

Fairmont State University
Board of Governors
Policy #48 Research Involving Human Subjects
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Part 1: Introduction

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A. Basic Definitions

1. ITRC and IRB

The Fairmont State (FS) Institutional Testing and Research Committee (ITRC) functions as the Institutional Review Board (IRB) for the Protection of Human Research Subjects. The IRB functions under the mandate of the presidents of FS and is responsible for reviewing all research involving human subjects. The 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 expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. 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 non-scientific areas. The IRB 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.

2. Research

"Research" is defined in the Code of Federal Regulations (45 CFR 46) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". Human subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".

Examples of activities that constitute research include

- any study intended to result in publication or public presentation
- class projects requiring the collection of human data outside of the class setting
- graduate student projects requiring the collection of human data outside of the class setting

Examples of activities that are not research would include any evaluation of an employee, course, program or service where such evaluation is *not* designed to lead to generalizable knowledge. Taste tests involving the use of FDA pre-approved consumables for the purpose of improving food service. If an activity does not involve research, it does not require approval or review by the IRB.

If you have any doubt as to whether an activity constitutes research, please consult with the current IRB chair.

3. Protocol

A protocol is the formal design or plan of a research activity; any protocol submitted to the IRB must include the elements specified under "Preparing a protocol for expedited or quorum review."

B. Purpose

The purpose of the IRB is to protect the rights and welfare of individuals who serve as subjects of research conducted by faculty, staff and students and to ensure institutional compliance with those ethical considerations contained in the Code of Federal Regulations (45 CFR 46 as well as 21 CFR 50 when applicable) and Title 133 series 31 of the West Virginia Higher Education Policy Commission. To meet these obligations, the IRB

- maintains guiding principles and operating policies (as contained in this document) demanding the highest professional standards in dealing with human subjects and
- reviews all research projects involving human subjects to ensure that appropriate standards are met and the research procedures do not infringe upon the safety, health, welfare, or life of those subjects.

C. Governing Principles

The IRB guidelines are based on these general ethical principles:

1. *The rights and welfare of all subjects must be adequately protected.* This principle applies to the need for safeguarding the physical and psychological well being of a subject and to preservation of the rights of privacy and self-determination.
2. *Risks must be minimized* by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. Whenever appropriate, investigators should use procedures already being performed on the subjects for diagnosis or treatment.
3. *Risks must be reasonable* in relation to anticipated benefits to subjects or to importance of the knowledge that may be gained. The IRB reviews research for scientific merit with respect to the risk or benefit to human subjects, including the anticipated benefits from the knowledge that may be expected to result.

4. *Recruitment and selection of subjects must be equitable and unbiased* within the confines of the purposes and design of the study; subjects must not be arbitrarily excluded on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status. Generally, attempts must be made to enhance the diversity of the research sample.
5. If an *informed consent and information form* is required, it must be provided to each subject or the subject's authorized legal representative and signed by each.
 - a. The informed consent process must be documented by an approved, current written "consent and information form," a signed copy of which must be given to the subject.
 - b. To the fullest extent possible, the subject's consent must be based upon an understanding of the research, the risks, possible discomfort, benefits, and alternative procedures.
 - c. The informed consent document must provide for the subject's ability to refuse participation or to discontinue participation at any time without prejudice.
 - d. The signed informed consent must be available for review by the IRB or federal regulatory authorities for 3 years after the study is closed.
6. It is the investigator's responsibility to monitor data collected during the research to ensure the safety of subjects. Adequate provisions must be made to protect the *privacy* of subjects and the *confidentiality* of data. In addition, the IRB must be satisfied that questionnaires and protocols involving sensitive issues (which could, if they became known outside the research, affect economic risks such as employment or place the subject at various physical or social risks) are carefully designed to avoid gathering more personal data than is absolutely essential to the research.
7. Additional safeguards must be included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence or who belong to potentially *vulnerable populations*.

D. Authority of the IRB

The IRB has the authority and responsibility to approve and monitor for compliance with sound ethical principles and applicable regulations all research involving human subjects conducted by university faculty, staff or students. In particular, the IRB has the authority to:

1. Approve or disapprove a protocol or to require modifications to a protocol including the consent form as a condition for approval.
2. Oversee the conduct of a study and require progress reports.
3. Suspend or terminate a study, or impose restrictions or require modifications to a study as a condition for continuation.

The IRB will not grant retroactive approval once data has been collected from human subjects.

E. Responsibilities of Investigators

1. Investigators must receive written approval from the IRB before they can involve human subjects in research projects. Failure to comply with this requirement is a direct violation of university policy.
2. All "key personnel" listed on the protocol application MUST satisfactorily complete Human Participant Protections (Human Research Ethics) training. The term "key personnel" includes the PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition.

A convenient method to satisfy this requirement is to satisfactorily complete the online course at (<http://www.research.umn.edu/consent/mod1soc/mod1sec0.html>) or at <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>). Upon completing this examination, the results will be a part of the IRB approval application and can be sent to the Department chair, ITRC chair or the research administrator.

Principal investigators are responsible for ensuring that all key personnel on their projects have received appropriate training.

3. Investigators must receive a written and signed "exemption approval" before involving human subjects in research projects that are exempt from IRB review.
4. Investigators must receive written and signed approval from the IRB prior to making any changes to a protocol (which includes a change in investigators who will have contact with subjects or records, modification of advertisements, consent forms, or procedures).
5. Investigators must comply within 60 days with all IRB requests for information concerning a protocol.

When the IRB requests additional information, clarification, simplification, or other changes before a protocol can be approved, it is the responsibility of the PI to provide such information to the IRB. This should be done in a timely fashion and in a form in which the IRB members can readily see what changes have been made and can determine whether the changes adequately address the initial deficiencies.

It is recommended that revisions to protocols in response to IRB criticism be presented in a manner similar to that used for grant applications or manuscripts where revisions are requested. A good way to accomplish this is to provide a fresh page indicated as "Response to IRB review" (or similar language). Each item should be addressed in the order in which it appears in the critique with the remedial action clearly indicated. All changes must be indicated by brackets. The IRB is composed of faculty members of the

various colleges at FS, as well as non-faculty members. All IRB members cannot be expected to be experts in the field of the Principal Investigator and, therefore, it is the responsibility of the PI to make sure that the changes are clear to the reviewers.

If the PI feels that the reviewer was in error on certain points, this can be discussed in the response, however, it might be more efficient to contact the IRB chair.

6. Investigators must notify the IRB of any adverse reactions, unforeseen events, or termination of human subject involvement for adverse reasons as soon as possible.
7. Investigators must keep copies of signed consent forms in research records. 8.

Consent forms must be signed by the research participant.

9. Protocols are subject to random internal quality assurance audits. It is the responsibility of the PI to keep records in order and to assist the IRB and the auditor in conducting any audits.
11. IRB record retention and access: All IRB records relating to a research study shall be retained for at least three years after the completion of the research.
12. Investigators affiliated with Fairmont State involved in research conducted at another campus or academic institute must obtain a copy of the hosting institutes IRB approval and submit a copy of that approval to the Fairmont State IRB.

Part 2: Categories and Procedures: Exempt, Expedited and Quorum Review

All research falls into one of the following four categories:

- A. Exempt Research
- B. Expedited Review
- C. Quorum Review
- D. Case Studies and Oral Histories

A. Exempt Research

"Exempt research" is research that does not require expedited or quorum review by the IRB, although it does require an "exemption approval." (See A.3 below.)

I. Criteria for Exemption from IRB Review

A project is exempt if **all** the research activities belong in one or more of the following categories found in 45CFR46-101 B:

1. Research conducted in established or commonly accepted educational settings, involving *normal educational practices*, such as:
 - a. research on regular and special education instructional strategies, or
 - b. 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), *surveys or interviews*, or *observation of public behavior*, unless
 - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. any disclosure of the human subjects' responses (or conduct) outside the research may place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (If this is suspected, the study will be subject to quorum review).

Some additional institutional restrictions apply:

Research involving the use of *educational tests* (cognitive, diagnostic, aptitude, achievement) may be exempt only if the results are used solely for student or institutional evaluations.

Research involving *observation of public behavior* will be exempt only if the subject's responses do not deal with sensitive aspects of personal behavior (for example, illegal conduct, drug use, sexual behavior or use of alcohol), and the investigator does not participate in the activities being observed.

Research involving *surveys or interviews* will be exempt only if

- a] no identifying information is collected,
- b] the subject's responses do not deal with sensitive aspects of personal behavior (for example, illegal conduct, drug use, sexual behavior or use of alcohol), and c] in case of electronic surveys, they must have the technology integrated in them that erases the return address (a letter from IT is required). WebCT surveys will not require such a letter.

3. Research involving the use of *educational tests* (cognitive, diagnostic, aptitude achievement), *survey procedures*, *interview procedures*, or *observation of public behavior* is not exempt if:
 - a. the human subjects are *elected or appointed public officials or candidates for public office*. (Public officials are defined as those individuals elected or appointed to local, state or federal office.); or
 - b. Federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of *existing data by retrospective review*—including documents, records, pathological specimens or diagnostic specimens—if
 - a. these sources are publicly available, and

- b. the information was recorded by the investigator in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects.
Please note that for this category, the application for exemption must always include a data collection sheet that itemizes all variables and identifies the source of the data.

