FSU Office of Research - Human Subjects Committee
Institutional Review Board (IRB)

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Florida State University Policy 7-IRB-1

Title of Policy: Institutional Oversight of Ethical Principles Regarding Research Involving Humans as Subjects

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New AUGUST 13, 2003

I. INTRODUCTION

This document establishes a policy of ethical principles by which human subjects research should be conducted.

II. POLICY

1. Florida State University, which includes faculty, staff, employees, and students, are guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (referred to as “The Belmont Report”) regardless of whether the research is subject to Federal Regulation or with whom conducted or the source of support or sponsorship.

2. The three quintessential requirements relevant to the protection of human subjects in biomedical and behavioral research as set forth in the Belmont report are:
   a) Respect for Persons: Involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy;
   b) Beneficence: Entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm; and
   c) Justice: Requires that the benefits and burdens of research be distributed fairly.

The principle of Respect for Persons underlies the need to obtain informed consent; the principle of Beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of Justice requires that subjects be fairly selected.
3. Florida State University holds a Federalwide Assurance of Protection for Human Subjects (Department of Health and Human Services), Number 00000168, approved on March 26, 2001, in which it agrees to uphold the ethical principles of The Belmont Report and to apply the Code of Federal Regulations (45 CFR Part 46) to all research involving human subjects regardless of sponsorship or support.

4. The Vice President for Research and the Associate Vice President for Research are responsible for exercising appropriate administrative oversight to ensure that Florida State University’s policies and procedures designed for protecting the rights and welfare of human subjects are effectively applied in compliance with its Federalwide Assurance with the Office for Human Research Protections (“OHRP”), Department of Health and Human Services.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.101,103
Florida State University Policy 7-IRB-

Title of Policy: Institutional Review Board Jurisdiction/Applicability

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This document establishes a policy on the authority of the IRB.

II. POLICY

1. The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Institution with which it is affiliated.

2. At Florida State University, the appointed University Human Subjects Committee serves as the IRB, and has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and University policy.

3. All research or clinical investigations involving human subjects regardless of funding source or sponsorship must be reviewed and approved by the IRB. No intervention, investigation, or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations as to the definition of “research”, “clinical investigation”, or “human subject” and their implications for the jurisdiction of the IRB under Florida State University policy are made by the IRB.

4. Florida State University’s Assurance with the federal government specifies that all research activities involving human subjects, and all other activities which even in part
involve such research, regardless of funding source or sponsorship, must be reviewed by the IRB (Human Subjects Committee) if one or more of the following apply:

a) the research is sponsored by Florida State University, or
b) the research is conducted by or under the direction of any employee, faculty, staff, student, or agent of FSU in connection with his or her institutional responsibilities, or
c) the research is conducted by or under the direction of any employee, faculty, staff, or agent of FSU using any property or facility of this institution, or
d) the research involves the use of Florida State University’s non-public information to identify or contact human research subjects or prospective subjects.

5. Definition of “Human Subject”: Pursuant to federal regulation, “human subject” is defined as “living individual(s) about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.” Therefore, only research activities involving data obtained through intervention or interaction with a living individual or involving identifiable private information regarding a living individual must be reviewed by the IRB.

a) Intervention includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
b) Interaction includes communication or interpersonal contact between Investigator and subject.
c) Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (the identity of the subject is or may readily be ascertained by the Investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject regarding a third party.

6. Definition of “Research”: Only certain activities involving human subjects qualify as “research” subject to the jurisdiction of the IRB. The federal regulations define “research” to mean “a systematic investigation (i.e. the gathering and analysis of information) designed to develop or contribute to generalizable knowledge”.

a) A major factor in determining whether an activity is research subject to IRB review depends upon the Investigator’s intent to “contribute to generalizable knowledge”, and whether there is a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge.
b) If the Investigator intends to publish or disseminate the results, the activity will
be viewed as intending to contribute to generalizable knowledge, and to be
research subject to the IRB’s jurisdiction. Activities that may result or be
included in a theses, dissertation, journal article, poster session, public speech
or presentation, or project report must be reviewed by the IRB.

c) Thus, if there is any possibility that the Investigator may want to publish or
disseminate the resulting data in the future, then the protocol must be
submitted for IRB review.

d) The determination as to whether an activity involving human subjects can be
defined as “Research” is the sole responsibility of the IRB, and not the
Investigator.

7. Definition of “Clinical Investigation”: A “clinical investigation” is an experiment using a
test article on one or more human subjects that are regulated by the Food and Drug
Administration or support applications for research or marketing permits for products
regulated by the Food and Drug Administration. Products regulated include food and
color additives, drugs for human use, medical devices for human use, biological products
for human use, and electronic products.

8. Standard Diagnostic or Therapeutic Procedures: The distinction between research and
treatment can become blurred in patient care settings, as well as in some educational and
training settings. An established and accepted diagnostic or therapeutic procedure that is
performed only for the benefit of a patient or student is generally not subject to the
jurisdiction of the IRB. If, however, there is a collection of data about a series of such
procedures or treatments for dissemination or generalization, then such activity would
constitute research within the purview of the IRB. Also, if patient care or assignment to
intervention is altered for research purposes in any way, the activity must be submitted for
IRB review. Similarly, a diagnostic procedure for research purposes that is added to a
standard treatment would also require IRB review.

9. Innovative Treatments or Procedures: Innovations in diagnosis, therapy, or treatment are
generally not subject to IRB review if they are applied to a patient for the sole purpose of
aiding that individual, although such innovations are governed by professional ethics (i.e.
obtaining informed consent). IRB review is required, however, when a systematic
investigation of such innovations is considered.

10. Emergency Use of an Investigational Drug or Device: Research activities may not be
commenced, even in an emergency, without IRB review and approval. If emergency care
is commenced without prior IRB review and approval, then the patient may not be
considered as a research subject; such emergency care may not be claimed as research, nor
may any data regarding such care be included in any report of a research activity. When
emergency care involves investigational drugs, devices, or biologics, the U.S. Food and
Drug Administration (FDA) requirements must be met. However, nothing in these policies
is intended to limit the authority of a physician to provide emergency medical care for
patients who need such care. Rather, the use of information collected about that treatment
for research purposes is prohibited.
11. Human Cell or Tissue Repository: Human cell or tissue research typically involves repositories that collect, store, and distribute human tissue materials for research purposes. Tissue repository activities involve the collectors of tissue samples, the repository storage and data management center and the recipient investigators. Human cell or tissue repositories do not qualify as human subject research if the material submitted to the repository satisfies both of the following conditions:
   a) the material, in its entirety, was collected for purposes other than submission to the repository (the material was collected solely for clinical purposes, or for legitimate but unrelated research purposes, with no additional material collected for submission to the repository); and
   b) the material is submitted to the repository without any identifiable private data or information (no codes or links of any sort may be maintained, either by the submitter or by the repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained).

12. Florida State University PI Initiated Research/Clinical Investigation: Research which is conducted by a FSU Investigator who initiates and/or conducts a clinical investigation, alone or with others, is considered to be FSU PI Initiated Research. In such a case, it is the Investigator’s responsibility to keep the IRB Office informed of any unanticipated problems involving risks to subjects or adverse events that were serious or unanticipated, and resulted in a change to the risk/benefit ratio, even if the event occurred at a location for which the FSU IRB is not the IRB of record.

13. Student- Conducted Research: All activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree must be reviewed by the IRB. For example, activities that must be reviewed and approved by the IRB include all master’s theses and doctoral dissertations that involve human subjects and all projects that involve human subjects and for which findings may be published or otherwise disseminated.

14. Research Practicums/Research-Methods Classes: Courses of study at FSU which are designed to train students and provide them with an opportunity to practice various research methods differ from research activities that would generally require IRB review in that the primary intent of the classroom project is for the student to become more knowledgeable about the research process. Additionally, such projects typically do not lead to generalizable knowledge and are not undertaken with that goal in mind. Therefore, simulations of research using human subjects and course-assigned data collection are not deemed to be research that is subject to IRB review so long as the activity meets the following requirements:
   a) the activities are designed for educational purposes only,
   b) the data will not be generalized or published outside the classroom,
c) the data will not result in an article, master’s thesis, doctoral dissertation, abstract, other publication or presentation, and 
d) the student volunteers or other participants are clearly informed that the activities are an instructional exercise and not actual research. Instructors are encouraged to become familiar with each student’s project, and to discuss it with the student. If the instructor determines that there is a possibility that the student’s proposed project may result in a formal presentation or publication, then he or she should recommend that the student submit the project for IRB review before beginning the study.

15. Case Studies: The use of a single human subject in research activities can constitute research that is subject to IRB review and approval when there is a clear intent before recruiting or interacting with the subject to use systematically collected data that would not ordinarily be collected in the course of daily life in reporting and publishing a case study. As a general rule, when a series of subject observations are compiled in such a way as to allow possible extrapolation or generalization of the results from the reported cases, that activity constitutes research that must be reviewed by the IRB. This type of activity must always be reviewed by the IRB when there is an intent to publish or disseminate the data or findings.

16. Defining a Project as Research after the Project has Commenced: If an investigator commences a project and later finds that the data gathered could contribute to generalizable knowledge or that he or she may wish to publicize the results, the investigator must submit a proposal to the IRB office for review as soon as possible. Investigators who attempt to circumvent FSU policies regarding human subjects research by collecting data as non-research and then applying to use them as existing data will face the possibility of their research not being approved. It is in the investigator’s best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.

