & Second letters of your letters of your father's first name
- Month you were born
- Date you were born

For example, if your mother's name was Sally and your father's name was George and you were born on May 1, you would enter:

S A G E 0 5 0 1

IO2.10 Appendix G: Deception

Sometimes information must be withheld from subjects to ensure natural reactions. Since this is, inherently, a breach of the concept of informed consent, the IRB has serious concerns which must be met before such research can be approved. These include:

- Deception cannot be used in any study where there is risk to subjects.
- No information can be withheld from subjects which could significantly affect their decision to participate (i.e., the subjects would likely participate anyway if they knew all of the information).
- The terms "Informed Consent" or "Consent Form" should not be used in deception research since there is no informed consent in this type of research.

All subjects should be debriefed as to the true nature of the research after their participation. This debriefing should address the reasons for the deception and reassure subjects that their reactions were normal. If believing erroneous information is not likely to be harmful to subject, the debriefing can be delayed until all subjects have completed their participation. Care should be taken not to inform subjects about information which might damage their self-esteem or hurt their feelings.

IO2.10 Appendix H: International Research

Research in foreign countries also presents special concerns regarding the rights and welfare of human subjects. In general, the IRB accepts the standards of the location in which the research is taking place; unless those standards grossly violate the basic principles of ethical human subjects research. In addition, the following issues apply to international human subjects research:

- All human subjects research in foreign countries must be reviewed by the full IRB, regardless of the nature of the research.
- All materials, including consent forms, must have English language translations included with the protocol.
- Documentation of permission from local authorities is generally required before approval can be granted.