5. Research and demonstration projects that are conducted by or subject to the approval of [federal] department or agency heads, and that are designed to study, evaluate, or otherwise examine:
- public benefit or service programs;
 - procedures for obtaining benefits or services under these programs;
 - possible changes in or alternatives to these programs or procedures; or
 - possible changes in methods or levels of payment for benefits or services under these programs.
6. Research involving only *taste and food quality evaluations 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 and 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.

Notes:

- If a consent form is used, the protocol cannot qualify for exemption.
- Any research in which the subjects are filmed or videotaped cannot qualify as exempt and must undergo expedited or quorum review.
- Focus group studies are not exempt.

II. Exempt Research Involving Children and protected or vulnerable populations

Children and other vulnerable populations cannot be subjects of exempt research. **III.**

Procedures for Exempt Research

If a study is eligible for exemption, a written approval must be obtained from the IRB before beginning any research activities involving human subjects. Studies that have received an exemption do not require any additional reviews for exemption unless a change is made in procedures, settings, or investigators.

B. Expedited Review

"Expedited review" is the review of a protocol by one or two IRB members and applies to certain types of minimal risk research as authorized by 45 CFR 46.110 and 21 CFR 56.110.

"Minimal risk" means that the probability or magnitude of physical or psychological harm does not exceed that encountered in ordinary daily life or during routine physical or psychological examinations or tests.

I. Research Eligible for Expedited Review

Research is eligible for expedited review if all of the research activities are minimal risk and belong in one or more of the following categories. The categories in this list apply regardless of the age of subjects, except as noted.

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml (about a pint) in an 8-week period, and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount may not exceed the lesser of 50 ml (about 3 and a third Tbs) or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
2. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

 - a. hair and nail clippings in a nondisfiguring manner;
 - b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - c. permanent teeth if routine patient care indicates a need for extraction;
 - d. excreta and external secretions (including sweat);
 - e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
 - f. placenta removed at delivery;
 - g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - j. sputum collected after saline mist nebulization.
3. 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 approved medical devices for new indications.)

Examples:

- a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - b. weighing or testing sensory acuity; c. magnetic resonance imaging;
 - d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
 - e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
4. Research involving materials (data, documents, records, or specimens that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) Please note that for this category, the protocol application must always include a data collection sheet that itemizes all variables that will be collected from the records/specimens to be reviewed.
5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. 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 in which there are potential identifiers if:
- a. the investigator does not manipulate* the subject's behavior, and b.
 - the research will not involve stress* to the subject, and
 - c. the research will not involve deception* of the subject.
- Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.
7. Continuing review of research previously approved by the convened IRB as follows: a. where
- i] the research is permanently closed to the enrollment of new subjects;
 - ii] all subjects have completed all research-related interventions;
 - iii] and 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.

* **Manipulation** The investigator attempts to change the subject's psychological or physical functioning.

* **Stress** Situations in which the demands on individuals tax or exceed their resources,

with a potential to endanger well being or health, or which involve questions about stressful life events.

- * **Deception** Procedures that conceal or mislead subjects about the procedures of a study and do not provide an accurate debriefing explaining the true purpose of the study.

All research eligible for expedited review requires informed consent. **II.**

Procedures Required for Expedited Review

The format and content of a protocol are specified in the next section titled "Preparing a protocol for expedited or quorum review" and are the same for both expedited and quorum review. The IRB screens all protocols for compliance with the required format, necessary signatures and inclusion of consent forms. The IRB then sends the protocol to one or two reviewers.

Protocols (applications) may be submitted at any time for this type of review. Investigators must have an official, written approval letter from the IRB before enrolling subjects in the study. The IRB approval is valid for a maximum of one year; if not reapproved by the anniversary date, the protocol will be closed. Note that approval of an addendum does not constitute re-approval for another year.

III. Results of Expedited Review

Reviewer(s) may:

- Approve the protocol.
- Require changes for approval under expedited review (changes must be made within 60 calendar days).
- Refer the protocol for quorum review.

Reviewers may not disapprove an expedited protocol or amendment.

Any protocol that does not fall in one of the above categories, will automatically be referred for quorum review.

C. Research Requiring Quorum Review

"Quorum review" is the review of a protocol by a quorum of IRB members attending a convened IRB meeting.

I. Criteria for Quorum Review

Quorum review is necessary for research involving risk of physical or psychological harm greater than that encountered in daily life or during routine examinations or tests; research involving deception, stress or manipulation also requires quorum review. Any research that

does not satisfy the requirements for exemption or expedited review will undergo quorum review.

II. Procedures Required for Quorum Review

Protocols requiring quorum review will be reviewed at scheduled IRB meetings. In order for a protocol to be considered, submit one copy (in paper or digital format) of all prepared material (includes protocol statement, abstract, consent forms – if applicable, discussion, debriefing and attachments).

Before a protocol can be reviewed, the IRB chair screens it for compliance with the required format, necessary signatures and inclusion of consent forms, and other necessary information.

III. Results of Quorum Review

At its convened meeting the IRB may:

- Approve the protocol as submitted.
- Require modifications or request additional information (must be received within 60 calendar days). For modified consent or assent forms, a new submission date *must* appear on the bottom left of each page. Depending on the nature of the information, a subcommittee or an IRB staff member will review the material. Approvals by subcommittee must be unanimous or the protocol will be referred to the next regularly scheduled IRB meeting.
- Invite investigator(s) to attend next meeting to address concerns.
- Disapprove the protocol. If disapproved, all signatories will receive a copy of the disapproval letter (including all co-PIs, deans, and chairs).

Investigators must have an official, written approval letter from the IRB before enrolling subjects in the study. The initial approval is valid for a maximum of one year; if not reapproved by the anniversary date, the protocol will be closed. Note that approval of an addendum does not constitute reapproval for another year. The IRB may decide (on a case-by-case basis, based primarily on the risk/benefit analysis of the study) that a protocol requires reapproval more often than once a year. If the IRB disapproves a protocol, any resubmittal must be accompanied by a new "Protocol Statement," including all appropriate signatures.

Investigators may invoke an appeal procedure if a protocol is not approved.

D. Policy on “Case Studies” and “Oral Histories”

Case studies are reports, usually of an individual case that has characteristics the investigator feels would be of interest to others. Case studies are ordinarily reported to peers or discussed with students as part of an educational experience. Occasionally case studies are presented at scientific meetings and may be published in medical journals. Oral histories are experiences and reminiscences of individuals recorded by a historian or other individual. These oral histories may be of general interest and may be published or presented in an oral format. Both of these activities are important, but neither, in most instances, meets the definitions of human subject research. Therefore they do not require IRB approval. However, it must be pointed out that there are instances in which case studies or oral histories do satisfy the definition of

research and would require IRB approval. If there are questions about a particular study and whether IRB approval is necessary, the IRB chair should be contacted.

Part 3: Preparing a Protocol for Expedited or Quorum Review

An IRB Protocol for both expedited and quorum review consists of the following elements:

- A. [Research Involving Human Subjects Application for Approval Form](#)
- B. [Human Subjects Research Protocol Application Form](#)
- C. [Investigator Assurance for Research Involving Human Subjects](#)
- D. [Other Relevant Attachments](#)

The IRB requires a uniform format to facilitate its review of protocols from various disciplines. Protocols must adhere to the forms provided by the IRB. All submissions must be legible and suitable for photocopying. The IRB may return protocols if any materials are not sufficiently legible or incomplete.

A. Research Involving Human Subjects Application for Approval Form

The Research Involving Human Subjects Application for Approval Form can be downloaded from the ITRC web page. The following information is required for the Approval Form.

1. Title of project: Provide the complete title. Where applicable, use the exact title listed in the grant/contract application.
2. Type of application: Check the appropriate category for new application, addended/modified, or other, adding written explanation.
3. Funding source: List any (internal or external) sources of funding for the project.
4. Principal Investigator: List the primary researcher involved in the project. This is the person that will be legally responsible for ensuring consent forms are signed and retained for a three-year period.
5. Co-Principal Investigator: For research conducted at FS, if the principal investigator is a FS student or someone outside of the University, a co-principal investigator who is a faculty member at FS must be named.

Training: It is the responsibility of the primary investigator to verify that all key personnel have received the following training:

Human Participant Protections (Human Research Ethics) training (all protocols); HIPAA Research Requirements training, if protected health information is involved; Good Clinical Practice training, if the study is a clinical trial and involves the use of drugs or devices.

Consultants/collaborators who meet the definition of key personnel, but with no anticipated contact with human subjects (including identifiable personal data and/or identifiable health information), are not required to complete such training.

6. Contact Name/E-mail/Phone for Questions/Problems/Emergencies: This may be the principal investigator, the principal investigator's faculty advisor, or anyone associated with the project who might be able to address IRB issues.
7. Does this project involve any collaborators not part of the student/faculty/staff at FS: Outside parties may require additional coordination and approvals.
8. Project Classification: Check the appropriate box for thesis, class project, faculty research, or other with attached explanation. If this is student research, faculty advisor(s) should be listed as co-principal investigators AND project collaborators on the Human Subjects Research Protocol Application Form.
9. Please attach a copy of the consent form: Check the appropriate box for copy attached or consent form not used.
10. Please attach a copy of the sponsor's grant application or contract as submitted to the funding agency: Check the appropriate box for copy attached or not applicable.
11. Human subjects exemption statement: Based upon criteria found in 45 CFR 46-101b and the overview of projects that may qualify for exemption, I believe that my project using human subjects should be determined by the IRB to be exempt from IRB review. Check the appropriate box, which in the case of an expedited or quorum review would be No.

