

**Human Subjects
Research**

**Institutional Review Board
(IRB)**

Guidelines

September 2009

Elizabethtown College
1 Alpha Drive
Elizabethtown, PA 17022



I. General Policies

The following policies apply to the protection of human subjects who participate in research conducted by Elizabethtown College employees or students. The policies apply to research conducted on campus and off-campus, to research funded by Elizabethtown College and by outside sources.

Research should not involve any physical, emotional, or psychological harm to the subjects, and should be conducted in accordance to federal guidelines.* [See Footnote] Any risks to subjects should be considered in the context of potential benefits of the study.

Researchers must protect the identity of the subjects. This involves not only confidentiality, but also protection against accidental or inferred identity. Clear procedures must protect the identity of the subjects.

Research normally should be conducted with a subject's full, prior consent. Deceptive or covert research will be acceptable only if the IRB determines that the use of deceptive techniques is justified by the study's scientific, educational or applied value, and when alternative methods not using deception are infeasible. Informed consent typically is obtained in writing.

Informed consent should provide the subject an opportunity to decline participation in the study. Specifically exempted, however, might be the case of research on student subjects that is necessary for institutional assessment. In such cases, consent should be obtained upon enrollment at Elizabethtown College.

The purpose of any proposed research should have clearly identifiable value to either the College or the wider scholarly community. Research without a clear value or scholarly merit will not be approved.

When research involves subjects in the Elizabethtown College community, (faculty, students, employees) results of the research should be made available to the College community and made available, if desired, to the subjects.

II. Research Activities and Human Subjects

The **research activity** regulated by this policy is defined as systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. A **human subject** is a living individual about whom an investigator (whether professional or student) in the process of conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Specifically covered are research activities involving observation, interviews, completion of surveys, and any other overt or covert data gathering procedures. Specifically exempted are College-funded research activities conducted as part of College courses (which will be governed by departmental policies and ethical guidelines of the relevant disciplines), as well as the types of institutional assessment, educational testing, and other activities described in 45 CFR 46.101(b). Anyone considering a research project who is unsure of whether the research is exempt from institutional review should contact the Chair of the IRB for clarification prior to initiating the project.

* See the procedures established in Code of Federal Regulations (CFR) Title 45, Part 46 (Protection of Human Subjects).

Elizabethtown's Institutional Review Board (IRB) must review and approve:

1. Research projects involving human subjects before any work is started;
2. Ongoing research involving human subjects at least annually;
3. All changes to research projects involving human subjects before implementation

III. Institutional Review Board

A. Composition

The Elizabethtown College Institutional Review Board (IRB) for human subject research has at least five voting members appointed by the Provost over staggered three year terms. The Provost shall appoint two of the members as chair and vice-chair for annual, renewable terms. The IRB shall not consist entirely of men, entirely of women, or entirely of members of one academic discipline. At least one member shall be a person whose primary training and research concerns are in nonscientific areas; for example, laws, ethics, civic leadership, and theology. At least one member shall be a person who is not otherwise affiliated with the College or part of the immediate family of a person who is affiliated with the college. The College IRB shall be comprised of no fewer than the following members:

1. Two faculty members
2. One College Life Professional Staff
3. One External Member
4. Others as appropriate

When research involves a category of vulnerable subjects (e.g., prisoners, children, individuals institutionalized as mentally disabled), the IRB shall include at least one member with a primary concern for the welfare of these subjects or in such cases, the IRB may invite a qualified person familiar with such populations to comment on a proposed research project. IRB members should be sufficiently qualified through their experience, diversity of racial and cultural backgrounds, and sensitivity to community attitudes, to establish respect for its advice and counsel in safeguarding human subjects.

To avoid conflicts of interest, an IRB member shall not participate in the IRB's review of any project in which the member is involved as a researcher or subject.

The IRB is responsible to the Provost.

B. Functions

Safeguarding the rights and welfare of subjects at risk in any research is the responsibility of the College. In order to discharge this responsibility, no research activity supported or funded by the College involving human subjects should be undertaken until those activities have been reviewed and approved by the IRB.

