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I. Introduction and Mission

Consistent with its Mission, Lewis University recognizes the ethical, legal, and federally mandated responsibilities to safeguard the rights and welfare of human participants in all research conducted under its sponsorship or on its premises. Through the integration of knowledge, wisdom, and justice, members of the Lewis University community affirm their respect for the pursuit of learning, careful reflection, and support of the dignity of all persons. The integration of these values provides the basis for the Institutional Review Board for the Protection of Human Participants (IRB) at Lewis University.

The federally mandated responsibilities of Lewis University come from the Department of Health and Human Services (DHHS), and are outlined in the Belmont Report and Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46.) These regulations mandate that all institutions engaged in research with human participants provide dual protections of Institutional Review Board for the Protection of Human Participants and informed consent.

This handbook provides information regarding the policies and procedures governing research with human participants. It is applicable to all faculty, staff, and students conducting or sponsoring research, who are considered members of the Lewis University community. *Individual researchers may not decide if their research requires review by the IRB* since all research with human participants is subject to consideration by the IRB.

Required Training

Evidence of formal training in research ethics for all researchers and their supervisors is mandatory. **A formal training module is available via the Internet: <http://phrp.nihtraining.com>**

This module guides the participant through key concepts involving research with human participants and results in a printable certificate. **Administrators, deans, department chairpersons, program directors, and individual investigators** are responsible to familiarize themselves with the policies and procedures in this manual and to complete an online training module or another training activity provided by Lewis University or another institution. Some individuals may have such a certificate from previous research or doctoral work. **A completion certificate for these individuals must be on file with the Institutional Review Board.**

Goals

The goal of the Lewis University Institutional Review Board (IRB) is to assure that, in research involving human participants, the rights and welfare of the participants are adequately protected. The IRB will review all planned research involving human participants prior to initiation of the research, approve research that meets established criteria for protection of human participants, and collaborate with principal research investigators to ensure that human participants are indeed protected. All academic and administrative units are covered by these guidelines and will submit proposals to the IRB.

Authority

The review process will be the same for all research involving human participants supported or otherwise subject to regulation by any federal department or agency, sponsored by any other extramural entity or initiated and funded with Lewis University. The authority held by the IRB includes decisions to approve, disapprove, require modifications, suspend, and terminate research projects involving human subjects.

The Lewis University IRB maintains primary approval rights, e.g., even if a project has been approved by another institution's IRB, the proposal must go through the review process at Lewis University.

Committee Membership

Federal policy requires that an IRB must have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their racial, cultural and community backgrounds to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas.

No IRB, however, may consist entirely of members of one profession.

The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. An IRB may, in its discretion, 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.

In order to meet the federal policy described above, members of the Lewis University IRB should possess varied backgrounds and expertise and include at least one member not affiliated with the University.

The Full Lewis University IRB consists of one voting representative from:

- College of Arts and Sciences
- College of Business
- College of Education
- College of Nursing and Health Professions
- The Institutional Research Office or a designee of the Chief Academic Officer of the University
- The community outside of the University
- An outside expert (or experts) when appropriate

IRB members from the four colleges are members of their respective Local (College) Review Board (LRB). Members of the LRB will be selected from regular faculty members in that College. The LRB will consist of three

or more members, one of whom will represent his or her college at each meeting of the University IRB. The responsibility for serving on the IRB may be shared among the LRB committee members on a rotating basis.

Each College will determine the membership and selection procedures for its LRB members and representative to the IRB. The administrative representative for the IRB is from the Office of Institutional Research and Planning. The University representatives, in conjunction with the Chief Academic Officer, will identify appropriate methods for the selection of community representatives or experts (when appropriate.)

Record Keeping

The IRB is scheduled to meet once a month to review research proposals or policy as needed. The minutes of its meetings are filed with the Office of the Provost.

A database of individuals who have been trained in research with human participants is maintained in the Office of the Provost.

Local Review Boards and the Institutional Review Board have the responsibility to maintain a record of all requests for review and the decisions regarding those requests. Research requests reviewed by LRBs are periodically sent to the Institutional Review Board Chair with an accompanying determination form for storage. All research requests that are reviewed by the LRBs or the IRB are catalogued and stored in the Office of the Provost.

All forms to be used in the Review process are available at the IRB site on Blackboard.

University Contacts

Office of Provost
(815) 836-5639

II. IRB Background and Guidelines

The Purpose of IRB and LRB

The Lewis University Institutional Review Board (IRB) is a committee of faculty and staff members who represent the four colleges and administrative services at Lewis University. The purpose of an IRB is to protect the rights of individuals who participate in student, faculty, or administrative research with human subjects. The focus of IRB oversight is to ensure the appropriate treatment of research participants through communication of research intentions and potential risks. To that end, researchers must provide the IRB with clear information about the purpose for their research, the involvement of participants, and the means for informed consent/assent of those participants. It is not the purpose of the University IRB to monitor whether research is warranted or if the research design, methodology and measurement instruments are sound; those questions can be effectively reviewed by faculty members, department committees and Local Review Boards for the individual colleges.

The Local Review Boards (LRB) for each college are subcommittees of the University Institutional Review Board. The purpose of each LRB is also to monitor the rights of individuals who participate in research. Though research guidance would generally be the responsibility of department leadership, the LRB of each college may assist departments with decisions about the need for IRB review, questions about methodology and the provision of review at the exempt level. The LRB is designed to provide direction and preliminary

review to its college members so that expedited and full review requests are likely to move successfully through the process.

Definitions

Is it research?

There are many ways in which students, faculty and staff members at Lewis University may interact professionally with other individuals. As representatives of Lewis University and our respective disciplines, we have a responsibility for treating those individuals ethically and equitably; though not all of our interactions - even those that gather information - can be considered research. Though all of our interactions with individuals require fair treatment, only **research** requires IRB/LRB review.