17. Failure to Submit Project for IRB Review: If an investigator knowingly engages in activities that qualify as research that is subject to IRB review without obtaining prior approval by the IRB, the data that are collected and the results may be deemed as not usable by the IRB. This would depend on the kind of research engaged in, the risks, the appropriateness and the intent of the investigator. Possible outcomes may include, but not be limited to, frequent reviews of the ongoing research, not allowing the research to be published, or not allowing the data to be used for thesis or dissertation requirements.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.101,102,103
Florida State University Policy 7-IRB-3

Title of Policy: Policy and Procedures Development

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

Revised

I. INTRODUCTION

This policy describes how policies and procedures are developed.

II. POLICY

1. Pursuant to 45 CFR 46.103, an Institution must assure that it has adequate written procedures in place to support compliance with the federal regulations governing research involving human subjects.

2. Any written procedures shall be approved by the IRB, and be presented to the Vice President for Research for his/her review and final adoption.

3. The Vice President of Research, Associate Vice President of Research, Chair or designated members of the IRB, or legal counsel to the IRB (Human Subjects Committee) shall perform periodic review of the written procedures and recommend to the IRB any revisions or additions to the procedures, consistent with federal regulations, guidelines, or rules and procedures governing Florida State University. Any such revisions approved by the IRB shall be presented to the Vice President of Research for his/her final adoption.

Minor revisions to any IRB blank forms, checklists, guides or webpages may be performed by IRB Office Staff as needed subject to the approval of Legal Counsel to the IRB. Any major revisions shall be presented to the IRB for review and approval.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-4

Title of Policy: Exempt Research Activities

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy describes the exempt review process and the type of research that qualifies for an exempt review.

II. POLICY

1. Certain research activities involving human subjects are exempt from the requirement that they receive IRB full or expedited review, and are provided in 45 CFR 46.101(b)(1) through (6). However, the FSU Assurance with OHRP provides that all research, including those which may qualify as exempt, receive review and approval by the FSU IRB. Only the IRB may determine which activities qualify for an exempt review. Investigators are not authorized to make an independent determination that research involving human subjects is exempt and must contact the IRB concerning the status of proposed research or changes in ongoing research.

2. Protocols receiving exempt status receive the same review process as expedited protocols at FSU. The Chairperson and one IRB member will review the initial application to determine eligibility for exempt status. The research activities in the application proposal must meet one of the specific categories of exempt activities listed in paragraph 3 below. A determination that a research activity is exempt must be documented on the review form, and include a citation of the specific category justifying the exemption pursuant to federal regulation. Note that all research activities, even those which meet the definition of eligible for exemption pursuant to 45 CFR 46.101, must still be reviewed and approved by the FSU IRB according to FSU policy and FSU’s assurance with OHRP.
3. The six specific categories of research activities determined to be eligible for exempt status are as follows:

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

   b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

      - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
      - Any disclosure of the human subject’s response outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation.
      - This exemption is NOT available for research involving children, unless the research is limited to observation of public behavior when the investigators do not participate in the activities being observed (see 45 CFR Part 46, Subpart D – Protections for Children Involved as Subjects in Research).

   c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) above, if:

      - The human subjects are elected or appointed public officials or candidates for public office; or
      - Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

   d) Research involving the collection or study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
e) Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in methods or levels of payment for benefits or services under those programs.

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

The exemptions provided in 45 CFR 46.101(b) do NOT apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. Additionally, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does NOT apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.101
Florida State University Policy 7-IRB-5

Title of Policy: Expedited Review

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy describes the categories of research eligible for the expedited review procedure of the IRB. This policy also outlines the roles of the IRB staff in completing the expedited review process. This policy also states what information must be provided to the IRB from the researcher to comply with the expedited review process.

II. POLICY

1. Federal regulations have established a list of categories of research that may be reviewed by the IRB through an expedited review procedure.

2. At FSU, the expedited review procedure consists of a review of research involving human subjects by the IRB Committee Chairperson and one of the more experienced reviewers designated by the Chair or IRB Secretary from among the members of the IRB. In reviewing the research, the reviewer may exercise all of the authorities of the IRB, except that the reviewer may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedures set forth in 45 CFR 46.108(b). All expedited protocols must be continually reviewed at least annually by the IRB. The standard requirements for informed consent (or its waiver, alteration, or exception) apply to all IRB approvals regardless of the type of review utilized by the IRB. The reviewer may refer the application to the full committee for review as warranted.

3. Appropriate Use of Expedited Review Procedures. Use of expedited review by the IRB must be restricted to those applications that fulfill one of the following categories listed in
a) Minimal Risk. Research activities that present no more than minimal risk to human subjects AND involve only the procedures listed in one or more of the specific categories (see paragraph 4 below) may be reviewed by the IRB via the expedited review procedure.

- Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).
- The categories in paragraph 4 below should not be deemed to be of minimal risk simply because they are included on the list.
- Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

b) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality were no greater than minimal.

4. Categories of Research Eligible for Expedited Review. The following expedited categories pertain to both initial and continuing IRB review:

a) Collection of hair and nail clippings, in a nondisfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

b) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor.

c) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such
procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

d) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

e) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

f) Voice recordings made for research purposes such as investigations of speech defects.

g) Moderate exercise by healthy volunteers.

h) The study of existing data, documents, records, pathological or diagnostic specimens.

i) Research on individual or group behavior or characteristics of individuals, such as studies or perception, cognition, game theory, or test development, where the research investigator does not manipulate subject’s behavior and the research will not involve stress to subjects.

j) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

k) Any other category specifically added to this list by DHHS and published in the Federal Register.

5. In conducting the expedited review, the designated reviewer must examine materials in sufficient detail to make the following determinations required under federal regulation and IRB Policy.

a) Risks to subjects must be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

b) Risks to subjects shall be reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the reviewers should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies those subjects would receive even if not participating in the research. The reviewers should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

c) The selection of subjects must be equitable. In making this assessment, the
reviewers should consider the purposes of the research and the setting in which the research will be conducted, and be cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

d) Informed consent must be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by federal regulation and institutional policies.

e) Informed consent shall be appropriately documented pursuant to federal regulation and institutional policies.

f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

g) When appropriate, there are adequate controls to protect the privacy of subjects and to maintain the confidentiality of data.

h) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, the IRB reviewers must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6. The materials to be provided to the Chairperson and designated reviewer shall be as follows:

a) Completed IRB application with appropriate signatures.

b) Full investigator’s or sponsor’s protocol.

c) Proposed informed consent document(s) and/or script as appropriate.

d) Copies of surveys, questionnaires, or videotapes.

e) Copies of letter of assurance or cooperation with research sites.

f) Relevant grant applications.

g) Investigator’s brochure.

h) Advertising/recruitment flyers intended to be seen or heard by potential subjects, including email solicitations.

7. The primary reviewer and the Chairperson reviewing the application shall determine a review interval for the research as appropriate to the degree of risk but not more than annually. The primary reviewers and/or Chairperson may decide to request full Committee review of a project.

8. A detailed listing of all projects reviewed and approved by Expedited Review must be provided to all committee members at the next convened full committee meeting. The documentation must include a citation to the specific permissible category or categories justifying the expedited review.
III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.110
I. INTRODUCTION

This policy states the authority the IRB has to make decisions regarding the research activities that fall within its jurisdiction. The policy also outlines the requirements for when a full committee review is necessary. The policy describes how full committee reviews should be decided and when conditional approvals are allowable during a full committee review.

II. POLICY

1. The IRB has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction.

2. The full committee review category is used for research that does not qualify for expedited or exempt review, and at FSU is reserved generally for protocols involving vulnerable subjects, such as children, prisoners, decisionally impaired persons, and pregnant women, fetuses, and neonates. The full committee review of protocols may occur only at convened meetings of the IRB Committee at which a quorum is present.

3. The full committee review category is used for research that does not qualify for expedited or exempt review. The full committee review of protocols may occur only at convened meetings of the IRB Committee at which a quorum is present.

4. Substantive review of protocols must take place at the convened meetings.

   a) Applications undergoing review must be individually presented and
discussed at a convened meeting of the IRB Committee.

b) The Secretary to the IRB shall assign a Primary Reviewer from among the Committee members for each full review protocol. The Primary Reviewer shall conduct an in-depth review of all pertinent documentation and present the protocol to the full Committee.

c) In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting.

5. The IRB Committee may only approve an application when its decision is based on consideration of the following:

   a) Risks to subjects are minimized, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

   b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB Committee should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

   c) The selection of subjects must be equitable. In making this assessment, the IRB Committee should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

   d) Informed consent shall be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by federal regulation.

   e) Informed consent will be properly documented, in accordance with, and to the extent required by federal regulation.

   f) When appropriate, the research plan shall make adequate provision for monitoring the data collected to ensure the safety of the subjects.

   g) There must be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

6. Determination of Review Interval. The IRB Committee shall determine an appropriate review interval at which to conduct continuing review of all full committee protocols. The review interval must be appropriate to the degree of risk, but not less than once per year. The records of the IRB Committee meeting should clearly reflect these
determinations regarding risk and approval period (review interval).

7. Consideration of Vulnerable Populations. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, the IRB Committee must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

8. Full Committee Determination of Conditional (Contingent) Approval. When the IRB Committee requests clarifications, protocol modifications, or informed consent revisions, IRB Committee approval must be deferred until the investigator timely submits satisfactory revisions. Such revisions must be finally approved by the IRB Chair, the Full Committee, or as otherwise specified by the Committee. The minutes of the IRB Committee meeting shall clearly reflect conditional approval with final review requirements.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103,108, 111
Florida State University Policy 7-IRB-7

Title of Policy: Procedures for reviewing expedited, exempt, and full committee applications

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy requires all research proposals involving human subjects be reviewed by the IRB prior to the start of the research project. This policy applies to all research conducted, regardless of funding. The policy outlines the procedure regarding how the applications are processed, reviewed and maintained.