The review and approval process considers the proposed methods for collecting data, obtaining prior informed consent (unless waived under conditions described below), and protecting the confidentiality of subjects. Since the "risks" to subjects are affected by these procedures, it is the responsibility of the principal investigator (PI) to be fully familiar with the Code of Federal Regulations (45 CFR 46) which governs the protection of human subjects and which forms the basis of College policy. The PI must demonstrate that appropriate safeguards will be followed for human subjects in order to receive IRB approval.

Overview of Reviews and Levels of Risks

Type of Review	Level of Risk	Application Form
Exempt*	None	Preliminary
Expedited*	No Apparent	Complete
Full**	Minimal***	Complete

* Does not require IRB meeting

** requires IRB meeting

*** The federal rules define **minimal risk** as a risk of harm to the subject from participation in the research that is no greater than the risk encountered in normal day-to-day activities or during routine physical or psychological examinations.

IV. TYPES OF REVIEW (Exempt, Expedited, Full)

A. Exempt from Review

Six categories of research [federal rules, 45 CFR 46.101(b)(1-6)], are eligible for exemption (see below). Although these six categories involve research with human subjects, the research does not expose participating subjects to psychological, social, or physical risks. The investigator/researcher should submit the project to the IRB Administrator with enough information to determine the exempt status of the project. If a project is judged exempt from review, it will not require continuing review and is not subject to the other rules governing human subject research (e.g., written consent).

In order to receive an exemption from review by the IRB, the research project must **involve no more than minimal risk to subjects, no ethical concerns, and ONLY procedures listed in one or more of the following categories of research** (Six types of Exempt Research).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, **unless** the information is obtained and recorded in such a manner that the 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.

Note: The exemption for survey and interview research does not apply to research in which the subjects are children, except for research involving observation of public behavior if the researcher does not participate in the activities being observed.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under item (2) above; **if** the human subjects are elected or appointed public officials or candidates for public office; **or** federal statute(s) require 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 Researcher in such a manner that subjects cannot be identified directly, or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of administrative units, and which are designed to study, evaluate, or otherwise examine methods and procedures of public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, **or** a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the USDA.

B. Expedited Review

Federal rules allow for expedited review of some research if it involves no more than minimal risk† and it falls within one of the categories defined in the federal rules (45 CFR 46.110) and OHRP guidance documents.

An expedited review is conducted by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

(Full text: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>)

Research That Qualifies For Expedited Review

1. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
2. Collection of data from voice, video, digital, or image recordings
3. Collection of data through noninvasive procedures
4. Research involving archival materials (data, documents, records, or specimens) that have been collected for non-research purposes.
5. Continuing review of research previously approved by an IRB as follows:

- a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
6. 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.
 7. HSC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
 8. Clinical studies of drugs and medical devices (as qualified by regulations).
 9. Collection of blood samples (as qualified by regulations).
 10. Collection of biological specimens by noninvasive means.

C. Full Review

Any research not covered under the exempt or expedited review categories is referred to the IRB for full committee review. The researcher may be invited to attend the review. The research may be either approved; approved pending modifications which must be verified by an IRB member (with revisions documented in IRB files); or not approved. Researchers will be notified in writing about the IRB's decision.

V. Application Procedures

The PI and/or department Chair (in the case of students) shall make a determination as to whether or not research will involve human subjects. When it is not clear whether the research will involve human subjects as defined in 45 CFR 46.102, the investigator should consult IRB. If human subjects are involved, the PI shall make a tentative determination of whether the research project is exempt from IRB review under the provisions of 45 CFR 46.101.

A preliminary application shall be submitted to the Provost's office. The preliminary application shall include: 1) a brief description of the research activity; 2) a description of the process for obtaining prior informed consent or a request of the purpose and methods for waiver of prior consent; (See Appendix C) 3) the method of protecting the confidentiality of subjects; and 4) a rationale for exempt status (if applicable).

The IRB Chair will determine if a project is exempt.

A. Expedited/Full Review

If it is clear that the proposed research activity involves potential risk to human subjects and is not otherwise exempt from IRB review, the PI shall submit a full proposal containing:

1. Title of project.
2. Name of principal investigator/association with the College/address/telephone/faculty sponsor and/or department Chair.
3. Other project participants (individuals or institutions/agencies).