The standard for defining **human participants research** is found in federal guidelines known as 45 CFR 46.102 and is called the Common Rule. According to these guidelines, **research** is defined as “**a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.**” **Human participant is defined as “a living individual about whom an investigator conducting research obtains:**

- 1. data through intervention or interaction with the individuals**
- 2. identifiable private information**

The two key issues in these definitions are the concepts of **generalizable knowledge** and **identifiable private information**.

Examples of Research Requiring Review

Some examples of interactions that require some level (exempt, expedited or full) of review include:

1. Lewis University students who conduct research using human participants for their thesis or dissertation must submit their proposal for review and approval prior to beginning data collection, since the nature of such work suggests the dissemination of findings through presentation or publication.
2. Lewis University faculty who conduct research using human participants must submit their proposal for review.
3. Lewis University students or faculty who use their Lewis University affiliation in publishing or presenting the results of research using human participants, must submit their proposal to the Lewis University review process, even if the study may originate with another university or organization. This is required even if the proposal has been approved by another institution. Copies of the approval by another institution should be submitted with the review request.
4. Individual class projects conducted by undergraduate or graduate level students should be submitted for review if there is any uncertainty whether the results might contribute to generalizable knowledge and might be presented outside the classroom environment by presentation or in writing.

The IRB considers certain groups of human subjects particularly vulnerable

in a research setting. These include: persons under the age of 18, prisoners and other confined/captive audiences, pregnant women, fetuses, individuals who are mentally disabled, and those who are economically or educationally disadvantaged. In reviewing research projects, the IRB will scrutinize those that systematically select participants from these groups as participants to ascertain that their use is adequately justified and that safeguards are implemented to minimize risks unique to each group. It is understood that participants in the general population may be pregnant, have a mental disability or be economically or educationally disadvantaged without our knowledge. It is when persons with those characteristics are specifically chosen to be studied that the IRB shows special concern for their rights and welfare.

Examples of Work Not Requiring IRB/LRB Approval

1. Class projects with human participants are often designed for teaching students about research methodology, not for the purpose of contributing to generalizable know or for presentation outside of the classroom environment. Teaching students how to conduct ethical research is an important part of many graduate and undergraduate programs. In these cases, IRB review is not needed **unless the studies investigate opinions, behaviors, and/or experiences regarding sensitive topics or with vulnerable groups such as, but not limited to, children, alcoholics, pregnant women, or prisoners; the project links the participant's name to the data in any way; or the project will**

be externally published or presented in a public forum. (Please see the list of sensitive issues at the end of this section). In conducting a classroom human participant research project, it is strongly recommended that the faculty member and student researchers complete the ethics training module and keep the certificate of completion on file for the semester. Student researchers should complete **Form A Request for Institutional Review and Assurances** and submit it to the instructor. If the instructor believes that the proposal deals with sensitive issues or vulnerable groups or that the results of the research are likely to be presented beyond the classroom, the student and faculty member should complete the appropriate additional form – **Form B Request Review or Form C Request for Full/Expedited Review** and send the request to their College LRB. **All independent class projects, senior theses, Masters and Advanced Degree research proposals that involve human subjects must be independently submitted for IRB review.**

2. Internal data collection for administrative or educational purposes, such as teaching evaluations, instructional rubrics, programs or presentations do not require review.
3. Surveys issued or completed by University personnel for the purpose of improving or developing services and programs of the University do not require review, as long as the privacy of the subjects is protected, the confidentiality of individual response is maintained, and

participation is voluntary, **unless the studies investigate opinions, behaviors, and/or experiences regarding sensitive topics. (See list of sensitive issues at the end of this section).** Any reports based on the data must be kept internally, unless the study has been reviewed.

4. Clinical practice designed to provide diagnosis, treatment or therapy to an individual does not need review as long as the intent of the practice is to enhance the well being of the client and the data are not used to contribute to generalizable knowledge or presented outside the clinical setting.
5. The field of journalism has well-established guidelines to protect human subjects. The field emphasizes public service and its first obligation is to the public. Journalistic ethics require that interviewees be clearly identified and that their quoted remarks are accurate. At the same time, confidentiality is granted in situations in which individuals would experience punitive responses if names were known. Journalists' first obligation is to the public's right to know. Surveys and interviews conducted by journalists are not considered research.
6. Biography or oral history involving a living individual that is not generalizable beyond that individual.

Sensitive topics of research that would require approval from the LRB/IRB may include, but are not limited to:

- 1. Sexual orientation**
- 2. Intimate partner violence**
- 3. Rape**
- 4. Incest**
- 5. Sexual molestation**
- 6. Sexual behaviors or attitudes**
- 7. Substance use and/or abuse**
- 8. Illegal behavior**
- 9. Eating disorders and behaviors**
- 10. Attitudes or practices or contraception, abortion and/or pregnancy**
- 11. Questions regarding mental disorders**
- 12. Prejudice and/or discrimination**
- 13. Religious orientation and/or view**
- 14. War or combat experiences of veterans**
- 15. Questions which may place a student in jeopardy with respect to grades**

Approval of Research

The IRB/LRB is authorized and organized to review any and all type of

research in which human participants may be at risk, including projects that are not subject to federal oversight provisions.

An application for approval of a new project is to be submitted to the LRB and a review determination must be made before beginning the research. Likewise an application for approval of a renewed project is to be submitted before the approved expiration date from the previous year. Approval cannot be given for more than one year at a time.