B. Human Subjects Research Protocol Application Form

The Human Subjects Research Protocol Application Form constitutes the second section of a protocol. The current version of the Human Subjects Research Protocol Application Form can be downloaded from the ITRC web page. Information required for this form is listed below.

1. Background: Provide a concise narrative review of the literature and basis for the study. Typically, this will be less than one half of a page in length.
2. Project/Study Description: Provide a concise narrative description of the proposed activity in terms that will allow the IRB or other interested parties to clearly understand what it is that you propose to do that involves human subjects. This description must be

in enough detail so that the IRB members can make an informed decision about the proposal.

3. Objective: Briefly state the objective of the study-what you hope to learn from the study.
4. Design and Procedures: Fill out the following information to outline the formal plan for the study. If a category is not applicable, leave it blank.
 - a. Location of study
 - b. Variables to be studied
 - c. Data collection methods (surveys, instruments used, etc.-please attach or provide description of any equipment.)
 - d. Factors that would lead to halting the study due to emotional or physical stress e.
 - Biological samples taken (if any)
 - f. Debriefing procedures for participants
5. Research Subjects: Provide the following information about your research subjects.
 - a. Source
 - b. Number: For multi-site studies, provide the estimated maximum number of subjects to be enrolled nationwide and separately list the estimated number of subjects to be enrolled by FS investigators. For studies involving only one site, estimate the number of subjects to be enrolled by FS investigators.
 - c. Characteristics: Describe any unique qualifiers for participation in the study.
 - d. Recruitment procedures: Attach any fliers, ads, posters, etc. used for recruitment. All such ads must have IRB approval before placement, and no deviation from the approved wording is permitted. A recruitment ad must clearly state if a placebo is involved.
6. Risk-Protection-Benefits: The answers for the three following questions are central to human subjects research. You must demonstrate a reasonable balance between anticipated risks to research participants, protection strategies, and anticipated benefits to participants and others.
 - a. Risks for subjects: Identify any foreseeable physical, psychological, or social risks for participants. State that there are no known risks if appropriate.
 - b. Minimizing risk: Describe specific measures used to minimize or protect subjects from anticipated risks.
 - c. Benefits: Describe any reasonably expected benefits for research participants, a class of participants, or society as a whole.
 - d. Minimal risk statement: Check yes or no to the following question: In your opinion, does the proposed research involve more than **minimal risk** to subjects? (“Minimal risk” means that “the risk of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”)
7. Confidentiality: Confidentiality is the formal treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the

understanding of the original disclosure. Explain how you are going to protect confidentiality of research subjects and/or records. Include plans for maintaining records after completion. It is a federal requirement to maintain consent forms for three years after the study completion.

8. Informed Consent: You must provide potential participants with information that informs them of their rights as subjects, i.e. explanation that the project is research and the purpose of the research, length of study, study procedures, debriefing issues to include anticipated benefits, study and administrative contact information, confidentiality strategy, and the fact that participation is entirely voluntary and can be terminated at any time without penalty, etc. Even if your potential subjects are completely anonymous, you must provide them with this information.

Answer yes or no to the following questions about the informed consent procedures.

- a. Are you using a written informed consent form? (If “yes” include a copy with this application. If “no” see next paragraph.)
 - b. In accordance with guidance in Title 45 Code of Federal Regulations Part 46, I am requesting a waiver or alteration of informed consent elements (See Section 7 above). If “yes,” provide a basis and/or justification for your request.
 - c. Does your Informed Consent document have all the minimum required elements of informed consent found in the Consent Form Template? (See Part 4) (Please explain)
 - d. Do you preserve the anonymity of subjects? (An anonymous subject is one whose identity is unknown, even to the researcher.) If “no” explain why and describe how you will protect the identity of subjects.
 - e. Are subjects debriefed about the purposes, consequences, and benefits of the research? Debriefing refers to a mechanism for informing the research subjects of the results or conclusions, after the data is collected and analyzed, and the study is over. (If “no” explain why.)
9. Project Information: The following items raise special concerns about safety, privacy, confidentiality, or other regulatory matters. Does your project involved any of the following? Check any applicable category. If you check yes to any of the questions below, you should explain them on an attached page.
- a. Deception of subjects
 - b. Shock or other forms of punishment
 - c. Sexually explicit materials or questions about sexual orientation, sexual experience or sexual abuse
 - d. Handling of money or other valuable commodities
 - e. Extraction or use of blood, other bodily fluids, or tissues
 - f. Questions about any kind of illegal or illicit activity
 - g. Purposeful creation of anxiety
 - h. Any procedure that might be viewed as invasion of privacy
 - i. Physical exercise or stress
 - j. Administration of substances (food, drugs, etc.) to subjects (Specify if drug or device is in a “non-FDA-approved” application.)
 - k. Any procedure that might place subjects at risk

I. Any form of potential abuse; i.e., psychological, physical, sexual

10. Subject Information: Indicate which populations will be the subject of research. Targeting subjects from any of these populations raises added concerns about the research risks and the informed consent process because such subjects are likely to be vulnerable to injury, coercion, or undue influence (see Part 6.) If any of these populations are added to the research at a later date, an amendment must be submitted and approval received from the IRB. If you answer yes to any of the questions below, you should explain them in one of the paragraphs above.

- a. Under 18 years of age
- b. Physically or mentally disabled
- c. Pregnant females as target population
- d. Subjects in institutions (e.g. prisons, nursing homes, halfway houses)
- e. Economically or educationally disadvantaged
- f. Unable to provide their own legal informed consent

11. Project Collaborators: List all persons involved with the research project or study in the following categories.

- a. FS Collaborators: This list should include anyone (including undergraduate and graduate students) who is collecting or analyzing data related to the project.
- b. Non-FS Collaborators: It is critical that you identify non-FSC collaborators, and initiate any coordination and/or approval process early, to minimize delays caused by administrative requirements.
 - i. Check yes or no to answer the following: Does your non-FS collaborator's organization have an Assurance with OHRP? (For Federalwide Assurance and Multiple Project Assurance (MPA) listings of other institutions, please reference the OHRP website under Assurance Information at: <http://ohrp.osophs.dhhs.gov/polasur.htm>). If yes, please enter your collaborator's MPA number.

Check yes or no to answer the following: Is your non-FS collaborator's IRB reviewing this proposal?

- c. Exempt Projects: 45 CFR 46-101b identifies six categories of research involving human subjects that may be exempt from IRB review. If you believe that your project qualifies for exemption, please indicate which exemption category applies (1-6). Please remember that only the IRB can make the final determination whether a project is exempt from IRB review, or not. This category should not apply to protocols being prepared for expedited or quorum review.

C. Investigator Assurance for Research Involving Human Subjects

The Investigator Assurance for Research Involving Human Subjects Form constitutes the third section of a protocol. The current version of the Investigator Assurance for Research Involving Human Subjects Form can be downloaded from the ITRC web page. The following information is required to complete this form.

The primary investigator listed on the Research Involving Human Subjects Application for Approval Form must read, agree to, and sign the following assurances.

As the Principal Investigator on this protocol, I provide assurances for the following:

- A. Research Involving Human Subjects: This project will be performed in the manner described in this proposal, and in accordance with Title 45 Code of Federal Regulation Part 46 available at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>, applicable laws, regulations, and guidelines. Any proposed deviation or modification from the procedures detailed herein must be submitted to the IRB, and be approved by the Committee prior to implementation.
- B. Training: I assure that all personnel working with human subjects described in this protocol are technically competent and have completed training in the treatment of human subjects.
- C. Extramural Funding: If funded by an extramural source, I assure that this application accurately reflects all procedures involving human subjects as described in the grant/contract proposal to the funding agency. I also assure that I will notify the IRB, and the funding/contract entity if there are modifications or changes made to the protocol after the initial submission to the funding agency.
- D. Study Duration: I also understand that as continuing reviews are conducted, it is my responsibility to provide timely and accurate review or update information when requested, to include notification of the IRB when my study is changed or completed.

D. Other Relevant Attachments

1. Provide a copy of each survey or other test instrument.
2. Provide a copy of each consent form, Federal or State agency forms, and any other cover letters that may be sent to subjects or to their parent(s) or legal guardian(s). Include also an explanation of any requested waiver or alteration of the informed consent or assent process. If the consent or assent forms are not in standard format, the protocol will not be reviewed. All consents must be translated into foreign languages, as appropriate, and must have an authorization signature and statement certifying that this is a true translation. Explain where the consent forms and assent forms will be kept.
3. Provide any advertisements to be used in recruitment of subjects.
4. If applicable, provide, from each institution or organization other than FS a current letter on that institution's letterhead granting permission for investigators to use its facilities or resources. This letter must refer specifically to the study in question by title and investigator.

5. If applicable, provide a copy of the protocol prepared by any other person or institution (e.g. drug companies, research sponsored by private companies) with which the study must comply.
6. If a study involves the use of a consultant, whether paid or non-paid, the consultant must sign a memorandum that he/she has read the protocol and agrees to serve as a consultant. Provide a copy of any collaborator/consultant agreements if applicable.
7. Provide other appropriate attachments (e.g., texts used for interviews, letters from radiation safety officers, etc.)

Part 4: Consent and Assent A.

Consent

B. Assent

C. Waiver or Alteration of the Consent Process D.

Waiver or Alteration of the Assent Process A.

Consent

Written informed consent is required, and copies of the most recent approved consent form must be used to enroll subjects in a study.

Informed consent is a person's documented, voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure.