4. Subjects of the study (describe how they will be obtained).
5. A summary of the research methods and procedures.
6. A discussion of how subjects will be debriefed, if needed.
7. A discussion of any and all risks and the procedures to minimize them.
8. Benefits to participants and non participants.
9. The nature of the subjects' participation and an assurance letter signed by the principal investigator certifying that:
 - a. The risks and welfare of the subjects will be adequately protected.
 - b. Any risks or discomfort to subjects (if any) have been clearly identified and are outweighed by potential benefits to the subject or by the importance of the knowledge to be gained.
 - c. Informed consent of subjects will be obtained by appropriate methods.
 - d. Any changes, which may alter the investigational situation, will be reported to the IRB.
 - e. The storage or disposal of the human subjects' data obtained in the study will follow proper guidelines of confidentiality
10. Informed Consent Procedures should Describe:
 - a. The information that will be given to human subjects in the project.
 - b. Risks and benefits to subjects in the project.
 - c. The procedures to prevent any violation of the subjects' right to privacy.
 - d. The provisions for the subject to respond to the information.
 - e. The procedures for the subjects to consent to participate.
 - f. The means for subjects to contact the principal investigators.
11. Waiver of Informed Consent. If applicable, a Principal Investigator (PI) may request a waiver or alteration of the requirement to obtain the informed consent and subjects prior to the research. This request must be supported by evidence that allows the IRB to conclude that:
 - a. The study will present no more than minimal risk to subjects.
 - b. Waiver of full informed consent will not adversely affect the welfare of subjects.
 - c. The subject cannot practicably be carried out without the waiver; and
 - d. When appropriate, subjects will be given pertinent additional information after they have participated in the study.

Completed proposals will be forwarded to the Office of Research and Planning (ORP). The ORP will review the application for completeness; assign a recommended status of exempt, expedited, or full review; and assign an IRB Protocol Number. If the application is given an exempt status, the ORP will notify the PI. Otherwise, the ORP will forward the information to the Chair of the IRB. The Chair of the IRB will determine whether an expedited review is appropriate as allowed by 45 CFR 46.110. If an expedited review is permissible, the full review procedure will be modified as determined by the IRB and the Chair.

For a full review, the IRB Chair will assign one principal reviewer to each proposal. The review process typically takes between **two weeks and four weeks**. Each member of the IRB will receive a proposal abstract and all associated materials for review. The PI may be asked to submit additional materials.

At the IRB meeting for a full review, the principal reviewer will present the proposal to the Board with his or her recommendations. Following a discussion of the proposal, the Board will determine the disposition of the proposal. This decision will typically be made within thirty days of the submission of the proposal to the Provost. The IRB Chair will return the proposal and materials to the Provost with a signed report of action form and/or letter indicating the outcome of the review.

The Provost will notify the PI of the decision. If the decision is negative, the notification will include a written explanation including reference to principles which the proposed research violates. A revised proposal may be submitted for re-examination. Materials and IRB decisions will be placed on file in the Office of Research and Planning.

VI. Policy for Student Researchers

Research Projects

In accordance with federal regulations and Elizabethtown policies, all research involving human subjects must be reviewed and either classified as exempt from (IRB) review or approved by the IRB prior to any research intervention with a participant.

All Elizabethtown students engaged in any kind of research project (including independent study, research credits, senior thesis, special projects, etc.) involving human subjects must obtain IRB approval before beginning the research. A student who submits a request for review (exempt, expedited or full review) must list a faculty member or instructor as an advisor. Approval may also be granted as part of a previously approved project by agreement of the principal researcher.

Department Guidelines

Academic departments may establish procedures for determining exempt projects or conducting expedited reviews if the reviews involve two faculty members other than the advisor to the project. Departmental procedures must be written and approved by the IRB.

Course Assignment versus Disseminated Research

Student projects conducted within an academic course that involve Human Subjects may be categorized as either a Course Assignment or Disseminated Research. Disseminated Research involves the formal presentation (e.g. poster, oral or written, seminar) of information to any audience beyond the course. Disseminated research must be reviewed by the College IRB. Course Assignments involve data collection and interpretation for educational purposes that are contained wholly within the course environment.

Course assignments must be planned and carried out with due consideration of Elizabethtown's ethical and legal responsibility to protect human subjects, especially when subjects are exposed to more than a minimal risk. "Minimal risk" is defined as risks anticipated in the proposed activity that are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

All projects involving special populations as subjects (e.g., prisoners; individuals with physical or mental disabilities; economically or educationally disadvantaged; institutionalized individuals; pregnant women; fetuses) require additional safeguards.