The six criteria that IRB/LRB must consider before approving any project which utilizes human participants are:

- 1. Are the risks low and reasonable in relation to the benefits?**
- 2. Are the risks minimized?**
- 3. Is the selection of participants equitable and free from unwarranted pressures?**
- 4. Do informed consent and debriefing forms adequately describe the research to subjects?**
- 5. Is the privacy or confidentiality of the subjects protected?**
- 6. Is the project monitored during the study to allow mid-study adjustments in risk-related procedures?**

At any time during the course of a project, should changes in the protocols, sponsor, principal investigator or informed consent procedures become necessary, a memo must be sent to the IRB/LRB Chair for authorization to continue under the revised conditions. If any unpredicted risks or consequences emerge during the research, the research

should be suspended and a memo must be sent to the IRB Chair for authorization to continue.

Local Review Board (LRB)

Each college will establish a Local Review Board. Lewis University policy requires that all research involving human participants must first be reviewed by the LRB of a college. The LRB serves as oversight of domain expertise for the evaluation of the quality and value of the proposed research. If there are concerns with the design or intent of a research proposal, the LRB should convey the LRB's finding to the student researcher and the faculty advisor who will then work with the student. In the case of a faculty researcher, the LRB would work with the faculty member. The faculty member or faculty sponsor/committee has the primary responsibility for ensuring the quality of the research proposal. The LRB is charged with assisting the University Institutional Review Board (IRB) in their review of the methodological and ethical aspects of research involving human participants. The LRB provides a peer-review service for the researcher and the IRB.

The LRB may complete review requests that are in the Exempt category of review. If the LRB determines that the research request requires a higher level of review, such as Expedited or Full, the LRB should review and then pass the request on to the Chair of the IRB with a recommendation about the type of review still required and an explanation.

The LRB is charged also with the responsibility of notifying the IRB and the investigator's department if the research participant's rights to fair and ethical treatment are compromised in

any manner. The LRB provides local oversight of the conduct of the research.

The administrative unit does not currently have an LRB. Administrative research proposals that require review will be first reviewed by the Administrative representative and the Chair of the IRB and then passed up to the IRB if additional review is necessary.

Timely Action

Reviews of proposals will be conducted in a timely manner. The University Institutional Review Board has developed a calendar of regularly scheduled meetings with deadlines for submitting proposals for Full review. This schedule would then allow Local Review Boards in the colleges to schedule their work in order to meet the next IRB deadline.

Research recommended by the LRB for Exempt status will be reviewed by members of a researcher's college LRB

Research recommended for Expedited status will be reviewed by the college LRB and will be sent on to the IRB Chair for additional review by an IRB member from another college.

Proposals that require a full IRB review will be discussed at a regularly scheduled monthly meeting of the IRB.

This time frame is subject to variation based on the number of projects submitted, their complexity, or the issues involved. Responsibility for changes recommended by the IRB will normally be delegated to the university representative responsible for conducting or supervising the research. Proposals, therefore, will need to be resubmitted only when substantive

changes in design or methods are requested by the IRB or chosen by the researcher.

Levels of Research Review

Exempt Review

Research that is Exempt fits into categories that represent studies that present minimal risk to participants, such as anonymity of responses and use of data that exists or is publicly available. It does not mean that the study is exempt from review. Exempt reviews are conducted by the college LRB.

Investigators must complete and submit **Form A, Request for Ethical Review Form and Assurances, Form B, Request for Exempt Review for Human Participants Research** and either submit a certificate showing that a training module has been completed or indicate that it is already on file with the Office of the Provost. In addition, any documents requested in the above forms should be attached. (See Appendix for forms.)

Common examples of exempt research are:

1. Anonymous surveys
2. Educational tests
3. Studies using human subject data that is publicly available
4. Observation of public behavior that does not put subjects at risk

Following is a more detailed description of Exempt Review and examples from Federal Guidelines that you may wish to review for further information.

Categories of Exempt Research That May Receive Exempt Review

The Department of Health and Human Services allows for exemption from the Policy for Protection of Human Research Subjects in certain categories of research. These categories include (HHS Policy, CFR Title 45, Part 46, Section 101):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - research on regular or special education instructional strategies OR
 - research on the effectiveness of, or the comparison among, instructional techniques curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior, unless:
 - information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND
 - any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation

of public behavior that is not exempt under category 2 of this section, if:

- the human participants are elected or appointed public officials or candidates for public office;
OR
 - 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 subject cannot be identified, directly or through identifiers linked to the subjects.
 5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
 - public benefit or service programs;
 - procedures for obtaining benefits or services under those programs;
 - possible changes in or alternatives to those programs or procedures;
OR
 - possible changes in methods or levels of payment for benefits or services under those programs.
 6. Taste and food quality evaluation and consumer acceptance studies:
 - if wholesome foods without additives are consumed
OR
 - if a food is consumed that contains a food ingredient at or below the level

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.

Expedited Review

Research at Lewis University that can receive an Expedited Review fits into categories that involve collection of samples and data in a manner that is not anonymous, but involves no more than minimal risk to participants. Expedited reviews are conducted by the college LRB and one other IRB member from another college.

Investigators must complete and submit **Form A, Request for Ethical Review Form and Assurances, Form C, Request for Expedited or Full IRB Review for Human Participants Research** and either submit a certificate showing that a training module has been completed or indicate that it is already on file with the Office of the Provost. In addition, any documents requested by the forms should be attached. (See Appendix for forms.)

Common examples of Expedited research are:

1. Studies including blood samples taken from healthy volunteers
2. Studies involving moderate exercise by healthy volunteers
3. Analysis of data collected via recordings
4. Studies of data or specimens that include identifying information
5. Linguistic and ethnographic studies

6. Studies involving focus groups
7. Minimal changes within one year to full review studies that have been approved

Following is a more detailed description of Expedited Review and examples from Federal Guidelines that you may wish to review for further information. It contains many specific biomedical examples.