Investigators must obtain legally valid informed consent from each subject or from the subject's legally authorized representative (power of attorney, or authorized court appointed guardian /representative) for any nonexempt research. Subjects document their consent by signing the most recent copy of the consent form approved by the IRB. Subjects must receive a copy of the signed consent form.

No consent may be assumed; so called "passive consent" is not legally valid consent. If the research includes a non-randomized control group, a separate consent form for that group of subjects is needed.

In exceptional cases, detailed in Section B, obtain the IRB's permission to depart from the usual procedure. Alternative procedures include

- oral narrative coupled with a short-form consent document (see Section C.1 below),
- oral consent for impaired or illiterate subjects (see Section C.2 below),
- waiver of consent form to preserve anonymity (see Section C.3 below),
- other waivers or alterations of the consent process (see Section C.4 below).

The IRB must approve all consent forms. Once the IRB has approved a consent form, a copy of the approved consent form must be used in the research and the IRB must approve any proposed changes. (See Part 5.)

1. Format and Style

Consent forms must adhere to the following requirements.

- a. Use departmental letterhead (8-1/2" x 11" paper) of the principal investigator. Leave a 1" margin on all sides of the IRB provided consent form.
- b. The print should be legible enough for copying purposes. The form should be in no less than a 12-point font type, and should be single-spaced, with double-spacing between paragraphs. Larger-than-normal type size may be necessary for some populations— such as children, the elderly, or the visually impaired. Divide the consent form into sections and use the descriptive headings provided (e.g., "Purpose," "Risks and Discomforts," "Confidentiality"), all of which should be in boldface type. Section titles may appear on a separate line or be underlined at the beginning of a paragraph.
- c. Number all pages. Use only one side of the page. Each consent/assent form should have its own, distinct pagination; each page should have the project title, a page number (in the bottom middle of the page, in the form "page xx of xx") and a line for the subject to initial and date (in the bottom right-hand corner of the page), signifying that the page has been read. The last (most recent) date of submission to the IRB should appear on each page (bottom left-hand corner of page).
- d. The IRB must approve your form if you do not use the IRB provided forms.
- e. Use the first person, as though the subject were explaining the study to someone else (e.g., "I understand that ..."; "Dr. X will give me . . ."). Only separate cover letters or narratives may speak to the subjects in the second person. A consent form to be signed by a parent, a guardian or authorized representative should be written in the first person, but refer to the subject in the third person (e.g., "I understand that my child will ..."; "Dr. X will give my child . . .").
- f. Use lay language throughout. Explain the nature of the project, the nature of the subject's participation, and the nature of the risks and benefits involved in language clearly understandable to the anticipated subjects (federal regulations suggest 7th-grade level).
- g. The IRB does *not* allow separate signature pages; at least some portion of the text must be on the signature page.
- h. The IRB will not accept consent or assent forms with excessive blank spaces in the text. i.

Multiple consent/assent forms should be labeled to indicate the targeted subject groups.

2. Contents and Structure

The consent form must contain all applicable items listed below (items 1–13).

The IRB may waive any of these requirements upon the written request of the investigator. Explain why the provision is unnecessary or inappropriate. (See Section B below.)

The IRB does not permit language by which the subject or his or her representative waives any of the subject's legal rights or releases the investigator, the sponsor, the institution or its agents from liability for negligence.

- (1) The words "Consent and Information Form" must be at the top of the first page. Following pages should have consecutive page numbers (in the bottom middle of the page, in the form "page xx of xx"), an abbreviated title at the top, a submission date at the bottom lefthand corner and an initial and date line at the bottom right-hand corner of the page (see 1.c above).
- (2) Give the complete title of the study on the first page of the consent form. If the title on the consent or assent form differs from the title of the protocol, explain why in the discussion section. The study title (abbreviated if necessary) should appear at the top of each page of the consent form.
- (3) "Introduction"
 - (a) Include the following statement or its equivalent:

"I have been asked to participate in this research study."
 - (b) Indicate who explained the study to the participant (if not in person, provide details on how the presentation was made, e.g., cover letter, phone call), who is conducting the study and what department is sponsoring the study. Include the names of all investigators (principal investigators as well as co-investigators) involved in the study. When an investigator's name first appears in the consent form, spell it out fully and include the individual's degree (e.g., Joe Johnson, M.D.; Kirk Douglas, Ph.D.; etc.) and then refer to the person as "Dr. Johnson" or Dr. Douglas in subsequent text.
 - (c) Inform participants if the research is being done to fulfill requirements for a master's thesis or classroom assignment. In that student researchers are not full representatives of FS, it is important that both potential research participants and FS be in agreement that proper oversight by FS exists for research conducted by students. Therefore, students completing protocols for review should provide the name of the faculty member or research associate supervising the research project. This information should be provided in the introduction of consent/assent forms, cover letters, and protocol statements.
 - (d) Identify any external support or sponsoring agency.
- (4) "Purposes"

Explain why the study is being conducted. If applicable, state that the investigational drug or device being used in the study has not yet received approval from the Food and Drug Administration or has not been approved for this application. State the approximate number of intended subjects and state the anticipated number of subjects in the FS component. For example, (If multicenter), "Approximately _____ people are expected to participate in this study nationwide. FS researchers hope to enroll about _____ people in this study."
- (5) "Procedures"
 - (a) If applicable, provide a brief explanation of standard therapy and any consents required for this therapy.
 - (b) Explain the randomization process in lay language and the likelihood of the subject's being assigned to a particular group.
 - (c) Describe the procedures to be followed. Explain in detail all experimental procedures, using one paragraph for each element.
 - (d) Do not list inclusion and exclusion criteria in the consent form.

- (e) State the expected duration of the subject's participation.
 - (f) Explain any special circumstances under which the investigator or the sponsor would terminate the subject's participation.
 - (g) If questionnaires or interviews are involved, inform subjects of the time involved, the nature of the questionnaire or interview, that they can see questions before they sign the consent form, and that they do not have to answer all of the questions. Explain that any subject, parent or guardian may review the questionnaire or interview questions before signing the consent or assent. Parents or guardians must be told that the child does not have to answer all questions.
 - (h) If audiotaping or videotaping is involved, the consent form must inform subjects of that procedure.
 - (i) Subjects *must* be informed that appropriate care will be available or an appropriate referral will be made if a particular problem or disease is discovered or if they have an adverse physical or psychological reaction to the study.
 - (j) If blood is drawn for research purposes, state the amount of each draw (in tablespoons or teaspoons), the frequency, and the total amount that will be drawn during the study (in tablespoons and teaspoons) as well as a fraction of a blood donation (a standard blood donation is approximately one pint, which is 32 tablespoons or 96 teaspoons)
- (6) "Plasma/Tissue Banking"
- (a) If on-site tissue banking for future studies is involved refer to appropriate Federal guidelines.
 - (b) If off-site tissue banking is involved, the following statements (as appropriate) must be included in the consent form:

"I understand that the study will also involve a system for storing blood fluid (plasma) or tissue to use in future research. None of these studies would be of benefit to me. For this purpose, an extra _____ will be used for future research purposes."

"As part of the ongoing scientific and biotechnological activities of the _____ and its agents, these blood samples or tissue specimens will be preserved and used for research and development purposes. As a result of these activities, an economic benefit may be derived directly or indirectly by the _____, individual researchers, and others engaged in these activities. By checking a box at the end of this consent form, I authorize the presentation and use of these specimens."

"Some research may require no identification of blood or tissue, so there would be no risk to me. This file will be kept to allow identification of samples. If further projects are planned that require use of identifiable samples, I will be contacted and my consent will be necessary to do such research. If I do not want to be contacted for future studies, I can check a box at the end of this form."
 - (c) *Required statements for end of consent form:*

I authorize the preservation and future use of my [tissue, blood, etc.]
 Yes No Initials _____
 I authorize future use of my [tissue, blood, etc.] without additional consent.
 Yes No Initials _____ (7)

"Risks" or "Risks and Discomforts"

- (a) Describe any known or foreseeable risks or discomforts to the subject. Use a table if available.
 Discuss each drug and its associated risks separately. Explain possible drug interactions. Differentiate between temporary and possible permanent side effects. Divide into likely, less likely and rare.
- (b) For studies involving radiation, state the nature of the radiation and the risks involved. (c) For drug or device studies and studies, explain that the treatment or procedure may involve risks that are currently unknown or unforeseeable.
- (d) If applicable, include the following statement for studies that may include female subjects:
 "This study may involve risks to the unborn child. For this reason, I understand that, if I am a female of child-bearing potential, I will not be allowed to participate in this study until I have had a pregnancy test and the test has indicated that I am not pregnant. I understand that I must use a medically approved method of birth control while I am participating in this study."
 Some investigational studies may require that males use appropriate contraceptive methods.
- (e) If applicable, include the possibility of genetic aberration of sperm.
- (8) "Alternatives"
 Alternative procedures or courses of treatment and their consequences and risks must be disclosed. Always state that nonparticipation is an option.
 If students are to receive class credit, the consent form must state that other opportunities are available to earn the same extra credit. For example: "I understand that I will earn extra credit for participating in this study. I also understand that other options are available for earning the same extra credit."
- (9) "Benefits"
 Describe any anticipated benefits to the subject or to others (such as generalizable knowledge).
- (10) "Financial Considerations"
 (a) Explain any costs associated with participation. For studies involving clinical treatment, explain any expenses that would not ordinarily be incurred with current treatment for the subject's condition. Also explain that the subject or the insurance carrier are usually billed. Include the statement: "I may wish to consult my insurance carrier prior to entering this study."
 (b) State if the drug, device, lab work, or tests will be given free of charge.
 (c) State whether subject must pay for the drug if it becomes commercially available during the study period.
 For example, in cancer studies, when applicable, include the following statement: "The Division of Cancer Treatment, National Cancer Institute, will provide me with the investigational agent _____ free of charge for this study. Should this agent become commercially available during the course of the study, however, I may be asked to purchase subsequent doses of the medicine. I understand that the other costs associated with treatment (including hospitalization, X-rays, and lab tests) will be billed to my insurance company or myself."