Suitable precautions must be taken to ensure the confidentiality of the results of any procedure pertaining to a particular person who is a participant in the activity.

Faculty/Instructor Responsibilities for Human Subjects Protection

- The faculty member/instructor is responsible to discuss research ethics with students in the context of assignments that involve human subjects.
- The faculty member/instructor should determine, prior to assigning a project, whether the project is a Course Assignment or Disseminated Research. Disseminated Research must be reviewed by an IRB. If a student research project is originally conducted as a course assignment, but develops into disseminated research, IRB approval must be obtained immediately.
- The faculty member/instructor should assure that all students planning to conduct research involving human subjects submit an application to the IRB in a timely manner. The IRB may request additional information, or require changes, before projects can be approved.
- If the faculty member/instructor is planning to use data from class assignments for disseminated research, IRB approval must be obtained.
- The faculty member/instructor should monitor student projects from beginning to end for impact on human subjects. Special attention should be paid to maintaining confidentiality, minimal levels of risk for participants, assuring freedom to withdraw without penalty, and providing informed consent to participants.

The faculty member/instructor should report unexpected adverse effects or complaints involving human subjects to the IRB.

VII. Changes in Protocols and Adverse Reactions

The researcher is responsible for ensuring that any changes to the protocol are submitted to the IRB for review **before** the changes are incorporated into the research. Researchers should note that only those procedures specifically approved by the IRB may be initiated.

New information which would affect the potential risk to subjects must be brought to the IRB's attention in a timely way. Adverse reactions by subjects to research interventions should be reported to the IRB immediately.

VIII. Continuing Review of Ongoing Research

The Federal rules mandate that ongoing research must be reviewed by the IRB at least once a year (except in the case of exempt research). Most protocols are approved for one year, although the review interval may be less if the IRB determines that it is necessary, for whatever reason, to review the protocol on a shorter review cycle.

It is the responsibility of the researcher to see that ongoing research is submitted for review before the approval lapses. If IRB approval lapses, the researcher must suspend any ongoing research interventions with subjects and must not recruit any additional subjects.

7-8-04 Draft

Appendix A

Definitions:

Federal regulations define *research* and *human subjects* as follows:

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (45 CFR 46.102)(d)).

A **Human Subject** is a living individual about whom an investigator (professional or student) conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information (45 CFR 46.102(f)).

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

Interaction includes communication or interpersonal contact between investigator and subject.

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

Appendix B

ETHICAL ISSUES:

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human of Research, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, provides the philosophical underpinnings for current federal laws that govern research involving human subjects.

Several basic ethical principles relevant to the ethics of research are described in The Belmont Report:

1. **Respect for persons** – This principle requires that researchers recognize that each individual's judgments and choices about participating in the research must be respected. For those not capable of deciding for themselves or classified by the government as vulnerable subjects (e.g., children, prisoners, pregnant women, fetuses), special protection must be made.

Research subjects or their legal representative usually must sign an informed consent form detailing the research to be done, the potential risks and benefits, and anything else that might influence their decision to participate. The IRB reviews the project to ensure that participation of subject is voluntary, and that the information provided to gain consent is adequate and appropriate. See pages 6-8 for more detail.

2. **Informed Consent** – Voluntary agreement to participate. See Appendix C for full description.
3. **Beneficence** – This principle embodies three concepts: 1) do not harm; 2) maximize possible benefits; and 3) minimize possible harms. All research should be designed to minimize risk and maximize benefit to the participant and to society. The IRB will review the project to determine if risks are outweighed by potential benefits.
4. **Justice** – This principle considers whether the benefits and burdens of participating in the research are fairly distributed among all populations to ensure justice. Researchers must be careful not to select already burdened or vulnerable groups who might be more easily coerced to participate. This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." The goal is to distribute burdens and benefits in just ways. The IRB reviews the project to ensure that subjects are selected fairly.

Appendix C

INFORMED CONSENT:

General Requirements

Informed consent is the process of communicating to prospective research subjects all that they need to know about participating in a research project, and then obtaining and documenting their agreement to participate. The procedures used in obtaining informed consent should be designed to educate prospective subjects in terms they can understand. Therefore, a consent form must be written in lay language.