- a. Research activities that (i) present no more than minimal risk to the human participants, and (ii) involve only procedures listed in one or more of the categories described below, may be reviewed by the IRB through the Expedited Review procedure. 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 participants.
- b. The categories in this list apply regardless of the age of the participant except as noted.
- c. The Expedited Review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks

related to invasion of privacy and breach of confidentiality are no greater than minimal.

- d. The Expedited Review procedure may not be used for classified research involving human participants.
- e. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB.

Categories of Research That May Receive an Expedited Review:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (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 an investigational device exemption application (21 CFR Part 812) is not required; or 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 participants, 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.
- b. from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Collection of biological specimens for research purposes by noninvasive means.

Examples:

 - hair and nail clippings in a nondisfiguring manner
 - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
 - permanent teeth if routine patient care indicates a need for extraction
 - excreta and external secretions (including sweat)
 - uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
 - placenta removed at delivery
 - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
 - 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
 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:

 - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
 - sputum collected after saline mist nebulization
 - 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 participant or an invasion of the participant's privacy
 - weighing or testing sensory acuity
 - magnetic resonance imaging
 - electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
 - 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 participants. 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 participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

8. Continuing Full Review of research previously approved by the convened IRB as follows:

- a. where the research is permanently closed to the enrollment of new participants; all participants have completed all research-related interventions; and the research remains active only for long-term follow-up of participants
- b. where no participants have been enrolled and no additional risks have been identified

- 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.

NOTE: Children are defined in the DHHS 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).

Full Board Review

Proposed research studies involving human subjects that do not qualify for Exempt or Expedited review must be reviewed by the IRB at a convened meeting. Full Board Review is required for studies that present more than minimal risk to participants or involve vulnerable populations, such as children, prisoners, institutionalized individuals, or persons with diminished capacity to consent.

Investigators must complete and submit **Form A, Request for Ethical Review Form and Assurances, Form C, Request for Expedited or Full IRB Review for Human Participants Research** and either submit a certificate showing that a training module has been completed or indicate that it is already on file with the Office of the Provost. In addition, any documents requested by

the forms should be attached. (See Appendix for forms.)

Procedural Considerations

Informed Consent Procedures

Investigators of a research project will obtain from the human participants or their legally authorized representatives, a suitable informed consent document. Particular care should be taken when working with participants with special needs. Department of Health and Human Services regulations require that informed consent information be presented in language understandable to the participant.

In addition, when research is conducted with minors, informed consent must be obtained from a parent/guardian. When working with the mentally disabled, informed consent must be obtained from a legally authorized representative. In addition to informed consent from a parent/guardian or legally authorized representative, the researcher should obtain assent from the minor or mentally disabled just before data collection begins. (See Appendix for sample forms.)

Basic Elements of an Informed Consent Document

All elements are required for studies, and projects will not be approved without them. This document must be given to subjects before they participate and they must sign and return it before data collection. Sample Informed Consent forms are included in the Appendix of this document. All forms should include:

1. a statement that describes the general purpose of the research, action to be

taken by subjects, and expected duration

2. name(s) of the principal investigator(s) and faculty supervisors for student research
3. a description of possible physical or psychological risks or discomforts and measures to minimize them
4. a description of benefits to participants or others, that justify conducting the research, as well as disclosure of alternative treatment
5. a description of any compensation to participants, including, but not limited to academic credit
6. a statement describing the level of confidentiality of data if data are not gathered anonymously

Please keep in mind that **confidentiality** refers to ensuring that the knowledge of the identities of the participants will not be shared with others, and **anonymity** refers to no connection between the data and the identities of the participants even through a separate coded list of names.

7. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is entitled, and that the participant may discontinue participation at any time and request withdrawal of earlier response without penalty or loss of benefits
8. a statement that the subject must be at least 18 years of age (unless approval is given by the subject's legally responsible agent)
9. a line for the date and both the printed name and signature of the subject

10. a line for date and both printed name and signature of legal representative of subject, when needed
11. an additional statement and signature line when a request for photo, video or audiotaping is requested
12. see the following section on Debriefing to determine whether the information is included in the **Informed Consent Form** or the **Debriefing Form**
13. a description of where data will be kept and for how long before destruction
14. a statement indicating that the study has been approved by the IRB at Lewis University

Debriefing Form

The following information needs to be provided to participants. It can be included as part of the original **Informed Consent** document or as a **Debriefing Form** if more appropriate.

1. names and phone numbers of a university representative to contact for information about the study. Subjects should be informed of a later date when results of the study will be available
2. a statement saying if you have questions regarding the rights of participants, please contact the Office of the Provost
3. a somewhat broader description of the purposes of the study, including elements that might have biased subject responses if the information was provided prior to participation
4. a description of appropriate actions to take if the study caused concerns or problems for the subject, including psychological discomfort

or the need for further information about a topic

Continuing Review by the IRB

Research that has been approved by the IRB/LRB via Exempt, Expedited, or Full Board review must undergo continuing review at least annually, unless the following criteria are met:

- no identifiers are associated with the data;
- if codes are associated with the data, the link between the codes and identifiers has been irretrievably destroyed.

The goals of Continuing Review are to ensure that the risk/benefit ratio is still acceptable, that the measures taken to safeguard participants are adequate, that the approved protocol is followed, and that the project reflects any changes that have been made in the regulations for human research since the last approval. The IRB may require changes in protocol or revisions in the consent form if the study's risks were originally underestimated, but the converse can also occur: the investigators and the IRB may have underestimated the benefit to research participants.

NOTE: Transcriptions that meet the above criteria may be retained, so long as the actual audio/videotapes have been destroyed. Tapes, even if unlabelled, are considered identifiable.