II. POLICY

1. Florida State University requires that all research proposals involving human subjects be reviewed by the University’s Human Subjects Committee (IRB), prior to any interaction with the research subjects. This requirement applies to all research conducted by faculty, staff or students, regardless of funding. Researchers are advised of this requirement through the University’s webpage, by grants administrators in the Office of Research, training in the CREATE program, and the Office of Graduate Studies.

2. The University IRB operates within the ethical principles set forth in the Belmont Report and the U.S. Code of Federal Regulations, Title 45 Part 46 “Protection of Human Subjects”.

3. Investigators are required to complete an Application for Review, to answer a series of questions about their research and to submit copies of all forms or other documentation to be used in the proposed research. These materials are initially submitted to the Secretary of the Human Subjects Committee (IRB) for a review of facial compliance.
4. Applications are received by the Office staff of the IRB via the online system (HSRS). The Secretary of the IRB completes a facial compliance review and a determination as to eligible categories of review (full, exempt, or expedited). After review by the Secretary, the applications are provided to the student assistant for creation of an actual project file.

5. The project files are uniformly maintained for inspection, retention as required by federal regulation, and eventual archiving pursuant to University process. Projects requiring full Committee review are added by the Secretary to the agenda for the next monthly IRB meeting. Projects that fall into the exempt or expedited categories, as described by 45 CFR 46 are handled as follows:

   a) For proposals eligible for exempt or expedited review, the applications are provided by the student to the Program Associate (PA) serving the IRB, and who facilitates the review process. The PA promptly selects one committee member based on background and experience and assigns a project for review and comment. The application proposal is sent to the reviewer via the HSRS system. The review notes, modification requests, or recommended approval from the reviewer are maintained in the project file. Upon receipt of such communication from the reviewer, the PA sends the file to the Chair for final review and approval.

   b) The Chair reviews the application, and any changes or modifications requested by the reviewer to ensure the changes have been made. If the Chair determines the project is ready for approval, the Chair completes the chair review form. The PA generates the approval letter. Such correspondence shall be maintained in the project file. The IRB approval as indicated in the generated form letter is effective for exactly one year (365 days) minus one day from the approval date. (The approval letter is provided to the student assistant to be placed in the file and transmitted to the researcher, the department chair, and if the researcher is a student, a copy of such will be sent to the faculty advisor.) The approved consent form is attached to the approval letter. The following information is added as a footer or stamped at the bottom of the consent forms: the date of approval; the application number; and the expiration (void) date, which is calculated to be one year minus one day from the approval date of the consent form and approval letter. Example: Project approved and approval letter dated June 1, 2003. Project and consent form approval begin on June 1, 2003 and remain in effect until May 31, 2004, the expiration date.

6. For projects reviewed by the full Committee, researchers may be required to attend the Committee meeting and answer any questions posed by the Committee members. A record of the discussion and revisions requested, if any, are noted in the minutes of the meeting, and may be excerpted and sent to the researcher as needed. If no revisions are needed the Secretary issues an approval notice letter to the researcher within a reasonable time.
thereafter. If revisions are required, the researcher is expected to provide same in a timely manner to the Secretary, who then forwards the revisions to the Chair for final review and approval. Date of approval for full committee projects is the date approved at the meeting. Consent form approval date is the same as the date of project approval, and the expiration date is one year (365 days) minus one day from the approval date. Example: Project approved at June 1, 2003 full committee meeting. Approval date on notice is June 1, 2003, and consent approval is June 1, 2003, and both will expire on May 31, 2004.

7. Note that approval notices contain information regarding the researcher’s obligation to obtain Committee approval prior to implementing any changes to the project’s previously approved procedures, to keep the Committee advised of any problems or injuries to subjects and of the need for renewal of the project if the research is not completed within one year.

The IRB office notifies the researchers of the need to renew their project approval prior to the approval’s expiration date. Renewal requests receive an “R” after the human subject’s application number on the project file. Projects are reviewed for renewal in the same manner as their original review, i.e. expedited projects are reviewed by the Chair and one Committee members, projects approved by full Committee are renewed by the full Committee. This process is called “Continuing Review” under the federal regulations. Researchers who do not respond to the renewal reminder are sent a notification that approval has been terminated and that no further research is authorized by the Committee. The Office of Research provides administrative support for the IRB (Human Subjects Committee). All applications are filed with the Secretary of the Committee and files are maintained within the Office of Research. The Chair conducts an annual review and this information is reported to the Vice President for Research.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-8

Title of Policy: Initial Application Materials to be Reviewed at Full Committee

Responsible Executive: Gary K. Ostrander
Approving Official: Gary K. Ostrander
Effective Date: Readopted –January 1, 2015
Revision History: New August 13, 2003

I. INTRODUCTION

This policy states that the IRB Committee must obtain sufficient information required by federal regulations when conducting the review of proposed research. The document outlines what reviewers need to submit obtain prior to review.

II. POLICY

1. The IRB Committee must obtain information in sufficient detail to make the determinations required under federal regulations, when conducting the initial or full Committee review of proposed research.

2. Materials to be provided to the IRB Committee.

   a) The following materials should be provided to the primary reviewer:

   1. A completed IRB application with a signature page.
   2. Full investigator’s or sponsor’s protocol.
   3. Proposed informed consent document(s) and/or script as appropriate.
   4. Copies of surveys, questionnaires, or videotapes.
   5. Copies of letters of assurance or cooperation with research sites.
   6. Relevant and complete grant applications.
   7. Investigator’s brochure.
   8. Advertising/recruitment flyers intended to be seen or heard by potential subjects, including email solicitations.
b) Materials to be provided to non-primary reviewers: All IRB Committee members shall receive copies of the above mentioned materials with the exception of the grant application. However, all materials and complete documentation shall be available to all members for review at the convened meeting, or prior to the meeting upon request.

c) These materials should be received by members via courier or mail sufficiently in advance of the meeting date to allow for review of this material.

3. Grant Application. The primary reviewer shall review the grant application, if any, to ensure that the research described in the IRB proposal is consistent with the grant application. A copy of the grant application or proposal shall be retained by the IRB Office and made available to any IRB member who may wish to review it. The IRB may require the investigator(s) to summarize and cross-reference materials, identify any IRB approved protocols that describe the proposed research, and either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies.

4. IRB Review of NIH Approved Informed Consent documents for NIH supported Multi-center Clinical Trials. The IRB Committee must receive and review a copy of the NIH approved sample informed consent document and the full NIH approved Investigator’s protocol as a condition for review and approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the investigator, approved by the IRB Committee, and reflected in the IRB Committee minutes.

5. Inclusion of Women, Children, Minorities, and other vulnerable populations in Research. NIH supported investigators must provide details of the proposed involvement of humans in the research, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any sub-population.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103,109, 115
Florida State University Policy 7-IRB-9

Title of Policy: IRB Quorum Requirement for Full Committee Review

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

The policy describes the necessary components of Full Committee IRB meetings. These components include establishing convened meetings, having a quorum, and a nonscientist member being present. The policy also explains conflicts of interest for Full Committee reviews.

II. POLICY

1. Except as provided when utilizing expedited or exempt review procedures, the IRB Committee may only review proposed research at convened meetings at which a majority of the voting members (a quorum) of the IRB Committee are present, including at least one member whose primary interests are in nonscientific areas. No official actions may be taken at a meeting unless a majority of the members are present.

2. Should there be a quorum failure of members during a convened meeting (for example, members with conflicts being excused, early departures, loss of a non-scientist), then the committee should cease from further voting until the quorum can be restored.

3. Except as provided when utilizing expedited or exempt review procedures, no IRB meeting shall be convened without a nonscientist member being present for the duration of the meeting. No official action may be taken by the full committee without the presence of a nonscientific member.
4. Telephone Participation. Whenever possible, the IRB Committee meetings shall take place with all participating IRB members physically present. However, circumstances may warrant conducting IRB Committee meetings via telephone conference call. In order for a telephone participation meeting to occur, each participating IRB Committee member must receive all pertinent material prior to the meeting, and be able to actively and equally participate and communicate in the discussion of all protocols. Official Committee actions may be taken at a meeting in which members participate via telephone. The minutes of such meetings shall clearly document the above, in addition to the usual regulatory requirements that must be demonstrated in the minutes.

5. Conflict of Interest. It is prohibited for any IRB Committee member to participate in the IRB Committee’s initial or continuing review of a project in which the member has an actual conflict of interest, or the appearance that a conflict of interest should arise or exist, except to provide information requested by the IRB Committee.

   a) IRB Committee members shall absent themselves from the meeting room when the IRB Committee votes on research in which they have a conflicting interest and such matter should be noted in the IRB Committee meeting minutes.

   b) In order to avoid any actual or perceived conflicts of interest, or the appearance thereof, no participating IRB Committee member may hold an equity interest (such as a partnership, stock, or profit-sharing) in the entity requesting IRB Committee review. No participating IRB Committee member may be paid more than reasonable compensation or receive more than reasonable benefits for IRB related activities. In addition, no IRB Committee member may receive compensation or benefits under arrangements that could impede or otherwise discourage the objective decision making that is necessary on behalf of human subjects.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.107,108
Florida State University Policy 7-IRB-10

Title of Policy: Final Action by the IRB Committee

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy describes the types of action that may be taken by the IRB Committee.

II. POLICY

1. Pursuant to 45 CFR 46.109, an IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by federal regulations and as described in FSU’s federal wide assurance.