The process of obtaining informed consent, and the documentation of informed consent, must comply with the requirements of the Common Rule (45 CFR 46.116 and 46.117). It should include the following eight elements of consent. In some cases, additional elements may be necessary as required by 45 CFR 46.116(b).

Eight Elements of Consent

1. A statement that the study involves research; an explanation of the purpose of the research and expected duration of the subject's participation; a description of procedures to be followed and identification of any procedures that are experimental
2. Description of risk or discomforts to the subject
3. Description of benefit to subject or others
4. Disclosure of alternative procedures, as appropriate
5. Description of the extent to which confidentiality will be maintained
6. For research that involves more than minimal risk, an explanation as to whether compensation and medical treatments are available if injury occurs
7. Explanation of whom to contact if questions arise about the research, the subject's rights, or whom to contact if research-related injury occurs
8. A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that the subject may discontinue participation at any time

Note: If the research study involves collections of images or audio recordings of subjects, the consent form must clearly state that fact. In addition, there must be a statement of how the material will be used, who will see the images or hear the recordings, and in what setting (e.g., research lab, classroom, professional meeting, public broadcast, etc.). If the investigator wants permission to share the materials with anyone other than the research staff or if the material contains sensitive information, the subject should be given the opportunity to view or hear the materials after they are collected and be told how long they will be kept. The investigator must obtain specific permission from the subjects to use this material.

Additional informed consent elements that are required if they apply to the study and are important for subjects to know

- Unforeseen risks statement (if applicable).
- Reasons for involuntary termination of participation (if applicable).
- Additional costs to participate (if any).
- Consequences for withdrawal (adverse health/welfare effects, if any).
- New findings statement (to be provided if relevant).
- Number of subjects (if it may have an impact on the decision to participate).
- Payments (incentives and/or expense reimbursements if any).

Documentation of Informed Consent

Informed consent is documented by the use of a written consent form that is approved by the IRB and signed by the subject or his/her legally authorized representative. A copy is given to the person signing the form. The consent form may be either of the following:

1. a written consent document that embodies the elements of informed consent described above;
or
2. a short form written consent document stating that the elements of informed consent described above have been presented orally to the subject or his/her representative.

In addition, when the short form and oral presentation method is used:

1. The IRB must approve a written summary of what is to be said to the subject or to the person representing the subject.
2. The short form must state that “the elements of informed consent required by the Code of Federal Regulations, Title 45, Part 46.116 have been presented orally to the subject or the subject’s legally authorized representative.”
3. There shall be a witness to the oral presentation and the witness shall sign both the short form and a copy of the written summary.
4. The person obtaining consent shall sign a copy of the summary.
5. A copy of the written summary shall be given to the subject or the person authorized to consent for the subject, in addition to a copy of the short form.

Waiver of Elements of Informed Consent

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

- The research involves no more than minimal risk to subjects;
- The waiver will not adversely affect the rights and welfare of subjects;
- The research could not practically be carried out without the waiver; and
- Whenever, appropriate, the subjects will be debriefed after participating in the study.

Waiver of Signed Informed Consent

The IRB may approve a waiver of signed informed consent provided:

- The research involves no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context;
- The waiver will not adversely affect the rights and welfare of subjects;
- The principle risks are those associated with a breach of confidentiality, where the consent documentation is the only record linking the subject with the research.

In the case of mailed questionnaires, the researcher must provide a written explanation of the study and inform subjects of their rights. The information can be provided in a cover letter that the subject can retain. In the case of telephone surveys, the investigator must provide a verbal explanation of the study and inform subjects of their rights. These explanations must be submitted to the IRB for approval.

Appendix D

SPECIAL POPULATIONS:

Research involving special populations require additional protections that must be described in the research proposals. Because these reviews are often more complicated, the investigator should allow extra time for review of projects involving special populations.

Children – 45 CFR Part 46, Subpart D

Children (anyone under 18 years of age) can participate as subjects of research only if there no greater than minimal risk to the children and the IRB finds adequate provisions are made for soliciting the assent of the children and the consent of the parents or guardians of children (see 45 CFR 46.408). The consent form should always indicate, regardless of the age of the child, that either the parent or the child may withdraw the child from participation in the research at any time. The assent form should be written in language appropriate to the age level of the children involved. Investigators should review Subpart D of the federal rules (45 CFR 46) to ensure that the proposed research follows federal rules for research involving children.