In order to seek a renewal on a previously approved research request that remains open, the researcher should send a letter to the IRB/LRB that originally approved the request and provide an update on the status of the research. Any changes to the original protocols need to be noted and approved.

Revision of an IRB Project

Once the IRB/LRB has approved a project, it must be carried out as planned. Any changes in participant population or number, recruitment plans, research procedures, study instruments, study sites, or major research personnel must be approved by the IRB/LRB.

Researchers planning a change should:

- write to the IRB/LRB chair citing the title, researchers and date of the approved study
- describe the proposed change in lay language
- explain why the change is needed
- describe the implications for the participants
- provide revised consent documents, if the change will affect the participants

Changing the Principal Investigator

If a principal investigator is on sabbatical leave from the University, an interim PI must be appointed. The IRB/LRB should be informed of this person's qualifications. If a researcher leaves the University permanently, the IRB/LRB should be notified both of any interim investigators and of the final replacement.

Incident, Adverse Event or Complaint Reports

If, during the course of the research, a human subject develops a medical or psychological problem that may be attributable to the research, the investigator must suspend the study immediately and report circumstances to the IRB/LRB. Unexpected problems whose nature, severity, and frequency were not described in the information provided to the IRB/LRB or to

participants must be reported to the IRB/LRB within 10 working days. Examples include unexpected complications in a participant, missteps in the consent documentation, or breaches of confidentiality. Sometimes a study must be suspended to ensure participants' safety. The report of the event should include:

- the facts of the case, including the date and a description of the participant(s)
- whether the event is related to the study's procedures or to the participant's condition
- the steps that have been taken to address the problem
- whether the event is likely to recur
- whether the event provides new information about the study's risks that should be conveyed to participants, in a revised consent form

These reports usually receive Expedited Review, but in some cases the full IRB is involved.

Participant Considerations

Cross-Cultural Research

Researchers engaged in cross-cultural research should give particular attention to the use of culturally appropriate assessment instruments and procedures, the language(s) used in the conduct of the research, and the language preference and language variability of the research participants. Researchers developing studies involving members of an unfamiliar racial, ethnic, cultural, linguistic, gender or sexuality group should develop a reasonable level of familiarity with, but would not be limited to, the language, behavior, social mores, customs and traditions of that

group. A researcher should consider consulting social and behavioral scientists and others who are more knowledgeable of, and experienced with, the intended study group before constructing a protocol.

Including Women and Minorities

Research benefits and burdens should be distributed fairly. If an individual or group is denied access to a clinical trial that might be beneficial or if some people are singled out to bear the burden of risks associated with a study, the requirement for fairness is not met. In accordance with the policies of the National Institutes of Health, the IRB requires researchers applying for federal funds to give breakdowns of their participant populations by gender and minority group. Studies with the potential to address issues relevant to both sexes must recruit both genders, and minority populations should be included in a study population wherever feasible. Researchers must justify the exclusion of women or minorities. The IRB makes exceptions only if there is adequate scientific justification for exclusion, such as when a disease predominates in one gender.

Students or Employees as Research Subjects

In addition to avoiding all obvious forms of coercion and undue influence, researchers must take precautions not to unintentionally or subliminally coerce anyone into studies. Subtle coercion often occurs when a potential research participant is also a student, employee, colleague, or subordinate. For this reason, researchers should avoid using their own students or employees as research participants. If there is a good scientific reason for including students, researchers should:

- Make sure students are confident that their participation will not influence class standing, grades, or other benefits under the control of the researcher.
- Limit the use of extra credit points as a reward for participating (they should be used only when the research is closely tied to the course subject matter and they should not raise a student's grade by a whole step, e.g., from a B to an A.)
- Keep financial rewards commensurate with the risks of participation. If possible, avoid using class time to recruit participants or complete study instruments. Inform students who might participate about the review process, the rationale for the study, the process of data collection, and the researcher's interest.
- Researchers who include colleagues or subordinates as research participants, must be able to provide a rationale other than convenience for selecting them and must show that the recruitment method does not lead colleagues to think they will be compromised by not participating. Recruitment through bulletin board advertisements or by a third party is preferable to direct recruitment.
- Information about how students and colleagues will be recruited and rewarded should be included in the information submitted to the IRB.

Children as Research Participants

If research involves greater than minimal risk, children can be included in the study population only if there is direct personal benefit to the child. This restriction applies to research in both the health sciences and the social sciences. A research protocol in either field that involves anything more than minimal

risk and that offers no demonstrated benefit to the participant, cannot involve children.

Payment for Participants

Researchers may pay research participants for their participation, but payment arrangements must be disclosed to the IRB and are subject to a stringent review. Payment arrangements affect the fairness of recruitment plans, the balance of risks and benefits, and the adequacy of informed consent. Although there are no fixed formulas for determining whether payment plans are acceptable, the IRB prohibits payment arrangements that appear to be coercive. Payment should not encourage participants to participate or continue to participate against their better judgment.

The amount paid to participants must correspond to the burdens of participation. For example, payment might defray parking charges or transportation costs. Payments may also be scaled to the time that participants spend in a study or to the biological materials they donate. The minimum wage provides a ready baseline for hourly rates for participation, and the Blood Bank's payment scale for plasma and other blood products offers a guideline for compensating participants for biological materials.

Researchers who are reluctant to pay cash may offer gift certificates or grocery vouchers. When children and adolescents are the participants, researchers sometimes reimburse parents for parking or transportation and give a token payment or gift certificate to the participant. Drawings and raffles are subject to the laws and regulations governing games of chance and are generally discouraged.

Participants should receive at least partial payment if they withdraw from a study. Withholding all payment until participation is complete is coercive. A modest lump sum can be paid after the participant's participation is complete if the arrangement is thoroughly documented in the consent form.