2. Such authority shall be implemented by final action by the IRB as described by this policy herein. Any final action of the IRB will be decided upon only after appropriate discussion and voting by a majority of the quorum members present. The investigator will receive a written notice which will include the type of action taken, the type of review accepted, and any other relevant instruction from the IRB.

3. The various types of action possible by the IRB Committee are as follows:

   a) Approved. This action means that the investigator has met all conditions and the project may be implemented.

   b) Conditional Approval. This action means that the IRB has required modifications in the project in order to secure the approval of the IRB. There are two levels of conditional approval:

   - Review by Committee Required. Responses to this level must be brought before the Committee for action at a regularly scheduled meeting for full review.
- **Review by Chairperson Required.** Responses to this level may be reviewed by the Committee Chairperson and, if considered satisfactory, the conditions may be removed by the Chair.

c) **Tabled.** This action is taken by the Committee whenever it has not completed its review or does not have sufficient information for definitive action. If the project is tabled due to insufficient information, the deficiencies noted will be transmitted to the investigator in the Committee minutes and no further action will be taken by the Committee until revisions of the project is submitted by the investigator.

d) **Disapproved.** This action means that the Committee has identified major conflicts or deficiencies in the project which cannot be remedied without major revision. Thus, the Committee will disapprove such a project.

e) **Administrative Termination.** This action is taken by the secretary to the IRB Committee, and occurs whenever there has been a failure to comply with any of the requirements of the IRB Committee.

f) **Reviewed, No Action Taken.** This action means that the IRB has reviewed the project and has found that the activity proposed is not “research,” does not involve human subjects, or otherwise does not fall within the purview of the IRB responsibility. The Chairperson or Office Staff shall respond in writing to the Investigator for this action.

### III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103,108,109
Title of Policy:  Amendments to Previously Approved Applications

Responsible Executive:  Gary K. Ostrander

Approving Official:  Gary K. Ostrander

Effective Date:  Readopted –January 1, 2015

Revision History:  New  August 13, 2003

I. INTRODUCTION

This policy outlines the process of amending previously approved research applications. All planned changes in previously approved applications must be submitted, in full, to the IRB prior to the implementation of those changes.

II. POLICY

1. For previously approved applications that were approved within the last year, all planned changes in the conduct of a study and/or changes to the consent document must be approved by the IRB prior to initiation.

2. Investigators must submit the exact text of an amendment or other revision to the protocol and any proposed changes to the consent document to the IRB. When there are numerous changes to the research protocol, a summary of the changes should also be included.

3. Changes to the informed consent document must take into account both prospective research subjects and, if applicable, research subjects already enrolled in the study. The latter may be addressed by using an addendum to the initial informed consent document or, less preferably, by re-consenting the subject using the modified informed consent document.

4. Minor changes proposed for previously approved research may be reviewed in an expedited manner. A minor modification is defined to mean a change that would not materially affect an assessment of the risks and benefits of the study, or does not
substantially change the specific aims or design of the study.

5. If major changes are proposed for previously approved research, then the IRB Committee must review and approve changes at a convened meeting before such changes can be implemented. A major modification is defined as any change which materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-12

Title of Policy: Cooperative Project/Multi-site projects – IRB Review

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

Revised __________

I. INTRODUCTION

This policy describes the process of IRB review when the proposed research will involve more than one institution.

II. POLICY

1. Cooperative research projects are those projects which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal regulations. An institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of any other qualified IRB, or make similar arrangements for avoiding duplication of effort.

2. FSU may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another DHHS Multiple Project Assurance (MPA). Such acceptance must be in writing, approved and signed by an official of FSU’s Office of Research, and approved and signed by correlative official of each of the other cooperating institutions.

Cooperative projects which are part of inter-institutional cooperative studies will be processed by the FSU IRB under the same guidelines as any other project. The approval by any extra-institutional cooperative IRB or Committee does not imply approval by the FSU IRB.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.117
I. INTRODUCTION

This policy outlines the renewal process for continuing research. Continuing review of research activities is necessary to determine whether the risk/benefit ratio has changed and should be reviewed at least annually. The policy also describes what information must be submitted for the IRB to review renewals.

II. POLICY

1. Continuing review of research activities is required to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to subjects, and whether any new information regarding the risks and benefits should be provided to subjects. All research protocols, including those which have been determined to be exempt in status, must be periodically reviewed at least annually, unless the following has occurred:

   a) A research protocol for which no new subjects will be enrolled (closed) shall be subject to continuing review until such time that the initial analysis of the data has concluded that no new information needs to be provided to enrolled subjects, and there is no further need to re-contact enrolled subjects to obtain additional research information.

2. Based on the continuing review, the IRB may require that the research be restricted, modified, or terminated.

3. Review by the full IRB Committee at a regularly scheduled meeting, is required unless the research is otherwise appropriate for expedited or exempt review.
a) The full IRB Committee must conduct a continuing review of a protocol using full committee review procedures if the protocol was initially reviewed by the full committee, unless the protocol has been modified such that it can be reclassified as eligible for expedited review. Note that research activities that have previously been determined to be exempt or expedited, may change so that a full review may now be required for continuing review.

b) When conducting continuing review by full IRB Committee, the IRB may use a primary reviewer system for continuing review. However, the full IRB Committee must be informed of the reviewers’ findings at the convened meeting. Primary reviewers shall receive a copy of the complete protocol including any modifications previously approved by the IRB Committee, any reported adverse events, and any monitoring or audit reports conducted since the last review. The full IRB Committee must discuss the protocol and make a determination with recorded vote.

c) A protocol that originally received an expedited or exempt review, may receive its continuing review on an expedited basis as well. Thus, the IRB Chairperson and designated IRB Committee members conduct the continuing review on behalf of the full IRB Committee.

4. Continuing review of protocols is required to be substantive and meaningful. The criteria for continuing review is the same as those for initial review. The IRB Committee (or the reviewers for protocols under an expedited procedure) must determine:

a) that the risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;

b) that the selection of subjects continues to be equitable;

c) that the informed consent continues to be appropriately obtained and documented;

d) that there are adequate provisions for monitoring the data collected to ensure the safety of the subjects, adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, and appropriate safeguards for vulnerable populations.

5. The full IRB Committee should receive and review:

a) the continuing review application (Request for Renewal);

b) a protocol summary and status report on the progress of the research which should include:
   - the number of subjects accrued, and the total number of subjects withdrawn from the study since the previous
review,
- a summary of any unanticipated problems involving risks to subjects or adverse events that were serious or unanticipated, and resulted in a change to the risk/benefit ratio since the previous review, even if the event occurred at a location for which the FSU IRB is not the IRB of record
- an explanation of any subject’s withdrawal from the research or any complaints about the research since the previous review,
- a summary of any recent literature, findings obtained thus far, amendments or modifications to the research, reports on multi-center trials and any other relevant information, especially information about risks associated with the research since the previous review

c) a copy of the current approved informed consent document as well as an unstamped copy of the informed consent document eligible to be stamped with continuing approval.

6. In addition, primary reviewers should receive a copy of the current, approved IRB application that should include any prior modifications previously approved by the IRB Committee and supporting documentation such as an investigator’s brochure, sponsor’s protocol, or grant application. Reviewers should also receive copies of any monitoring or audit reports conducted since the last review.

7. The currently approved consent document should be reviewed to ensure that the information is still accurate and complete. Any significant findings that may relate to a subject’s willingness to continue participation should be provided to the subject in an updated consent document.

8. Amendments and addenda to a research protocol may be submitted at the time of continuing review. The amendment may not be implemented by the investigator until review and approval by the IRB Committee.

9. Continuing IRB review is required as long as individually identifiable follow-up data are collected on subjects enrolled in HHS-supported Cooperative Protocol Research Program (CPRP) protocols.

10. The IRB Committee must conduct continuing review of protocols at intervals appropriate to the degree of risk, but not less than once per year. The interval is set for each protocol. The phrase “not less than once per year” means that the research must be reviewed within one year of the date of the IRB meeting at which the research was approved (with or without revisions) even though the research activities may not begin until after the IRB Committee has given approval.
a) Factors to be considered by the IRB in determining the appropriate interval for review include the following:
- involvement of vulnerable populations,
- research conducted internationally,
- the involvement of recombinant DNA or other types of gene transfer protocols,
- the use of waiver of informed consent procedures,
- research for which subjects would be exposed to additional risks, such as breach of confidentiality, number or severity of Serious Adverse Events (SAE),
- previous suspension of the research due to compliance, record-keeping, or other concerns,
- recommendations from other institutional committees.

b) The intervals for review shall be assigned a surveillance level described as:
- Yearly - require review at annual intervals,
- Six Months – requires every six months intervals
- Other – requires more frequent review interval whenever risks are greater than minimal.

11. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Any requests for extensions beyond the expiration date will not be granted.

12. If the continuing review does not occur within the required period the project will be administratively terminated. No further subjects may be enrolled until continuing review has occurred and the administrative termination is lifted.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103,109
Florida State University Policy 7-IRB-14

Title of Policy: IRB Audits and Monitoring

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy states that the IRB has the responsibility for internal and external auditing and monitoring efforts to be in compliance with federal regulations and IRB policies. The policy further details when auditing and monitoring efforts should be utilized by the IRB.

II. POLICY

1. The Institutional Review Board is charged with the responsibility for internal and external auditing and monitoring efforts in order to ensure the protection of human subjects and compliance with federal regulations and IRB policies. The IRB has the authority to observe, or appoint a designee to observe, the informed consent process and the IRB approved research.

2. The Vice President of Research, Associate Vice President of Research, and/or the Chair of the IRB may direct an experienced designee to initiate periodic and/or directed audits when deemed necessary.

   a) A periodic audit is a systematic method to audit IRB approved research on a regular basis.

   b) A directed audit is an audit conducted in response to identified concerns that require an IRB determination.