- (d) Describe any monetary rewards, payments, or incentives for participating; include an explanation of the extent to which payment will be made if the subject withdraws or is removed from the study prior to its completion, including any proration or bonus for completing the study.
- (11) "Voluntary Compensation"
- For studies involving more than minimal risk,
- (a) state that medical treatment will be available if injury occurs:
"If I am injured as a result of this research, treatment will be available. Responsibility for that treatment will be borne by a] sponsor; b] insurance; or c] subject. "
 - (b) state if any money will be paid voluntarily as compensation for injury that occurs as a consequence of the research
 - (c) state if no money will be paid voluntarily, in which case the following sentence is mandatory:
"Compensation for my injuries will not be provided voluntarily by the investigator, sponsor, Fairmont State, or other associated affiliates." (12) "Contact Persons"
 - (a) Provide the name(s) and telephone number(s) of the principal investigator(s) for questions about the research and whom to contact in the event of a research-related injury (provide day and evening phone numbers).
 - (b) Inform subjects that if they have questions concerning their rights as subjects of research, they may contact the Chair of the IRB.
- (13) "Confidentiality"
- (a) The following statement is mandatory:
"I understand that any information about me obtained as a result of my participation in this research will be kept as confidential as legally possible."
 - (b) State that research records will, as appropriate, become part of a participant's hospital or medical records.
 - (c) For all studies, the following statement is mandatory:
"I understand that my research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the sponsor, federal regulatory authorities, or the IRB without my additional consent."
 - (d) Explain how confidentiality will be maintained.
 - (e) Explain any foreseeable circumstances under which the investigator might be required to give information about the subjects to third parties (e.g., mandatory reporting of infectious diseases, mandatory reporting of information concerning child abuse).
 - (f) If there is a probability of using the materials for public dissemination of the results of the research, include the following:
"In any publications or presentations that result from this research, neither my name nor any information from which I might be identified will be used without my consent."
 - (g) State where audio and videotapes will be kept, how their confidentiality will be maintained and when they will be destroyed.
- (14) "Voluntary Participation"
- (a) State that participation is voluntary.

- (b) State that refusal to participate or withdrawal from the study involves no penalty to the subject and will not alter future care. As appropriate, add that grades and class standing, special educational placement, participation in school or other approved extracurricular activities, etc. will not be affected (for students or trainees), that status on the team will not be affected (for athletes), that job standing will not be affected (for employees or subordinates). If applicable, state that data will continue to be collected even if the subject withdraws.
 - (c) State that the subject's questions about the research have been answered.
 - (d) For studies involving more than minimal risk, the following statement (or its equivalent) is mandatory:
 "In the event new information becomes available that may affect my willingness to participate in this study, this information will be given to me so that I can make an informed decision whether or not to continue my participation."
 - (e) Include a statement telling subjects they will receive a copy of the signed consent form.
- (15) Include lines for the following signatures, each to have the date and time of the signature:
- (a) the subject or the subject's legal representative (if the subject is unable to sign),
 - (b) the investigator or co-investigator (an exception is made for community based studies),
 - (c) the person (other than the investigator or the co-investigator) obtaining the consent in community-based studies,
 - (d) the attending physician (if applicable and if different from investigators),
 - (e) initial any check boxes

3. Conflict of Interest

If a conflict of interest may be present, the subject must be informed of the nature of this conflict in the consent form.

B. Assent

Assent is an agreement by an individual who is unable to give legally valid informed consent to participate in research.

Written informed assent is required unless the IRB approves a waiver or alteration.

When potential research subjects are not competent to give legally valid informed consent, respect for a person's autonomy mandates that the investigator obtain their voluntary assent to participate, in addition to obtaining the informed consent of a parent, guardian, or other legally authorized representative.

Assent is generally required whenever

- subjects are children between the ages of 7 and 18 or
- intellectually or emotionally impaired subjects are not legally competent to give their informed consent.

Subjects manifest their "assent" to participate by signing an assent form which, like the consent form, explains the nature of the research project, the nature of the subjects' participation, and the nature of the risks and benefits involved.

The IRB must approve all assent forms. Once the IRB has approved an assent form, that form must be used; the IRB must approve any proposed changes. (See Chapter 5.)

Format, Style and Content

The format, style and content of the assent form are essentially the same as for a consent form, except:

- a. the language should be appropriate for the age and capacity of the subjects; b. certain provisions may be omitted if they would be confusing or would not be meaningful to the subjects.

The following items ordinarily are included in an assent form in appropriate language (see Section A.2 for specifics):

- (1) The words "Assent Form" at the top of the page
- (2) The title of the study
- (3) The statement "I have been asked to be in this research study." (4)
- (5) (6) (7) (8)

"Purpose"

"Procedures"

"Risks" or "Risks and Discomforts"

"Benefits"

"Confidentiality" [omitting (b) and (c)]

"Voluntary Participation" [omitting (d)]

(9)

C. Waiver or Alteration of the Consent Process

1. Narrative with Short-Form Consent for Emergency Situations

In rare instances, such as studies of subjects in emergency situations, the IRB may approve the use of a narrative coupled with a short-form consent.

Procedure

- a. The investigator must provide a written version of the narrative that contains all the information and elements of the standard consent form; this narrative may be read to the subject verbatim or may be paraphrased. (The narrative may be in the first or second person.)
- b. The subject (or the subject's authorized representative) signs only a short-form consent which states that the subject willingly agrees to participate in the research described in the narrative.
- c. A witness must be present when the narrative is read to the subject. The witness signs the narrative and the short-form consent to verify that the narrative and written information were the same.
- d. The investigator signs the narrative and the short-form consent.
- e. The investigator gives the subject signed copies of the narrative and the short-form consent.

To use this procedure, the IRB requires three items:

- justification in section C of the protocol
- the narrative that will be read to the subjects
- the short-form consent

2. Oral Consent and Waiver of Signed Consent Form for Impaired or Illiterate Subjects In rare instances, such as with impaired (e.g., blind or dyslexic) or illiterate subjects who are fully capable of consenting but are not capable of reading or signing a consent form, the IRB may approve the use of an oral consent. In such cases, the investigator reads a narrative to the subject in the presence of a witness, and the witness signs a form to verify the subject's oral consent.

Procedure

- a. The narrative must be read or paraphrased from a document that contains all elements of the standard consent form. (The narrative may be in the first or second person.)
 - b. After the narrative is read, the subject indicates consent orally.
 - c. A witness must be present when the narrative is read to the subject. The witness signs the narrative and a "Verification of Oral Consent" form to verify that the narrative was presented essentially as written and that the subject consented.
 - d. The investigator signs the narrative and verification form.
 - e. The investigator gives the subject a signed copy of the narrative and the verification form.
- To use the oral consent process, the IRB requires three items:

- justification in Section C of the protocol
- the narrative that will be read to the subjects
- the verification of oral consent form that will be signed by the witness and the investigator

3. Waiver of Signed Consent Form to Preserve Subject Anonymity

In some instances—especially in research involving only the use of educational tests, questionnaires, surveys, interviews, or observation—the principal risk to the subject would be a breach of confidentiality. When data are recorded so that subjects cannot be identified, the only record linking the subject and the research would be the consent document. In such cases, the IRB may waive the requirement of signed consent if it finds the risks resulting from a breach of confidentiality warrant such action. In these cases, after the subject has read a narrative that contains all elements of the standard consent form, he or she may provide explicit oral consent or implicit consent by means of voluntarily participating in the research. **Procedure**

- a. All subjects must receive an information sheet, signed by the investigator and containing all elements of the standard consent form.
- b. The information sheet must be in the form of a cover letter and may be in the first or second person. The cover letter should include all the elements required in a consent form.
- c. Subjects must have an opportunity to read it before deciding whether to participate. To obtain a waiver of signed consent, the IRB requires the following:

- justification in Section C of the protocol and explanation of why it is appropriate
- a copy of the information sheet that will be read by the subjects

4. Other Waivers or Alterations

The IRB may approve substantial alterations to or waive any element of written informed consent only if all of the following conditions apply:

- a. The research involves no more than minimal risk to the subjects.
- b. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- c. The research could not practicably be carried out without the waiver or alteration.
- d. Whenever appropriate, the subjects will receive additional pertinent information after participation.

These conditions apply, for example, to any research that would involve participants in research *without their prior informed consent* or to any research that would involve *deception* of subjects through incomplete or misleading information in the consent process. Protocols in which the investigator seeks a waiver or alteration of the consent process under this provision may be eligible for expedited review by two IRB members. Protocols requesting waiver of both consent and assent will undergo quorum review.