Advertisements

Advertisements are part of the informed consent and participant selection process. Samples of all advertisements, such as emails, flyers, newspaper ads, radio and television announcements, bulletin board tear-offs, and posters, along with an explanation of other methods of recruiting participants, must be submitted to the IRB/LRB.

Advertisements should be submitted with the application or as soon as the principal investigator decides to use them. The content of advertisements should be limited to:

- names of the investigators the university identified by name and contact information
- purpose of the research
- general eligibility criteria
- straightforward and truthful descriptions of benefits (e.g. free treatment) and risks

Advertisements should not claim, explicitly or implicitly, that the research is treatment or is superior to any current practice. Extravagant attention-getting devices such as extremely large, bold typefaces and dollar signs are prohibited. Advertisements should not pressure readers into participating.

People cannot always be depended upon to make phone calls and contacts. Even

with good intentions, they forget, become busy, etc.

If participants have to contact others, they may have to use their time to make at least two phone calls, one to other potential subjects and one to the investigator. Participants should not be required to do extra work if there is no practical risk involved.

Participants might not accurately describe the research and its purposes or they might prep other participants to provide particular responses.

Number of Participants

The application must specify the number of study participants to be recruited and tested, grouped by age, gender, and population diversity. This assures a representative research sample and prevents aggressive over-recruitment. Exceeding the recruitment limits agreed to by the IRB is a protocol violation unless the IRB gives written permission.

If it is difficult to predict how many participants will be eligible or be attracted to a study, the optimum number should be specified. Responses such as “don't know” or “as many as we can recruit” to questions about the number of participants are not acceptable. A discussion of the problems faced in recruiting participants should be included.

Multi-center studies, in which data will be pooled and recruitment may vary, present a special problem for investigators. The application should provide information about the total picture, including both the number of participants to be studied at the University or by University researchers and information on overall recruiting.

Closing a Research Project

Investigators are responsible for closing their projects once they have completed the data collection, analysis, and writing phases of their projects. Researchers should send a letter to the IRB/LRB indicating that their projects have been completed. Once this letter is submitted, the project will be closed and all research activity must cease.

If investigators depart the University prior to completion of the research, they must close their projects. Persons no longer affiliated with the institution include students who have graduated and faculty and staff who are no longer employed by the University. Individuals must close their projects unless another individual at Lewis is willing to assume full responsibility for the project as the principal investigator.

Record Keeping

Institutional Review Board

The Institutional Review Board maintains files of all proposals that have been reviewed. Files contain the original proposal, including the consent form, assent and debriefing form when applicable and research protocol, a copy of the IRB response and approval, any responses to IRB requests and any additional correspondence with the investigators. The Institutional Review Board also keeps copies of the minutes of their meetings. In addition, it maintains records of individuals trained to conduct human research at Lewis University. These files are maintained by the Office of the Provost.

Researchers

Researchers should maintain a file of all documents concerning the use of humans in research, including original

paperwork whenever possible and a copy of everything else. The principal investigator's records should be a mirror image of the IRB's records: where the IRB holds an original, the principal investigator should hold a copy, and vice versa. Files should be maintained for a minimum of 3 years.

efficient but ethically superior review system.

The documents that researchers should have on file include:

- a copy of the original application submitted to the IRB, including the consent form, research protocol, and completed forms
- an original of the IRB's response,
- a copy of responses to IRB stipulations or requests for additional information,
- the original notice of approval,
- a copy of the "Certification of Approval" sent by the IRB to any funding agencies,
- copies or originals of all other correspondence with the IRB,
- copies of completed letter of Continuing Review and attachments,
- the original notice of renewal of approval and certification, where applicable copies of any inspection or audit reports.

System Evaluation

In as much as this process is time intensive for researchers and the IRB, it is essential that it be under scrutiny for efficiency and timeliness in meeting the joint obligations of researchers and ethical review arbiters. Each year the IRB should examine a sample of projects to determine the consistency of the Exempt Reviews and to examine the system as a whole. Adjustments should be made, on a controlled basis, to maintain a consistent, predictable,

III. IRB Human Research Proposal Process and Forms

Introduction

Investigators do not have the authority to determine whether their research involving humans is exempt from Full Review. Although research that involves only minimal risk is sometimes exempt from Full Review, it is never exempt from the Local Review Board.

Overview of Lewis University Institutional Review Board Process

The IRB approval process at Lewis University consists of the following steps:

First, all researchers must have completed a training module in research ethics and submit evidence of such successful completion when submitting a proposal.

Second, researchers submit appropriate forms and materials to their Local Review Board.

Third, the Local Review Board will review the request and send it to the IRB Chair if further review is needed.

Fourth, members of the IRB/LRB will make one of the following three recommendations:

- a. The Board will approve the request with no changes.
- b. The Board will approve the request contingent upon IRB recommended changes to the study.
- c. The Board will not approve the study.

At the completion of the study the researcher will close the study with the IRB office.

How do I know which forms to submit to whom?

The following decision questions should help you determine the proper forms to submit to your LRB. All research review begins with the Local Review Board (LRB) for the college.

Administrative reviews can be submitted to the Administrative Representative. LRB members are listed at the Blackboard site. All submissions

must include **Form A Request for Ethical Review and Assurances**.

Question 1

Does the activity involve human participants?

Information collected about deceased individuals or from commercial or public repositories or registries does not need IRB approval.

NO You do not need IRB approval.

YES Go to the next question.

Question 2

Is the proposed activity research?

NO You do not need IRB approval.

YES Go to the next question.

Question 3

Does the research meet the criteria for exemption?

There are six categories of exemption. All follow the general rationale that the research exposes participants only to the same small physical, social, and psychological risks that they take in living every day.