Assent means a child's affirmative agreement to participate in research; mere failure to object should not be construed as assent. Ordinarily for children 12 years and older, written assent is required. For children under 12, verbal assent may be obtained. The researcher must inform the IRB about the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding where assent must be obtained and how it will be documented.

Note: The exemption from review for survey and interview procedures or observations of behavior does not apply to research with children as subjects, except for research involving observation of public behavior when the investigator does not participate in the activities being observed. This type of research must be reviewed by the full IRB (e.g., it does not qualify for either exempt or expedited review).

Prisoners – 45 CFR Part 46, Subpart C

A prisoner is defined by federal rule as any individual involuntarily confined or detained in a institution. This definition includes individuals detained in other facilities by virtue of statutes or procedures which provide alternatives to criminal prosecution or incarceration in a penal institution as well as individuals being held prior to arraignment, trial or sentencing. Additional time is required to schedule an IRB meeting when prisoner research is involved. Projects involving prisoners must be reviewed by a full IRB; they cannot receive an expedited review.

Institutionalized People

Institutionalized individuals require special consideration. Written permission for the conduct of the research at the institution must be obtained from the appropriate officials at that institution. In addition, if the subjects are not capable of giving consent for themselves, it must be obtained from their legal guardians. If subjects are capable of giving consent, the consent form should be written in language appropriate to the subjects.

Other Vulnerable Populations – 45 CRF Part 46, Subpart B

Investigators conducting research on pregnant women, human fetuses, and neonates should Subpart B of the federal rules (45 CFR 46), which includes additional protections required.

Appendix E

Other Issues:

INTERNATIONAL RESEARCH

Field research done outside of the United States, especially in non-western societies or places where the subjects do not speak English may pose problems in obtaining documentation of informed consent.

In these situations, it is sometimes impossible, for a variety of reasons, to obtain written consent. If that is the case, the investigator must provide the IRB with a statement of the reasons why it should waive written consent, and also provide an acceptable alternative method of obtaining oral consent, which is appropriate to both the subjects and their culture.

COLLABORATIVE RESEARCH

Research conducted either at other institutions and/or in collaboration with researchers at other institutions generally also require approval of the IRB at the other institution as well.

USE OF DECEPTION IN RESEARCH

The use of deception in research raises special problems that the IRB will review closely. One consideration is whether the deception is necessary. A researcher proposing to use deception should justify its use. Present federal rules prohibit deceptive techniques that place subjects at more than minimal risk.

A second consideration is debriefing. The IRB expects researchers to debrief subjects who have been deceived during research activities. The debriefing should include a detailed description of the ways in which deception was used. The researcher is responsible to ensure that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, should be explained to the IRB as a part of submitted protocols.

Appendix F

FEDERAL REQUIREMENTS AND GUIDELINES:

The Department of Health and Human Services (DHHS) policy as expressed in Title 45, Part 46 of the Code of Federal Regulations, also known as 45 CFR Part 46, is the heart of the federal policy on protecting human subjects in research. In 1991, many federal agencies accepted Subpart A, the general provisions of 45 CFR Part 46, as the federal Common Rule. Each "Common Rule agency" publishes an identical version of this Federal Policy for the Protection of Human Subjects in its own section of the Code of Federal Regulations. The DHHS Office for Human Research Protections (OHRP) exercises an important leadership role among Common Rule agencies.

The Federal Policy applies to all research sponsored by the Common Rule agencies. In addition, the Food and Drug Administration (FDA) has the authority to regulate a wide variety of research activity, including all research that involves biological products, drugs, and medical devices, regardless of who sponsors the research. The FDA's core policies are published as Title 21, Parts 50 and 56 of the Code of Federal Regulations. Subject-specific FDA regulations apply to research that involves:

- new pharmaceuticals (21 CFR Part 312)
- biological products (21 CFR Part 600)
- medical devices (21 CFR Part 812)

Some federal agencies impose requirements above and beyond those in the Common Rule. For example, DHHS policy includes additional protections for fetuses, pregnant women, human in vitro fertilization (Subpart B, 45 CFR Part 46), prisoners (Subpart C), and children (Subpart D). Agency-specific requirements apply to research sponsored by that agency.

In addition to the federal Common Rule and the FDA regulations, the OHRP Guidance Documents are the third key source of information about legal requirements.