3. Monitoring and/or auditing activities may include, but are not limited to the following:
a) Request progress reports from investigators.  
b) Examine research records, including copies of signed consent forms.  
c) Contact research subjects.  
d) Assign observers to sites where research involving human subjects and/or the informed consent process is being conducted.  
e) Audit advertisements and other recruiting materials as deemed appropriate by the IRB.  
f) Review projects to verify from sources other than the investigator that no unapproved changes have occurred since previous IRB review.  
g) Other monitoring or auditing activities deemed appropriate by the IRB.  

4. The IRB may suspend or terminate research if the information gained during the monitoring or auditing process indicates that human subjects in a research project were exposed to unexpected serious risk or harm, or that the federal regulations or the policies of the IRB were not met.  

5. The IRB may request additional safety monitoring or the creation of an independent data safety monitor.  

6. For research activities involving vulnerable populations such as fetuses, children, pregnant women, prisoners, or the decisionally impaired, the IRB shall determine that adequate provisions have been made by the investigator for monitoring the actual consent process. The IRB may oversee the actual informed consent process, not limited to the following:  

   a) verifying that subject selection is appropriate and observing the actual informed consent process by which individual consents are obtained, or  
   b) monitoring the progress of the activity and intervening as necessary, including visits to the activity site and continuing evaluation to determine whether any unanticipated risks have developed.  

7. The results of any auditing or monitoring activity by the IRB shall be reported in writing to the Chair of the IRB. The IRB Chair shall determine the need for full IRB Committee review. The results will be placed on the agenda or the next regularly scheduled meeting for action as appropriate. In addition, all auditing and monitoring information will be maintained in the IRB file and provided to the primary reviewer at the time of the next continuing review.  

8. If the auditing or monitoring of a research activity reveals that a human subject has been exposed to unexpected serious harm, such finding shall be reported to the Chair of the IRB, the Vice President of Research, and Associate Vice President of Research. The finding and related study shall be placed on the agenda of the next regularly scheduled
meeting for discussion and action. However, a decision may be made to suspend or terminate the research prior to the next regularly scheduled IRB meeting as circumstances may require.

9. The IRB may determine which projects require verification from sources other than the investigator to ensure that no unapproved changes have occurred since the previous IRB review. To accomplish this task, the IRB may conduct audits or inquiries to collect information and/or observe or utilize a designee to observe, the informed consent process and conduct of the research.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103,111, 117
Florida State University Policy 7-IRB-15

Title of Policy: Reporting of Unanticipated Problems Involving Risk or Adverse Events

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

Revised ____________

I. INTRODUCTION

This policy describes the responsibility and authority of the IRB for reviewing unanticipated problems involving risk and adverse events reported by the Investigator. The policy outlines the responsibility the Investigator has in reporting unanticipated problems involving risk and adverse events.

II. POLICY

1. The IRB is charged with the responsibility of reviewing reported unanticipated problems involving risks to subjects and adverse events in accordance with this policy. The IRB may elect to vote to suspend or terminate the study or direct the Investigator to contact subjects for re-consenting or to provide additional information regarding subject safety.

2. Investigators must address risks to subjects in the initial IRB application. Plans for safety monitoring, reporting of adverse events and/or unanticipated problems involving risks to subjects, and procedures for transmitting information to the IRB must be described in the initial application.

3. The Investigator shall be responsible for submitting to the IRB any independent data safety monitoring reports in a timely manner.

4. Investigators shall be responsible for informing governmental and/or other sponsors of any adverse event and/or unanticipated problems involving risks to subjects in accordance with the sponsors’ policies and regulations.

5. Investigators are responsible for informing the appropriate institutional committees and federal agencies (such as the FSU Biosafety Committee, OHRP, FDA) of any adverse events and/or unanticipated problems involving risks to subjects in accordance with FSU policies and federal regulations.
6. Prior to, and at the time of IRB continuing review of an approved research study, it is the Investigator’s responsibility to keep the IRB office informed of any unanticipated problems involving risks to subjects or adverse events that were serious, unanticipated, and resulted in a change to the risk/benefit ratio, even if the event occurred at a location for which the FSU IRB is not the IRB of record. The Investigator shall be responsible for the documentation, investigation, and follow-up of all possible study-related adverse events and unanticipated problems involving risks to subjects.

7. The level and promptness of an IRB review of adverse events and unanticipated problems involving risks to subjects depends upon the following:

   a) the seriousness of the event,
   
   b) the relationship of the event to study participation,
   
   c) whether the event is described in the study procedures, investigator’s brochure and/or the informed consent documents,
   
   d) whether the event occurred to a subject enrolled at a location for which an FSU Investigator is involved in the conduct of the research or is responsible for the reporting of unanticipated problems or adverse events to a regulatory agency, and
   
   e) whether the event changes the risk/benefit ratio.

8. The FSU IRB has identified three categories of adverse events and/or unanticipated problems involving risks to subjects and manner of response:

   a) Level I – For events or problems occurring to the subject enrolled at an FSU site or at a site in which an FSU Investigator is involved in the conduct of the research or is responsible for the reporting of adverse events and/or unanticipated problems involving risks to subjects to a regulatory agency, the response shall be as follows:

      - All SERIOUS and UNANTICIPATED adverse events or problems involving risks to subjects that may possibly be or are known to be related to the research activity must be reported promptly to the IRB office utilizing the FSU IRB Adverse Event Report Form for each event. The report and underlying events shall receive a full committee review. However, if there is no change to the risk/benefit ratio, or the research proposal or consent form, then an expedited review shall be utilized. (Note that the Chair or designee, at the time of the expedited review, may refer any adverse event to the full committee for review).

      - All NON-SERIOUS and UNANTICIPATED adverse events or problems involving risks to subjects that may possibly be or are known to be related to
the research activity must be reported promptly to the IRB office utilizing the IRB Adverse Event Report Form. An expedited review shall be utilized provided there is no change in the risk/benefit ratio, the research proposal or the consent form. (Note that the Chair or designee, at the time of the expedited review, may refer any adverse event to the full committee for review).

b) Level II – For events occurring to the subject not enrolled at an FSU site or a site in which an FSU Investigator is not involved in the conduct of the research and the Investigator is not responsible for the reporting of unanticipated problems or serious adverse events to a regulatory agency, the response shall be as follows:

- All SERIOUS and UNANTICIPATED adverse events or problems involving risks to subjects that may possibly be or are known to be related to the research activity and the Principal Investigator has determined that there is a change to the risk/benefit ratio of the research, then an amendment request must be submitted to the IRB. An expedited review shall be utilized, unless the Chair or designee refers the matter to a full committee for review.

- All NON-SERIOUS and UNANTICIPATED adverse events or problems involving risks to subjects that may possibly be or are known to be related to the research activity and the PI has determined that there is a change in the risk/benefit ratio of the research, require the submission of an amendment request to the IRB. An expedited review shall be utilized, unless the Chair or designee refers the matter to a full committee for review.

- Events not resulting in changes to the risk/benefit ratio yet are of importance to the study or the IRB should be included in a summary format submitted with the Application for Continuing Review (renewal). Individual reports of such adverse events or unanticipated problems involving risks to subjects are not required to be submitted to the IRB, but must be retained in the PI’s files for reference.

c) Level III – All adverse events and/or unanticipated problems involving risks to subjects occurring in a human gene transfer protocol, regardless of relation to the study, must be reported promptly to the IRB, the FSU Biosafety Committee, and NIH Office of Biotechnology Activities, and other applicable regulatory agencies, such as the OHRP, and the FDA. The phrase “Human Gene Transfer” is defined as the deliberate transfer of recombinant DNA, DNA or RNA derived from recombinant DNA, into human subjects.

9. A Serious Adverse Event is defined as any experience that suggests a significant hazard, contraindication, side effect, or precaution, and includes any experience that is a:

a) Death;
b) Life-threatening emergency;
c) Persistent or significant disability/incapacity;
d) Inpatient hospitalization or prolongation of existing hospitalization;
e) A congenital anomaly/birth defect;
f) Any other experience that suggests a significant hazard, contraindication, side effect or precaution that may require medical or surgical intervention to prevent one of the outcomes
10. An Unanticipated Problem Involving Risks to Subjects, as referenced in 45 CFR 46.103(b)(5) may be an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (such as a headache following a spinal tap, intestinal bleeding associated with aspirin therapy, a loss of confidentiality, protocol deviation possibly effecting risk to the subject).

11. The FSU IRB has the authority to suspend or terminate approval of research that has been associated with unexpected serious harm to participants and/or others. When an IRB elects to take such action, the Chair shall promptly report this action, in writing, to the Investigator, including the rationale for the decision. Such action shall also be promptly reported to the Vice President for Research, the Associate Vice President for Research, the Department Head, and the Dean of the Investigator’s School. Regulatory authorities such as the OHRP, FDA, NIH, or other federal sponsoring departments or agencies shall also be promptly notified by the IRB Office or any terminations for cause or suspensions for cause.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103, 113
Florida State University Policy 7-IRB-16

Title of Policy: Suspension or Termination of IRB Approval for Cause

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

Revised ____________

I. INTRODUCTION

This policy explains the authority of the IRB to suspend or terminate approval of research that is not in accordance to IRB policies, federal regulations, or has been associated with unexpected serious harm to subjects.

II. POLICY

1. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB Policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects. Serious or continuing noncompliance with the determinations of the IRB may result in the IRB withdrawing approval for a study. Failure to provide a response in a timely manner to a request of information for continuing review is considered cause for suspension or termination of IRB approval. Any letter of suspension or termination of approval to an Investigator shall include a statement of the reasons for the IRB’s action. The Investigator shall have an opportunity to respond in writing or in person to the letter of suspension or termination.