NO Go to next question

YES Fill out Form A and Form B. Submit to your LRB. Remember, investigators do not have the authority to determine whether their research involving humans is exempt from Full Review.

Question 4

Does the research meet the criteria 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. You may be eligible for an Expedited Review.

YES and *NO* Fill out Form A and Form C.

Submit to your LRB. They will be able to help determine whether the review can be Expedited or Full.

Question 5

Is this a class-related project?

YES and NO Submit Appropriate Forms to your instructor.

The Human Research Review Process Decision Tree

1. Does the activity involve human research?
 - Information from archives, about deceased individuals STOP
 - Information from living humans GO TO 2

2. Is it research? (see page 6)
 - Restricted only to a classroom demonstration STOP
 - Educational practices, only for improvement without ID STOP
 - Aimed to gather generalizable knowledge GO TO 3
 - Sensitive or private information GO TO 3

3. All researchers complete the Research Ethics Training Module GO TO 4
If borrowing copyright protected material, secure permission to use.

4. Does the research require exempt, expedited or full review? SUBMIT TO LRB
 - A. Exempt: Risks are everyday risks (see page 11) USE Forms A & B
 - Submit data instruments; permission to use
 - Informed consent
 - Ethics certificates

 - B. Expedited: Minimal risk research (see page 12) USE Forms A & C
 - Submit data instruments; permission to use
 - Informed consent
 - Ethics certificate

 - C. Full Review: Research with more than minimal risk, deception or vulnerable populations. (see page 15) Use Forms A & C
 - Submit data instruments; permission to use
 - Informed consent and assent forms
 - Ethics certificates

 - C 1. Research involving deception Use Forms A, C & D
 - Submit data instruments; permission to use
 - Informed consent and assent forms
 - Ethics certificates
 - Debriefing procedure

5. Follow the IRB recommendations on your project to use, modify, or resubmit.
6. If there is a change in the protocols, principal investigator or consent/assent procedures (see page 18) Contact the IRB/LRB for approval
7. If research lasts more than 1 year, submit request for renewal to LRB.
8. Research complete? (see page 19) Notify IRB in writing
Maintain file of forms, data for 3 years.

NOTE: Examples of sample consent, assent and debriefing forms can be found on the Lewis University Blackboard site. This forms can be modified to fit your specific use. This site also contains word documents of forms A-D.

Find the Institutional Review Board for Human Research site under Faculty/Staff or Student tab in Blackboard.

<http://lewisuniversity.blackboard.com/>

Form A

Request for Institutional Review and Assurances

(To be completed for all research requests)

PLEASE NOTE: ALL PERSONS INVOLVED IN RESEARCH MUST COMPLETE A TRAINING MODULE FOR HUMAN PARTICIPANT RESEARCH AND SUBMIT THE CERTIFICATE WITH PAPERWORK

Investigator(s): List all Faculty, Staff, and/or Students conducting this research:

Name	Location	Phone
P.I. _____	_____	_____
Co-P.I. _____	_____	_____
Co-P.I. _____	_____	_____

Faculty Sponsor (if applicable) _____

Designate one person as the primary contact to receive IRB communications and provide an address.

Name of Primary Contact	Address
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Title of Research Project:

Location(s) at which research is to be conducted (provide name and address):

Funding Source (if applicable):

Anticipated Dates of Study: From ___/___/___ To ___/___/___

Anticipated Number of Human Research Subjects:

Students _____ Parents _____ Teachers _____ Others (describe) _____

- | | | |
|--|-----|----|
| 1. Will this study include MINORS as research subjects? | Yes | No |
| 2. Will this study involve DECEPTION of human subjects? | Yes | No |
| 3. Will subjects be PAID ? | Yes | No |
| 4. Will this study involve materials that may be HAZARDOUS to human subjects? | Yes | No |
| 5. Will this be a DRUG STUDY ? | Yes | No |
| 6. Will this study include PRISONERS as research subjects? | Yes | No |

- | | | | |
|----|---|-----|----|
| 7. | Will this study include subjects who have a COGNITIVE IMPAIRMENT that interferes with the ability to provide informed consent? | Yes | No |
| 8. | Will this study include PREGNANT WOMEN as research subjects? | Yes | No |
| 9. | Will this study include HUMAN TISSUES as the subjects of research? | Yes | No |

I certify that the above information is correct:

I have read and approved of the protocol:

Investigator

Date

Faculty Sponsor (if appropriate)

Date

If you answered “No” to Questions 1-9, you *may* qualify for an exemption from full IRB review; proceed to Form B. If you answered “Yes” to *any* of Questions 1-9, you *must* complete the information required on Form C.

Investigator’s Assurance

I certify that the information provided in this application for review is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants, conduct of the study and the ethical performance of the project. I agree to comply with all IRB policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human participants in research, including, but not limited to, the following:

- The project will be performed by qualified personnel according to the Lewis University IRB certified protocol.
- No changes will be made in the protocol or consent form until approved by the Lewis University IRB.
- Legally effective informed consent will be obtained from human participants if applicable.
- Adverse events will be reported to the Lewis University IRB in a timely manner.

I further certify that the proposed research is not currently underway (except for those protocols of research previously approved and currently seeking renewal) and will not begin until approval has been obtained.

Principal Investigator’s Signature _____ Date _____

Faculty Sponsor’s Assurance for Student or Guest Investigators

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

- I agree to meet with the investigator on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- I insure that the investigator will promptly report significant or untoward adverse effects to the Lewis University IRB in a timely manner.

If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence and I will advise the Lewis University IRB by letter of such arrangements. I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Faculty Sponsor’s Signature _____ Date _____

The faculty sponsor must be a member of the Lewis University faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.