D. Waiver or Alteration of the Assent Process

When an intervention or procedure involved in the research may directly benefit the subject and is available only through participation in the research, the consent of the subject's parent(s) or guardian(s) is sufficient, and the subject's assent is not required. The assent of the subject should nevertheless be solicited; in such cases, a short form assent document may be used. The subject should be given a signed copy of the consent form or narrative and a signed copy of the short-form assent document. To use a short-form assent, the IRB requires three items:

- justification in Section C of the protocol and explanation of why it is appropriate
- the narrative that will be read to the subject, if different from the consent form to be signed by the subject's parent(s), guardian(s) or legally authorized representative
- the short-form assent

Part 5: Changing a Protocol

- A. [Definitions](#)
- B. [Submissions Required](#)
- C. [Emergency Changes](#)

Protocols should be pre-planned to preclude recurrent amendments.

Investigators must obtain IRB approval prior to instituting any changes to a protocol. See Section C below for procedures involving emergency changes without IRB approval. When changes to a protocol are submitted for approval, the entire amended protocol and consent form are subject to review for compliance with current IRB standards.

A. Definitions

• **Major** changes are those that directly affect the level of risk to the subjects and must undergo quorum review. Examples include:

- the addition of new, and vulnerable populations as subjects,
- increasing the sample size in vulnerable populations, or
- any change in strategies, drug dosage, or period of administration of drugs.

In the case of amendments involving "major" changes, please see Part 2, Section C for submission requirements for quorum review.

• **Minor** changes are those that do not affect the level of risk to subjects and may be eligible for expedited review. Examples include:

- changing the project duration,
- increasing or decreasing the sample size,
- relocating the site of the study,
- changing co-investigators, or
- substituting *comparable* questionnaires or test instruments.

If in doubt as to whether proposed changes qualify as major or minor, contact the IRB staff. At the discretion of the IRB staff or the IRB chair, submission of a new protocol may be required.

B. Submissions Required

1. Describe in detail the nature of the requested changes, the reasons for making each change, and any possible effect the changes may have on subjects. Revision descriptions should satisfy any sponsor requirements e.g. protocol numbers, version dates. If necessary, use additional sheets. Describe changes to the consent forms detailing section/page etc.

2. If adding a new site, attach the appropriate letter(s). If adding new investigators or changing investigators, include the new investigator's(rs') name(s); the principal investigator and all new co-investigators must sign this form.
3. For changes to consent forms, assent forms, cover letters, or ads, submit a new document with hand-drawn brackets around any modifications on the new document (indicate on the first page of consent/assent etc., which pages are revised). Also submit a clean copy of the new document for IRB approval. If the sponsor has requested a change, include a copy of the new documentation from the sponsor (except to the extent any such statement would violate or otherwise be contrary to any confidentiality or nondisclosure obligations).
4. For modifications to any other attachment(s), submit the document(s) with hand-drawn brackets around any modifications on the new document (indicate on the first page of the document, which pages are revised).
5. The IRB staff will return the approved forms and the revised, approved consent form(s) and attachments. These newly approved forms immediately replace all previous forms.

C. Emergency Changes

If changes to an IRB-approved protocol become necessary to avoid an immediate hazard to subjects, the investigator may make those changes without prior IRB approval, but—the investigator must attempt to obtain prior authorization from the IRB chair. The following is required:

- the investigator must notify the IRB within five (5) days of making an emergency change and
- the investigator must submit, within ten (10) days, a written request to amend the protocol.

The IRB will review the request to amend the protocol and also determine whether any change made without prior approval was justified.

Part 6: Special Populations as Subjects of Research and Research Conducted in Non-Campus Settings

Whenever subjects in a study may be vulnerable to injury, coercion or undue influence, the study must include additional safeguards to protect their rights and welfare. Special populations requiring additional safeguards are:

- A. [Children](#)
- B. [Persons who are intellectually or emotionally impaired](#)
- C. [Pregnant women and fetuses](#)
- D. [Prisoners](#)
- E. [Persons who are illiterate or whose primary language is not English](#)
- F. [Students or trainees](#)
- G. [Employees or subordinates of investigator\(s\)](#)
- H. [Research conducted in non-campus settings](#)

A. Children

1. Definitions

A "child" is anyone who has not reached the legal age for consent when and where the research will be conducted. In West Virginia, the age of consent is 18 years, unless the child is an "emancipated minor"—a child over the age of 16 who has been declared emancipated by court order.

"Assent" is the agreement, by a child or any individual who is unable to give legally valid informed consent, to participate in research. Mere failure to object is not assent.

For a clarification of risk levels as they apply to research involving children, see the NHRPAC report at <http://www.hhs.gov/ohrp/nhrpac/documents/nhrpac16.pdf>.

2. Criteria for Approval

The IRB will approve research involving children only if it falls within one of the following categories:

- a. The research involves no more than minimal risk.
(Requires the consent of one parent or guardian.)
- b. The research involves more than minimal risk but presents the prospect of direct benefit to individual subjects, which is sufficient to justify the risk.
(Requires the consent of one parent or guardian.)
- c. The research involves more than minimal risk and presents no direct benefit to subjects but is likely to yield important generalizable knowledge about the topic under study.
(Requires the consent of both parents—see below under 3.)

d. The research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

(Requires the consent of both parents—see below under 3.)

See Part 2.B and Part 2.C for information on exempt and expedited research involving children.

3. Consent and Assent

All research that involves children as subjects requires the signed informed consent of the child's legal parent(s) or guardian(s). If the consent of both parents is required (see 2.c and 2.d above), one parent can consent if the other parent is deceased, unknown, incompetent or not reasonably available or when only one parent has legal responsibility for the care and custody of the child.

All children must provide their written assent unless they are under age 7, or incapable of understanding, or the intervention or procedure involved may directly benefit them and is available only through participation in the research. The investigator(s) should attempt to obtain written assent even though it is not a prerequisite for participation; a short-form assent document may be used. The IRB has authority to waive the assent requirement.

B. Persons with an Intellectual or Emotional Impairment

1. Definition

A person with an "intellectual or emotional impairment" is one whose cognitive or emotional functions are affected or whose capacity for judgment and reasoning is significantly diminished, either by a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), a developmental disorder (e.g., mental retardation), or a neurological disorder. These individuals may be vulnerable to coercion or may not be able to give legally valid informed consent, and protocols involving them will receive quorum review.

2. Criteria for Approval

The IRB will approve research that targets intellectually or emotionally impaired persons only if it falls within one of the following categories:

- a. The research involves no more than minimal risk.
- b. The research involves more than minimal risk but presents the prospect of direct benefit to individual subjects, and this benefit is sufficient to justify the risk.
- c. The research involves more than minimal risk and presents no direct benefit to subjects but is likely to yield generalizable knowledge about the subjects' condition.
- d. The research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of intellectually or emotionally impaired persons.

3. Consent and Assent

If an impaired subject is capable of giving legally valid informed consent, you must obtain his or her consent according to the requirements in Part 4. The contents and language of the consent form should be appropriate to the nature and extent of the subject's impairment.

If an impaired subject has a legally authorized representative, informed consent from the legal representative and assent from the subject must be obtained in accordance with the procedures and criteria applicable to research involving children.

C. Pregnant Women and Fetuses

1. Definitions

"Pregnancy" encompasses the period of time from the confirmation of implantation by biochemical or biophysical means until intended or unintended passage or removal of the embryo or fetus. The state of pregnancy is defined by the presence of the embryo or fetus, whether alive, not alive, or of uncertain or unknown status.

"Embryo" describes the developing human during organogenesis, generally spanning the first three months after conception. "Fetus" refers to the growing human during the months of pregnancy after that.

A "fetus" is the product of conception from the time of implantation until birth by expulsion or extraction and until it is determined to be viable.

"Viable" refers to the ability of the fetus, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration.)

"Nonviable fetus" means a fetus *ex utero* (outside the body) which, although living, is not viable.

"Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movements of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

"In vitro fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means. **2. Criteria for**

Approval

The IRB will approve research involving pregnant women and fetuses only if **all** of the following conditions are met:

- a. Appropriate studies on animals and nonpregnant subjects have been completed (within policy limitations).
- b. The risk to the fetus is minimal, except where the purpose of the activity is to meet the health needs of the mother or the fetus.
- c. The risk to the fetus is the least possible risk for achieving the objectives of the research.
- d. Investigators involved in the study will have no role in any decisions regarding (i) the timing, method or procedure used to terminate the pregnancy, or (ii) the viability of the fetus.
- e. When termination of a pregnancy is involved, no changes from standard procedures which may cause more than minimal risk to the fetus or to the pregnant woman may be introduced solely for purposes of the research.
- f. No monetary or other inducements may be offered to terminate a pregnancy for purposes of the research.

3. Special Considerations

a. *The fetus in utero*

The fetus *in utero* may be involved as a research subject only if the purpose of the research is to meet the health needs of the particular fetus, and the fetus will be placed at the minimum risk necessary to meet such ends or the risk to the fetus is minimal and the purpose of the research is to obtain important biomedical knowledge which cannot be obtained by other means.

b. The fetus ex utero

Until it has been ascertained whether or not a fetus is viable, a fetus *ex utero* may be involved as a research subject only if there will be no added risk to the fetus and the purpose of the study is to develop important biomedical knowledge which cannot be obtained by other means; or the purpose of the research is to enhance the possibility of survival of the fetus to the point of viability.

c. The nonviable fetus

A nonviable fetus may be involved as a research subject only if vital functions will not be artificially maintained solely for purposes of the research, experimental procedures which would of themselves terminate heartbeat or respiration are not used, and the purpose of the research is to develop important biomedical knowledge which cannot be obtained by other means.