2. All suspensions or terminations of approval for cause must be promptly reported to the Associate Vice President for Research at Florida State University. The Vice President for Research shall notify the relevant Department Head, the Dean of the Investigator’s School, and the Chairperson of the IRB Committee.

3. Regulatory authorities such as OHRP, the FDA, NIH or other federal sponsoring departments or agencies shall be promptly notified by the Vice President of Research of any terminations or suspensions for cause.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.113
I. INTRODUCTION

This policy describes that the IRB has the right to use consultants to assist in the review of issues beyond the expertise of the IRB.

II. POLICY

1. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. However, such individuals may not vote with the IRB.

2. The consultants may be selected from within or outside of Florida State University. The IRB may reserve final action on a project until the consultant’s opinion is obtained and any questions raised by the consultant have been answered by the Investigator.

3. The record keeping of the IRB should reflect the name, area of expertise, and manner of utilization of the consultant(s).

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.107
I. INTRODUCTION

This policy states that the FSU IRB may require the principal investigator or co-investigator to be present at the Committee meeting and the procedure of having the investigator present.

II. POLICY

1. The FSU IRB may require the principal investigator or co-investigator, capable of answering questions relating to the application, protocol, study design and safety, to be present during the review of each new study. If no investigator is present for the meeting, then the research proposal will be tabled until the next convened meeting of the IRB. Should the investigator know ahead of time that he/she will be unable to attend, the IRB office should be timely notified.

2. Principal investigators are asked to wait outside the meeting room, until such time as an IRB staff member calls the investigator into the meeting room when it is time to present his/her study.

3. The Investigator is asked to give the Committee a brief overview of the study. The Committee shall then ask any questions they may have at that time.

4. After questioning has ceased, the investigator is asked to leave the meeting room so that the Committee can complete their discussion and voting.

5. Any requests to observe an IRB meeting may be submitted to the Chair or IRB Secretary for consideration. The requesting party shall receive verbal or written notice by the IRB
Office of approval to observe. Individuals who receive such approval are requested to maintain confidentiality regarding the specifics of any research to the extent permitted under Florida law.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-19

Title of Policy: Procedure for Human Subject Database Information

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy summarizes the Human Subject Database framework and design.

II. POLICY

1. The IRB support staff shall have access to the database (HSRS) information for human subjects.

2. The database utilizes .NET framework, including technologies such as HTML/XHTML, JavaScript, AJAX, C#.NET, ADO.NET, ASP.NET, and Microsoft SQL Server database system.

3. The system uses client server architecture to facilitate the remote access for submission and review, and provides an online administration panel to track and manage the applications and reviews.

4. The system is maintained by the Office of Research programmer.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-20

Title of Policy: Prompt Reporting of Serious or Continuing Noncompliance

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy states that all reports of serious or continuing noncompliance in human subjects research must be investigated by the IRB Office and Associate Vice President of Research. The policy outlines the authority of the IRB concerning issues of noncompliance.

II. POLICY

1. All credible reports of inappropriate involvement of human subjects in research must be investigated by the IRB Office and Associate Vice President of Research. Such reports of noncompliance may come from any source including IRB Committee members, investigators, subjects, institutional personnel, the media, anonymous sources or the public. The results of the investigation will be reported to the Vice President of Research. Thereupon, the Vice President shall notify the Department head, Dean of the Investigator’s School, and the Chair of the IRB. When applicable, notification will also be forwarded to the Faculty Advisor. Regulatory authorities such as OHRP, FDA, NIH, or other federal sponsoring departments or agencies will also be promptly notified by the Associate Vice President of Research of any serious or continuous noncompliance.

2. Between IRB continuing reviews of a protocol and at the time of continuing review of a protocol, it is the Investigator’s responsibility to keep the IRB Office informed of any unanticipated problems involving risks to subjects or adverse events that were serious, unanticipated, and resulted in a change to the risk/benefit ratio, even if the event occurred at a location for which the FSU IRB is not the IRB of record. An investigator is responsible for the accurate documentation, investigation, and follow-up of all possible study related adverse events. Investigators are also responsible for informing government and other sponsors of any unanticipated events, as appropriate.
3. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.113
Florida State University Policy 7-IRB-21

Title of Policy: Investigator Qualifications

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

Revised

I. INTRODUCTION

This policy describes qualifications of student conducted human subjects research and defines conflict of interest issues the IRB must consider during review.

II. POLICY

1. Florida State University’s Federalwide Assurance with the federal government specifies that all human subjects research that is conducted by or under the direction of any employee, faculty, staff, student, or agent of FSU in connection with his/ her institutional responsibilities must be reviewed by the IRB.

2. Student Conducted Research. All activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree must be reviewed by the IRB. For example: Master’s theses and doctoral dissertations that involve human subjects and all projects that involve human subjects and for which findings may be published or otherwise disseminated. Note: all student/fellows applying for IRB review must obtain the signature of their faculty advisor on the Signature Page of the IRB application.

3. Conflict of Interest. The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. The IRB should then consider conflict of interest issues in their review of applications. When appropriate, the informed consent document should state that all clinical investigators are required to comply with FSU’s Conflict of Interest Policies.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-22

Title of Policy: General Responsibilities of Investigator

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

Revised __________

I. INTRODUCTION

This policy explains the responsibilities of the Investigator in relation to human subject research and the FSU IRB.

II. POLICY

1. **Human Subject Protection.** The individual Investigator is the ultimate protector of the subject’s rights and safety. Each Investigator is obligated to be personally certain that each subject is adequately informed and freely consents to participate in the Investigator’s research.

2. **Use of Investigational Devices and/or Investigational Drugs.** Prior to the initiation of any research involving an investigational device or drug, the Investigator is responsible for obtaining the IND or IDE from the FDA in accordance with federal regulations.

3. **Additional University Committee or Institution Approval.** Prior to the initiation of any research that requires additional review and approval form other University committees or institutions, it is the responsibility of the Investigator to obtain the necessary approval from that committee and/or institution. Examples of prior approvals include the FSU Biosafety Office, and Superintendent’s Office for school systems where research will be conducted.

4. **Supervision and Auditing of Research.** It is the responsibility of each Investigator to assure that all procedures in a study are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them
under the laws of Florida and the policies of FSU. It is the responsibility of the Investigator to regularly review the research process and address any deficiencies identified in the process.

5. **Investigator Training.** Each Investigator is encouraged to complete periodic training to remain up-to-date with federal regulations, FSU policies and procedures, and compliance expectations. Each Investigator must ensure that key personnel who are responsible for the design and conduct of the study are adequately trained with regard to the use of human subjects in research. Such training may be through NIH or CREATE program at FSU.

6. **Congruence with Funding Proposals.** Each investigator shall ensure that the IRB protocol is consistent with the proposal for funding for extramural or intramural support. Further, the Investigator should act as a liaison between the IRB and the sponsor.

7. **Amendments/Requests for Change to IRB Application.** It is the responsibility of the Investigator to not deviate in any way from the IRB approved protocol until the Investigator has received written approval from the IRB.

8. **Researcher Records.** Investigators must maintain research records for at least three (3) years from the date of completion of the research. All records must be accessible for inspection and copying by authorized representatives of the IRB and the department or agency supporting the research. Beyond three years, requirements for record retention vary with the type of research conducted and the provisions of the Investigator’s funding source. It is the Investigator’s responsibility to clearly understand the retention requirements of the sponsor.

9. **Adverse Events.** The Investigator must report to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or others that occur in the course of the research in accordance with FSU policy.

10. **Confidentiality and Privacy.** The conditions for maintaining confidentiality and privacy of the subjects and the research records are required for the life of the data. These rules apply equally to any and all research conducted or assisted by students, staff, and faculty. Note: Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations.

11. **Prisoner Research.** If a subject becomes a prisoner after enrollment in research, the Investigator is responsible for reporting in writing this situation to the IRB promptly.
12. **Additional Requirements for Activities Involving Fetuses, Pregnant Women, or Neonates.** For activities involving fetuses, pregnant women, or neonates, the Investigator must ensure that adequate provision has been made for monitoring the actual informed consent process.

13. **Continuing Review.** All approved research proposals, including those which qualify for exemption in accordance with 46 CFR 46.101(b), must receive continuing review at intervals appropriate to the degree of risk as determined by the IRB. Continuing review must be conducted not less than once per year. It is the responsibility of the Investigator to provide the IRB with all of the information requested for Continuing Review in a timely manner.

**III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY**

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-23

Title of Policy: Investigator Checklist

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy provides an Investigator checklist for completing human subjects research and ensures that the Investigator is in compliance with applicable federal and state laws and local policies and guidelines.

II. POLICY

1. The Principal Investigator agrees to abide by the federal regulations for the protection of human subjects.

2. The Principal Investigator (“PI”) agrees to maintain raw data (including audiotapes and videotapes) and completed consent forms available for 3 years beyond the completion of the study for Human Subjects Committee verification at any time.

3. If the data collection or testing of subjects is to be performed by persons other than the PI (i.e. student assistants), the P.I. will assume full responsibility for supervising those persons to ensure that human subjects are adequately protected.

4. The PI is encouraged to have all existing and future key personnel complete the FSU Human Subjects training before they are involved in this study.

5. The PI agrees to report all changes of key personnel, protocols, and informed consent regardless of review status.
6. The IRB shall not grant final approval of NIH projects until the PI and key personnel working on the project have completed the NIH human subjects training. Proof of such completion of training shall be included in the application file.