Form B

Request for Exempt Review

REQUEST FOR EXEMPT HUMAN PARTICIPANTS REVIEW

NAME _____ DATE _____
(Principal Investigator / Instructor)

TITLE OF RESEARCH PROJECT

BEFORE YOU MAY INITIATE ANY PHASE OF HUMAN SUBJECTS RESEARCH, THE INSTITUTIONAL REVIEW BOARD MUST REVIEW AND APPROVE: A SUMMARY OF YOUR RESEARCH PROTOCOL YOUR DATA COLLECTION INSTRUMENT, AND YOUR INFORMED CONSENT FORMS. EXAMPLES OF INFORMED CONSENT FORMS ARE CONTAINED WITHIN THE LEWIS UNIVERSITY POLICIES AND PROCEDURES APPENDIX. PLEASE FOLLOW THESE INSTRUCTIONS CAREFULLY.

Attach a copy of

1. A one-page research protocol, to include:
 - setting for research (school, classroom, clinic, hospital, etc.)
 - anticipated dates of study
 - complete subject description including number, ages, adults, minors over 12, minors under 12, vulnerable populations (numbers 6, 7, 8 from Form A,) how selected or recruited
 - procedures including permissions from the site used, methods for attaining informed consent of subjects, methods for protection of anonymity or confidentiality of subjects, methods for protection from harm
 - data collection procedures including when administered, how administered, who administers
 - possible benefits and risks to subjects
 - where results will be disseminated (include on consent form)
 - where results will be kept for 3 years in locked storage
2. All consent forms
3. All data collection instruments except copyrighted instruments, which require a letter giving written approval for use

I claim exemption for the above titled research based on the following criteria

(check one or more of 1-6 and 7):

- 1 Research will be conducted in established or commonly accepted educational settings, involving normal education practices, such as research on regular and special education instructional strategies, or research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods. Please list the courses in which the research will be conducted _____
- 2 Research involves the use of educational tests such as, cognitive, diagnostic, aptitude, achievement.
- 3 Research employs survey procedures or interviews which do not include minors.
- 4 Research is limited to observations of public behavior of adult subjects.
- 5 Research is limited to observations of public behavior with children as subjects in which the investigator does not participate in the activities being observed.

- 6 Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens which are publicly available.
- AND
- 7 All information is recorded in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects.

RESEARCH INVOLVING SURVEY OR INTERVIEW PROCEDURES IS NOT EXEMPT FROM HUMAN SUBJECTS REVIEW IF CHILDREN ARE INVOLVED. RESEARCH INVOLVING OBSERVATION OF PUBLIC BEHAVIOR WITH CHILDREN AS SUBJECTS IS EXEMPT ONLY IF THE INVESTIGATOR DOES NOT PARTICIPATE IN THE ACTIVITIES BEING OBSERVED.

I have received training on the Federal Regulations (45 CFR 46) relating to Human Subjects research and am familiar with university policies for this area of research. I agree to abide by all pertinent regulations and policies.

I certify that all information submitted in this application for IRB approval is correct:

I have read and approve of the protocol:

Investigator / Instructor

Date

Faculty Sponsor (if appropriate)

Date

Form C

Request for Expedited/Full Review

REQUEST FOR EXPEDITED OR FULL IRB REVIEW FOR HUMAN PARTICIPANTS RESEARCH

NAME _____ DATE _____
(Principal Investigator / Instructor)

TITLE OF RESEARCH PROJECT

BEFORE YOU MAY INITIATE ANY PHASE OF HUMAN SUBJECTS RESEARCH, THE INSTITUTIONAL REVIEW BOARD MUST REVIEW AND APPROVE A SUMMARY OF YOUR RESEARCH PROTOCOL YOUR DATA COLLECTION INSTRUMENT, AND YOUR INFORMED CONSENT FORMS. PLEASE FOLLOW THESE INSTRUCTIONS CAREFULLY.

Attach a copy of

1. A one-page research protocol, to include:
 - setting for research (school, classroom, clinic, hospital, etc.)
 - anticipated dates of study
 - complete subject description including number, ages, adults, minors over 12, minors under 12, vulnerable populations (numbers 6, 7, 8 from Form A,) how selected or recruited
 - procedures including permissions from the site used, methods for attaining informed consent of subjects, methods for protection of anonymity or confidentiality of subjects, methods for protection from harm
 - data collection procedures including when administered, how administered, who administers
 - possible benefits and risks to subjects
 - where results will be disseminated (include on consent form)
 - where results will be kept for 3 years in locked storage
2. All consent forms (If minor, include ASSENT procedures).
3. All data collection instruments except copyrighted instruments, which require a letter giving written approval for use

I have received training on the Federal Regulations (45 CFR 46) relating to Human Subjects research and am familiar with university policies for this area of research, and I agree to abide by all pertinent regulations and policies.

I certify that all information submitted in this application for IRB approval is correct:

I have read and approve of the protocol:

Investigator / Instructor

Date

Faculty Sponsor (if appropriate)

Date

IRB Action:

Date: _____

Form D Use of Deception

USE OF DECEPTION IN HUMAN RESEARCH

NAME _____ DATE _____
(Principal Investigator / Instructor)

TITLE OF RESEARCH PROJECT

1. What is the nature of the deception used in this study? Please note that the *Informed Consent Form* may not include the deception.
2. Why is the use of deception essential in this study?
3. What are the specific risks associated with the deception?
4. Are there any anticipated benefits to the subject by the use of the deception?
5. Describe your debriefing procedure. If none, please justify. Include the name(s) of person(s) providing debriefing, the point at which debriefing occurs, and the nature of the debriefing (for example, written or oral) If no debriefing is planned, please justify.