4. Consent for Research Involving Pregnant Women or Fetuses

The mother of the fetus must be legally competent and have given her informed consent for any research involving herself or the fetus. The mother's consent alone is sufficient if the purpose of the activity is to meet the health needs of the mother, the father's identity or whereabouts cannot be reasonably determined, or the pregnancy resulted from rape. In all other circumstances, informed consent must also be obtained from the father of the fetus.

D. Prisoners

1. Definition

A "prisoner" is an individual involuntarily confined in a penal institution, including persons (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing alternatives to criminal prosecution or incarceration in a penal institution. These protocols will receive quorum review. **2. Criteria for Approval**

The IRB will approve research targeting prisoners only if:

- a. The research is (1) a study of possible causes, effects and processes of incarceration and of criminal behavior; (2) a study of prisons as institutional structures or of prisoners as incarcerated persons; (3) a study of conditions particularly affecting prisoners as a class; or (4) a study of practices (both innovative and accepted) having the intent and reasonable probability of improving the health and well being of the subjects.
- b. Any possible advantages to the prisoner resulting from participation in the research must not be of such a magnitude that they impair the prisoner's ability to weigh the risks of the research against the value of such advantages in the prison environment.
- c. The risks involved in the research must be commensurate with risks that would be accepted by nonprisoner volunteers.
- d. Procedures for the selection of subjects within the prison must be fair to all prisoners.
- e. Adequate assurance exists that participation in the research will have no effect on the subject's parole, and the investigator must clearly inform each prisoner of this fact in advance.
- f. If this is an NIH-supported study, a prisoner advocate or representative must review the study.

E. Persons Who Are Illiterate or Whose Primary Language Is Not English

1. Illiterate Subjects

If the research targets subjects who are illiterate, the protocol should use a verifiable oral consent process. (See Part 4, section c.2.)

2. Subjects Whose Primary Language Is Not English

If the research targets subjects whose primary language is not English, the protocol must include a consent form written in the subjects' primary language and a certification that the translation is accurate.

F. Students or Trainees

1. Students in General

The fact that a person is a student can affect that person's ability to make a voluntary and uncoerced decision about participating as a subject of research.

If prospective subjects are students at FS or any institution associated with the study, the consent form must state that class standing or grades or status on an athletic team will not be affected by refusal to participate or by withdrawal from the study.

If students are to receive class credit, other opportunities must be available to earn equivalent credit, and the consent form must so indicate.

2. Students or Trainees of an Investigator

Except in special circumstances, the IRB will approve a protocol involving the investigator's current students or trainees as subjects only if the study is designed to assure anonymity, including whether or not any particular individual elected to participate. (One method of assuring anonymity is for all contact with subjects to be made by persons other than the investigator.)

G. Employees or Subordinates

1. Employees of Institutions Associated with the Study

If prospective subjects are employees of FS or any institution associated with the study, the consent form must state that job standing will not be affected by refusal to participate or by withdrawal from the study.

2. Employees or Subordinates of an Investigator

Except in special circumstances, the IRB will approve a protocol involving the investigator's current employees or subordinates as subjects only if the study is designed to assure anonymity, including whether a particular individual elected to participate or not. (One method of assuring anonymity is for all contact with human subjects to be made by persons other than the investigator).

H. Research Conducted in Non-Campus Settings

Exclusion: Cooperative Agreements

These projects involve populations outside the University setting in which investigators may have little or no contact with subjects, or otherwise be able to identify individual participants. This would include:

1. Community-based projects
2. International projects
3. Electronic, web-based or internet-based projects

1. Community-based research protocols

Definition

Community-based research typically involves a population of subjects located outside the University. These include research protocols conducted in non-campus settings that involve participants from schools, churches, unions, etc. The principal investigator may have little or no direct contact with the research subjects. Such research may be behavioral, and/or epidemiological, or health services related. The Institute of Medicine (1979) defined health services research as "inquiry to produce knowledge about the structure, processes or effects of personal health services."

Another characteristic of community-based research is the concept of "service learning" in which community subjects are encouraged to have input into the conduct of the project. **Criteria for**

Approval

Investigators are encouraged to describe procedures *broadly enough to accommodate very minor changes of an inconsequential nature* during the conduct of the research. Multiple amendments to an approved protocol are discouraged. If there are questions about whether or not proposed changes are "inconsequential" in nature, they should be submitted to the IRB. Researchers or their agents must acquire signed permission from responsible personnel before advertising for, or in any way soliciting, subjects within private practices, clinics, or hospital settings. This signed permission must be kept on record for potential IRB review. For research taking place in K-12 school settings, researchers must provide to the IRB written approval, on official district or school letterhead, from school administrators (district superintendent or designee, or building principal) documenting that the research projects will minimally impact instructional practices.

Consent and Assent

Because of the unique nature of community-based research, the IRB may approve substantial alterations to or waive any element of written informed consent only if all of the following conditions apply:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will receive additional pertinent information after participation

These conditions may apply to certain community-based and/or health services research protocols. If the above conditions are met, the consent/assent format may be altered so as to be simpler and more informative. This may especially apply to situations where very large numbers of study subjects are anticipated, such as cross-sectional surveillance of health status within a community.

The following alterations in consent process may be approved by the IRB:

- a. Description of the research may be detailed in letter form signed by the principal investigator for retention by study subjects.
- b. The consent/assent forms may be part of the data collection form to be retained by the principal investigator for a period of 3 years. Different times lines for retention of data and consent/assent forms may apply to research that is published.
- c. Language describing the study may be simplified as appropriate to the average level of understanding/literacy of members of the community participating in the study. However, all essential elements in the standard consent/assent must be specifically addressed.
- d. The consent form may deviate from the standard 8 X 11" page format, and may include graphic design of a descriptive nature as long as the intent is to be simpler and more informative.

2. International Projects

This includes research projects conducted at sites outside the US. Cultural and socioeconomic differences between the researcher and the targeted populations necessitate special attention to study design, intervention, risk-benefit analysis and informed consent. An expert from that culture must verify that no cultural mores will be violated by the protocol.

3. Electronic, Web-based or Internet-based Projects

Taking advantage of the wider availability of electronic mail and internet services, researchers may choose to use electronic means of interaction, intervention and data collection. This creates special concerns in the informed consent process and the protection of human subjects. Some suggested means of obtaining informed consent /assent and protecting participants include setting up a separate URL that contains the required cover letter or consent/assent form as a front page (cover letter/consent/assent page 'a') for (study page 'b') study instrumentation and interventions. This cover letter/consent/assent page (page 'a') should indicate that by clicking on a link from page 'a' to page 'b', subjects are consenting to participate. Page 'a' should also include an e-mail address in addition to a telephone number(s) to withdraw consent and remove data, to the extent possible, upon request of the respondent. Additional requirements include:

- a. The body of the e-mail or attachment contains the approved cover letter or consent/assent forms. (or a note indicating that the IRB approved form is on file).
- b. Inform the participants that by replying to the e-mail, completing the requested task(s) constitutes consent.
- c. Replies to the researcher should be directed first to the appropriate Information Technology agent to remove identifying information that is provided automatically by emailing systems.

If recruitment of participants requires obtaining e-mail lists or names for mailings, the researcher should ensure the following:

- a. Obtain these by written agreement with the source company, professional organization, government agency, or other source.
- b. In initial contacts with potential participants, provide the source of the e-mail address(es) and refer to the written agreement.

Part 7: Recruitment and Selection of Subjects

- A. [Equitable Selection of Subjects; Nondiscrimination](#)
- B. [Advertisements](#)
- C. [Recruiting Patients or Clients](#)

A. Equitable Selection of Subjects; Nondiscrimination

1. General Guidelines

Recruitment and selection of subjects must be equitable within the confines of the study. No subjects may be arbitrarily excluded on the basis of national origin, gender, race, religion, creed, education, or socioeconomic status.

2. Economically Disadvantaged Subjects

a. *Added Costs*

The IRB is concerned if added costs are so great as to preclude participation by the economically disadvantaged.

b. *Financial Remuneration, Reward or Reimbursement*

Financial remuneration, reward, reimbursement for expenses, or other inducement for participation should not be so great as to be coercive to potential subjects.

B. Advertisements

Advertisements used to recruit subjects **must** state that the study is a **research** project.

Recruiting advertisements must clearly state that the project is research and should include **only**

1. the name of the investigator and FS affiliation
2. a statement that the project is research
3. the purpose of the research and, in summary form, the eligibility criteria for subjects
4. the location of the research
5. if appropriate, a brief description of the procedures (including if research involves a placebo)
6. a description of the potential benefits
7. the person (and telephone number) to contact for further information

For drug or device studies, no claims may be made, either explicitly or implicitly, that the drug or device is safe or effective for the purposes under investigation or that the drug or device is in any way equivalent or superior to any other drug or device. When applicable, the recruitment ad must state that a placebo is involved in the study.

C. Recruiting Patients or Clients

- Physicians, psychologists, counselors, lawyers and others who have confidential relationships with patients or clients may not release the names of patients or clients without obtaining their express permission to be in a research study.
- Investigators *may not* contact subjects directly when subject pool is developed from a patient or client base of one of the above mentioned professionals.
- A flier may be used in a clinic provided appropriate administrative approval has been obtained from the director of the clinic.

Part 8: Continuing Review, Adverse Event Reporting and Quality Assurance Audits

- A. [Protocol Reviews](#)
- B. [Reporting Adverse Events](#) C. [Closing a Study](#) D. [Comprehensive Review](#)
- E. [Quality Assurance Audits](#)

A. Protocol Reviews

When the IRB approves a protocol, it determines how frequently it will review the research and what specific information it will request beyond that on the standard review form.