7. Nature and Purpose of Research:
   a) Is it research?
   b) Controversial/Sensitive areas
   c) Importance/Value

8. Scientific Background:
   a) Background/Rationale
   b) Previous animal/clinical trials
   c) Literature support

9. Subject Population:
   a) Appropriate to goals of study
   b) Number of subjects
   c) Special subject characteristics: “special populations”
   d) Inclusion/exclusion criteria
   e) Justification for “vulnerable population”
   f) Methods used to identify potential subjects
   g) Recruitment process
   h) Selection process

10. Research Design:
   a) Design will enable valid conclusions
   b) Special problems/risks imposed by design: randomization, pre-randomization, placebo control, blinded, etc.
   c) Can design be modified to decrease risks and still yield valid data?
   d) Need for monitoring of study (i.e. safety monitoring board)

11. Risk/Benefit Ratio:
   a) What are the potential risks/discomforts?
   b) What are inconveniences and/or burdens: cost to subject, time, visits,
travel, etc.?
c) Risk classification category: less than minimal, greater than minimal, life-threatening
d) Probability of risk/harm
e) Safeguards adopted to minimize risk/harm
f) How will injury/harm be detected?
g) Benefits to subject (if any intended or anticipated)
h) Benefit to population of patients with subject’s condition
i) Benefit to society
j) Have efforts been made to maximize possibility of benefit?
k) Are risks/discomforts/burdens balanced by potential benefits?
l) Is risk/benefit ratio comparable to that of alternatives to participation?
m) If no benefit to subject, can risks, discomforts and burdens be justified on basis of generalizable knowledge to be obtained?
n) Risk/benefit ratio in research involving special subjects – i.e. children

12. Processing of Research Data:

   a) How will data be recorded and maintained?
b) Sensitive data? Need for special protections?
c) Provisions to protect anonymity or confidentiality
d) To whom will data be disclosed? Will data contain identifiers or be coded?
e) Will proposed statistical treatment of data yield valid results?

13. Monitoring:

   a) Any need for special monitoring or reporting?

14. Informed Consent Process:

   a) Who will solicit consent?
b) Will subjects have the capacity to provide consent?
c) Timing/Setting in which consent will be solicited
d) Should subject advocate or other individual be present during consent process?
e) Verbal vs. written consent; request for waiver

15. HIPAA applicability:

   a) Are you requesting/accessing protect health information from a covered
b) If you need authorization or other forms to access PHI, are the forms acceptable to the covered entity?

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-24

Title of Policy: Research Involving Pregnant Women, Human Fetuses and Neonates

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy outlines the additional requirements and conditions for human subject research that involves pregnant women, human fetuses and neonates. The additional requirements are imposed under existing IRB policies and other applicable federal, state, or local laws.

II. POLICY

1. This policy applies to all research, development, and related activities involving pregnant women, the fetus, and neonates. The requirements within this policy are in addition to those imposed under existing IRB polices and other applicable federal, state, or local laws.

2. Definitions as used in this policy shall mean as follows:

   a) “Pregnancy” encompasses the period of time from implantation until delivery. A woman shall be presumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

   b) “Fetus” means the product of conception from implantation until delivery.

   c) “Neonate” means a newborn.

   d) “Viable” as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of
45 CFR 46.

e) “Dead fetus” means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

f) “Nonviable neonate” means a neonate after delivery that, although living is not viable.

3. Pregnant women or fetuses may be involved in research if all of the following conditions are met:

a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

c) Any risk is the least possible for achieving the objectives of the research;

d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of 45 CFR 46.

e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of 45 CFR 46, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted form rape or incest.

f) Each individual providing consent under paragraphs (d) or (e) above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

g) For children as defined in 45 CFR 46.402 (a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of 45 CFR 46.

h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

j) Individuals engaged in the research will have no part in determining the viability of a neonate.

4. Additional protection is required for research involving neonates. A neonate of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
a) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

b) Each individual providing consent as required in this paragraph (4) have been met as applicable.

c) Pertaining to neonates of uncertain viability, until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

- The IRB determines that the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

- The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accord with subpart A of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

d) Pertaining to nonviable neonates, after delivery nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:

- Vital functions of the neonate will not be artificially maintained;

- The research will not terminate the heartbeat or respiration of the neonate;

- There will be no added risk to the neonate resulting from the research;

- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

- The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of 45 CFR 46, except that the waiver and alteration provisions of 45 CFR 46.116 c and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

e) Pertaining to viable neonates, a neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord by the requirements of subparts A and D of 45 CFR 46.
5) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities. Note: If information associated with material described here within is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of 45 CFR 46 are applicable.

6) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. Note that such research may be conducted or funded by HHS pursuant to the requirements set out in 45 CFR 46.207.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.204 – 207
Florida State University Policy 7-IRB-25

Title of Policy: Special Categories of Research: Children in Research

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

Revised ____________

I. INTRODUCTION

This policy explains the additional federal requirements that must be met to include children in human subject research. The policy also includes classification categories for research involving children.

II. POLICY

1. The special vulnerability of children makes consideration of involving children as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving children. The IRB may approve research involving children only if special provisions are met. The IRB must classify research involving children into one of four categories and document their discussions of the risks and benefits of the research study. The four categories of research that may be approved by the IRB are based on degree of risk and benefit to individual subjects, and are set out in the paragraphs below. Note: Under this policy, “children” includes all those who have not yet reached their 18th birthday.

2. Category One – Research Not Involving More than Minimal Risk. When the IRB finds that no greater than minimal risk to children is present, the IRB may approve the proposal only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in this policy herein.

3. Category Two – Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subject. If the IRB finds that more than minimal risk to children is presented by an intervention or procedure but that the intervention or
procedure holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject’s well-being, the IRB may approve the research, provided the IRB finds that:

a) the risk is justified by the anticipated benefit to the subjects;
b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in this policy herein.

4. **Category Three – Research Involving Greater than Minimal Risk and No Prospect of Direct Benefit to Individual Subjects, but Likely to Yield Generalizable Knowledge about the Subject’s Disorder or Condition.** If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, the IRB may approve the research provided the IRB finds that:

a) the risk represents a minor increase over minimal risk;
b) the intervention or procedure presents experiences to subjects that are reasonable commensurate with those inherent in their actual or expected medical, dental, psychological, social, or education situations;
c) the intervention or procedure is likely to yield generalizable knowledge about the subject’s disorder or condition which is of vital important for the understanding or amelioration of the subject’s disorder or condition; and
d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth below.

5. **Category Four – Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children.** If the IRB does not believe the research proposal meets any of the requirements set forth above, it may still approve the protocol provided:

a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
b) the Secretary of the DHHS, after consultation with a panel of experts in pertinent disciplines (i.e. science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
that the research in fact satisfies one of the conditions set forth above, or
- that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, the research will be conducted in accordance with sound ethical principals, and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth below.

6. **Requirements for Permission by Parents or Guardians and for Assent by Children.**

   a) **Adequate Provisions for Child’s Assent.** The IRB must find that adequate provisions are made for soliciting the assent of child subjects when in the judgment of the IRB the children are capable of providing assent. In making this determination, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child’s age, experience, maturity, and condition.

   b) **Waiver of Assent.** If the IRB determines either of the following two conditions are true, then the assent of the children is not a necessary condition for proceeding with the research.

- The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research. Therefore, when the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of research, the IRB may determine that the assent of the child is not necessary. Note: In the events of a child’s dissent, which should normally be respected, such dissent may be overruled by the child’s parents, at the IRB’s discretion. When research involves the provision of experimental therapies for life-threatening diseases, however, the IRB should be sensitive to the fact that parents may wish to try anything, even when the likelihood of success is marginal and the probability of extreme discomfort is
high. Should the child not wish to undertake such experimental therapy, difficult decisions may have to be made. In general, if the child is a mature adolescent and death is imminent, the child’s wishes should be respected.

c) "Assent" is defined, for purposes of this policy, to mean a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

d) Adequate Provisions for Parents’ or Guardian’s Permission. The IRB must find that adequate provisions are made for soliciting the permission of each child’s parents or legally authorized representative.

- Research not involving greater than minimal risk. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research not involving greater than minimal risk when the provisions of Paragraph 2 above are met.

- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects when the provisions of Paragraph 3 above are met.

- Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition. When the research is approved under Paragraph 4 above, and permission is to be obtained from parents, both parents must give their permission unless one 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.

- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. When the research is approved under Paragraph 6 above, and permission is to be obtained from parents, both parents must give their permission unless one 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.
e) **Waiver of Parental or Guardian Permission.** If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or legally authorized representative permission is not a reasonable requirement to protect the subjects (i.e. abused or neglected children), it may waive the consent requirements described above, provided both an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is not inconsistent with federal, state, or local law. The choice of a mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

f) **Documentation.** Permission by parents or guardians shall be documented in the same manner as required for subjects under the Documentation of Consent Policy. When the IRB determines that assent of a child is required, it shall also determine whether and how assent must be documented.

g) **Wards of the State or Other Agency.** Children who are wards of the state or any other agency, institution, or entity can be included in research approved under Paragraph 4 or 5 of this policy only if the IRB finds and documents that such research is related to their status as wards, or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

7. **Pediatric Expertise on the IRB Committee.** An IRB Committee considering a protocol involving children, should assess its need for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities and consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with children. The IRB may invite nonvoting individuals to assist in the review of issues which require expertise beyond that available among voting IRB members.

**III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY**

BOG 1.001(3)(m), 45 CFR 46.401-409, Subpart D
Florida State University Policy 7-IRB-26

Title of Policy: Special Categories of Research: Prisoners as Research Subjects.