At a scheduled meeting, the IRB reviews all protocols submitted by the deadline and can:

- approve for renewal
- require additional information prior to approval for renewal
- suspend or terminate the research

1. Continuing Reviews

Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All research must be reviewed at least annually.

It is only after research has begun that the real risks can be evaluated. The IRB must rely on preliminary results, subject complaints, important new information, and adverse event reports received to determine if the information should be communicated to subjects. The IRB must also determine whether special precautions or requirements that had previously been imposed on the research protocol can be relaxed or whether more stringent requirements may be needed. It may be necessary to regularly review some protocols after each subject is enrolled, every month or some other period shorter than only once per year. It may be necessary to receive verification from sources other than the investigator to show that no material changes have occurred since the previous review. This may include, among other things, information from subjects that they were unfairly treated or that the degree of risk that they experienced was greater than had been agreed upon at the beginning of the research.

It is our experience that most research projects do not need to be reviewed more often than once per year. However, there are instances where this is not the case; this policy is designed to help identify projects where more than one review per year is required.

All protocols must be re-approved by the anniversary date, i.e., the renewal application must be reviewed for compliance with current IRB standards, and any requested revisions must be

approved before that date. Renewal applications must include copies of consents, assents, and other forms if appropriate, cover letters and ads. If renewal approval has not occurred, the protocol will be suspended, and no subjects may be enrolled until re-approval has been granted.

a. Quorum Reviews

All protocols that initially underwent quorum review will ordinarily undergo quorum review for re-approval. Protocols that have never enrolled subjects or that are only conducting long-term follow-up will undergo expedited review, (unless there has been activity on the study, such as amendments or adverse events)

b. Expedited Reviews

All protocols that initially underwent expedited review will undergo expedited review for re-approval unless there is a "major" change or an increase in risk to subjects.

Continuing Protocol Review forms should be obtained investigators three months before the renewal date to allow time for review and possible revision.

No consent or assent form may be used that has a date beyond that of the one-year anniversary of the previous review. All consents and assents must have a date on each page.

Investigators must make revisions or comply with requests for additional information within 60 days. Once the renewal has been approved, the principal investigator will receive notice on the approval of consent, assent, or other form if appropriate, cover letter or ad and the original renewal application form.

2. Protocols Closed to Accrual

Continuing reviews are required for all protocols which are closed to accrual but for which participants are subject to follow-up. At this time, the investigator must inform the IRB of any new information, either in the literature or received from the sponsor, which may be of interest to subjects who participated in the study. Any new information to be given to the subjects must accompany the review form.

3. Noncompliance with the Review Process

Noncompliance with the review process may result in suspension or termination of the project. **B.**

Reporting Adverse Events

All clinical investigators are required to report to the sponsor any adverse events that may be caused by the investigational product. The investigator is also required to report to the reviewing IRB any injury (harm caused by involvement in research), deaths and unexpected serious adverse experiences.

A serious adverse experience is any adverse experience that results in any of the following outcomes: death, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. An adverse event that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment it may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An unexpected adverse drug experience is any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure or which is not consistent with the risk information described in the current protocol.

A written report of all adverse events that occur at FS and all those that are reported by the sponsor must be made to the IRB within five days of the occurrence or notice. Such reports must be accompanied by the signature of the principal investigator. If the PI is unavailable, an authorized co-investigator can sign. At least two IRB members who are knowledgeable in the procedures and techniques used in the research must review the report. The IRB may require changes to the consent form as a result of adverse events or it may require information to be sent to the subjects.

C. Closing a Study

When a drug or device study has been completed, a summary report must be submitted to the IRB. This report will include:

- the number of subjects enrolled
- any adverse events at FS
- preliminary results

D. Comprehensive Review

In addition to the standard continuing review, the IRB may undertake a comprehensive review of any approved project, including on-site inspection of all records pertaining to the research.

E. Quality Assurance (QA) Audits

Protocols are subject to random internal QA audits. These audits will focus on adherence to protocol, the adequacy of the consent process, and the availability of appropriately processed documentation. It is the responsibility of the PI to keep records in order and to assist the IRB and the auditor in conducting any audits. PIs and program coordinators are strongly encouraged to periodically conduct self-audits.

Part 9: Noncompliance

A. [Action by the Chair](#) B.
[Action by the IRB](#)

Whenever questions arise concerning possible noncompliance with IRB guidelines and other applicable regulations, the chair and the IRB have the authority to investigate and take appropriate action to ensure compliance or to terminate the research.

Any sanctions for noncompliance will be determined in accordance with FS policy and may involve referral to the Academic Integrity Committee for appropriate action.

A. Action by the Chair

1. Authority

The chair, with the support of at least two other IRB members, has discretion to temporarily suspend research if there exists

- substantial evidence of noncompliance;
- reasonable suspicion of noncompliance, which may be associated with more than minimal risk to human subjects; *or*
- information suggesting that the research involves substantially greater risk than was anticipated at the time of initial IRB approval.

2. Procedures

If the chair does suspend research, he or she will:

- a. promptly and in writing notify the investigator(s) and the IRB chair of the suspension and the reasons for it.
- b. refer the investigator(s) to this section of the guidelines.
- c. offer the investigator(s) an opportunity to meet immediately with the chair.
- d. place the matter on the agenda for the next IRB meeting, at which time the IRB may confirm or rescind the suspension, convert the suspension to a termination, or take any other action consistent with its authority and obligations.

B. Action by the IRB

1. Authority

If the IRB finds research has been conducted in violation of IRB guidelines or other applicable regulations, it may

- disallow the publication of data collected during periods of noncompliance,
- require destruction of data collected during periods of noncompliance,
- impose restrictions as a condition for continuation of the research,
- suspend or terminate the research,
- take other action as appropriate.

2. Procedures

- a. Questions or concerns regarding noncompliance with IRB Guidelines should be directed to the chair of the IRB. The IRB may involve the university's general counsel.
- b. If the IRB believes further action may be appropriate, it will investigate the matter in question.
- c. The IRB may suspend research during the investigation.
- d. The IRB will notify the investigator(s) of the nature of the concerns that have been raised and the time, date and place of the meeting to discuss them. The investigator will have an opportunity to attend and explain. It is the duty and responsibility of the principal investigator to cooperate with the IRB and to provide any documentation the IRB may request.

3. IRB Decisions

Within seven calendar days of its decision to uphold a suspension, the IRB will provide written notice to the investigator(s) and to the department chair(s), dean(s), vice president(s), office of the provost, and if appropriate, the office of the general counsel. In accordance with FS's policy. The IRB will submit an initial report of any serious or continuing noncompliance with IRB requirements to any appropriate federal or state agencies as required by law. This report will include a statement of the reasons for the IRB's decision and other appropriate information; copies of this report will be sent to all appropriate parties.

See Chapter 10 for appeal procedures available to the investigator(s). Should the investigator(s) choose not to appeal, the decision of the IRB will stand, and the IRB will so notify all appropriate parties. The notification will include a statement of the reasons for the IRB's decision and a description of any action taken by the IRB.

Part 10: Appeal Procedures

If an investigator disagrees with any IRB decision or action, he or she may request reconsideration by either appearing before the IRB or by requesting an advisory review panel. This request must be made to the Office of the Provost, in writing, within seven calendar days of the investigator's receipt of the IRB's notification.

The entire appeal process must be completed within 120 calendar days of the investigator's receipt of the IRB's notification to suspend or terminate a study.

The decision of the IRB becomes final under any of the following circumstances:

- The investigator chooses not to appeal.
- The investigator fails to notify the Office of the Provost, within seven calendar days of receipt of the IRB's notification, of a decision to appeal.
- The investigator or a representative fails to appear before the IRB at its next regularly scheduled meeting.
- The investigator fails to request formation of an advisory review panel within seven calendar days after appearing before the IRB.
- The investigator fails to make documents concerning the study available to the advisory review panel within seven calendar days of being requested to do so.

The IRB will notify all appropriate parties.

A. Investigator Appears before the IRB

An investigator may ask to appear before the IRB to request that the IRB reconsider a decision; this appearance **must** be at the next regularly scheduled IRB meeting. The IRB may affirm, modify or reverse its original decision. Within seven calendar days, the IRB will notify the investigator of its decision. If the investigator is still dissatisfied, he or she may now have seven calendar days to request (in writing to the Office of the Provost) formation of an advisory review panel.

B. Advisory Review Panel

An investigator may request reconsideration based on the report of an advisory review panel.

The advisory review panel must be formed within 15 calendar days of the investigator's request for its formation.

1. Composition

An advisory review panel shall consist of three persons who are chosen as described in. **2.**

Meeting and Report

Within 30 calendar days of its formation, the panel will complete its investigation and transmit to the IRB chair a written report of its findings and recommendations. During its investigation, the panel may involve the office of the university's general counsel. The IRB will consider this report at a regular or special meeting held within 30 calendar days of the chair's receipt of the report.

The IRB will provide written notice (within seven calendar days) of its decision to the appropriate investigator(s) and to their department chair(s), dean(s), and vice president(s), the office of the provost and members of the advisory review panel.

In accordance with FS's policy, the IRB will submit a final report concerning noncompliance with IRB requirements to department chair(s), dean(s), the office of the provost and the university's general counsel. This report will include a statement of the reasons for the IRB's decision and a description of any action taken by the IRB.