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

Revised ___________

I. INTRODUCTION

This policy explains the special provisions needed to conduct research with prisoners. This policy complies with federal regulations to provide a unique definition of minimal risk as it pertains to prisoner subjects.

II. POLICY

1. The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. Therefore, if a protocol involves the use of prisoners as subjects, both the general IRB policies apply and the special requirements outlined in this policy apply. Note: the IRB may approve research involving prisoners only if these special provisions are met.

2. The federal regulations provide a unique definition of “Minimal Risk” as it pertains to prisoners as research subjects, and such definition differs from the definition of minimal risk in the Common Rule. The definition for prisoners requires reference to physical or psychological harm, and reads as follows: “Minimal Risk” is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

3. Definition of Prisoner. As used in this policy, “Prisoner” means any individual involuntarily confined or detained in a penal institution. The term is intended to
encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

4. This Policy applies to all research involving prisoners as subjects when one of more of the following apply:

- The research is sponsored by Florida State University; or
- The research is conducted by or under the direction of any employee or agent of FSU in connection with his or her institutional responsibilities; or
- The research is conducted by or under the direction of any employee or agent of FSU using any property or facility of FSU; or
- The research involves the use of FSU’s non-public information to identify or contact human research subjects or prospective subjects.

5. This Policy applies whenever any human subject in a research protocol becomes a prisoner at any time during the protocol, even after the research has commenced. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the future incarceration of the subject.

- If a subject becomes a prisoner after enrollment in research, the Investigator is responsible for reporting in writing this situation to the IRB immediately.
- Promptly upon receiving the Investigator’s notice or otherwise becoming aware of the prisoner status of a subject, the IRB should review the protocol again with a prisoner representative to the IRB. The Committee should take special consideration of the conditions of being a prisoner. The IRB should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of the subject’s participation by the Investigator without regard to the subject’s consent.
- Upon this review, the IRB can either approve the involvement of the prisoner subject in the research in accordance with this policy or determine that this subject must be withdrawn from the research.

6. Composition of the IRB When Prisoners are Involved. If an IRB regularly reviews research that involves prisoners consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these subjects.

a) To review a protocol involving prisoners as subjects, a majority of the IRB (exclusive of prisoner members) shall have no association with the prison involved, apart from their membership on the IRB, and at least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate
background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB only one IRB need satisfy this requirement.

b) If a prisoner representative (“PR”) is selected to serve on the IRB Committee, the person must have a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals could include present or former prisoners, prison chaplains, prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights or prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.

c) The IRB must meet the special composition requirements for all types of review of the protocol – initial review, continuing review, protocol amendments, and reports of unanticipated problems involving risks to subjects.

d) The IRB must notify OHRP of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative.

7. Specific Findings of IRB Required to Approve Research. When reviewing a protocol in which a prisoner is a subject, the IRB must make additional findings as follows:

a) The research under review represents one of the following categories of research:

- A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- Research on conditions particularly affecting prisoners as a class (i.e. vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject;

b) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the
prison, are not of such a magnitude that his or her ability to weigh the risks of
the research against the value of such advantages in the limited choice
environment of the prison is impaired;

  c) The risks involved in the research are commensurate with risks that would be
     accepted by nonprisoner volunteers;

  d) Procedures for the selection of subjects within the prison are fair to all
     prisoners and immune from arbitrary intervention by prison authorities or
     prisoners. Unless the Investigator provides to the Board justification in writing
     for following some other procedures, control subjects must be selected
     randomly from the group of available prisoners who meet the characteristics
     needed for that particular research project;

  e) The information is presented in language which is understandable to the
     subject population;

  f) Adequate assurance exists that parole boards will not take into account a
     prisoner’s participation in the research in making decisions regarding parole,
     and each prisoner is clearly informed in advance that participation in the
     research will have no effect on his or her parole; and

  g) Where the IRB finds there may be a need for follow-up examination or care of
     participants after the end of their participation, adequate provision has been
     made for such examination or care, taking into account the varying lengths of
     individual prisoners’ sentences, and for informing participants of this fact.

8. Permitted Research Involving Prisoners. For research conducted or supported by HHS to
involve prisoners, two actions must occur. First, the IRB must certify to OHRP that it has
reviewed and approved the research under the federal regulations and second, that OHRP
must determine that the proposed research falls within one of the categories of permissible
research as described in Paragraph 7(a) above.

  a) If an Investigator wishes to engage in non-HHS supported research,
     certification is not required. However, the IRB should apply the standards of
     this policy and the federal regulations in reviewing the research.

  b) Should the research involve conditions particularly affecting prisoners as a
     class, or not satisfy the stipulations at Paragraph 7(a) above, the research should
     proceed only after the IRB has consulted with appropriate experts, as
     determined by the IRB.

  c) The IRB certification to OHRP should consist of a certification letter stating
     that the IRB has been constituted properly according to federal regulation, that
     the IRB considered and made the required seven (7) findings set forth in 45
     CFR 46.305, and that the IRB “finds that category (insert which category
     applies) of 45 CFR 46.306 permits this research to go forward with prisoners
     as human subjects.” The certification letter should also provide a brief
     description of this research sufficient to allow OHRP to determine whether or
     not to concur with the IRB, and whether OHRP needs to consult with
     appropriate experts and publish a Federal Register Notice. The IRB Office
     should retain a copy of this letter.
9. **Prisoners Who Are Minors.** When a prisoner is also a minor (i.e. an adolescent detained in a juvenile detention facility is a prisoner), then the Policy regarding Children in Research will also apply.

10. ** Expedited Review of Research Involving Prisoners Not Allowed.** The full committee must review research involving prisoners as human subjects.

11. **Exemption from Review of Research Involving Prisoners Not Allowed.** Research that would otherwise be exempt from the requirement that it receive IRB approval is not exempt when the research involves prisoners.

12. **Documentation.** When approving a protocol involving prisoners, the minutes must document that the Committee made the findings required above. The IRB must classify research involving prisoners into one of the seven categories described within Paragraph (7) above and document their discussions of the risks and benefits of the research study.

13. **Federal Bureau of Prisons.** The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau. The IRB should review the regulations at 28 CFR Part 512 when considering such research.

**III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY**

BOG 1.001(3)(m), 45 CFR 46.301-306, Subpart C
Florida State University Policy 7-IRB-27

Title of Policy: HIV Testing

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

Revised

I. INTRODUCTION

This policy states that investigators must comply with applicable federal and state laws and local policies concerning the study of the human immunodeficiency virus (HIV). The policy also outlines the responsibility of the IRB during the review of HIV-related research protocols.

II. POLICY

1. Investigators at Florida State University must comply fully with all applicable federal and state laws, and local policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality and privacy where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

2. During its review of an application, the IRB should consider and the Investigator’s protocol must address issues of obtaining informed consent, confidentiality, the notification process, the timeliness of informing individuals, and counseling of the individuals and others designated by the individual (i.e. sexual partners).

3. General Policy: Where HIV testing is conducted or supported by the Public Health Service, including both research and health services activities, domestic and foreign, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling unless the situation calls for an exception.

4. Exceptions to General Policy:

   a) Pertaining to an individual. Where there are compelling and immediate reasons that justify not informing a particular individual that he or she is seropositive (i.e.
indication that an individual might attempt suicide), the particular individual need not be informed of HIV test results. When this exception is utilized, the details of the exception must be documented by the Investigator or another responsible person at the testing facility. The principal investigator must promptly report the exception to the IRB Office without identifying the individual. It will be presented to the next scheduled IRB Committee meeting for review and approval of the exception.

b) Pertaining to Protocol Design. Because circumstances may exist in which extremely valuable knowledge might be gained from research involving subjects who would be expected to refuse to learn their HIV antibody results, an exception included in the protocol design may be proposed to the IRB reviewing the research protocol. The IRB shall consider the particular circumstances of the research study, the characteristics of the target research subjects, and other factors, and may approve a testing procedure that would allow research subjects to participate without being informed of their individual results. In proposing such an exception, the investigator must demonstrate to the satisfaction of the IRB that:

- research subjects will be informed of their risk of infection;
- research subjects will receive risk reduction counseling whether they receive test results;
- there is sound reason to believe that a requirement for test notification counseling whether or not they receive their test results;
- there is sound reason to believe that a requirement for test result notification would significantly impair collection of study information that could not be obtained by other means;
- the risk/benefit ratio to individuals, their partners, and society will be periodically reevaluated by the IRB so that the study might be revised or terminated if it is determined that it is no longer justifiable to allow subjects to continue to participate without receiving their HIV test results.

c) Foreign Sites. Activities conducted at foreign sites should be carefully evaluated for account for cultural norms, the health resource capabilities and official health policies of the host country. The IRB Committee must consider if any modification to the policy is justified by the risk/benefit evaluation of the research.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116
I. INTRODUCTION
This policy explains that under federal law, researchers performing data collection about sensitive issues can obtain a Certificate of Confidentiality that will provide protection against compulsory disclosure. The policy explains all the protections granted by the Certificate of Confidentiality.

II. POLICY

1. When an Investigator will be performing data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences), such a study requires the protection of confidentiality beyond preventing accidental disclosures. Under federal law, researchers can obtain an advance grant of confidentiality, known as a Certificate of Confidentiality, that will provide protection against compulsory disclosure, such as a subpoena, for research data. The Investigator should describe in the IRB application any conditions under which confidential information might be disclosed and create an informed consent document that accurately reflects those conditions, including any voluntary disclosure by the researcher. The IRB is required to determine whether the risks to subjects are minimized, informed consent is appropriate, and privacy and confidentiality protections are adequate.

2. A Certificate of Confidentiality provides protection for the researcher and the subjects against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research. See Public Health Service Act 301(d), 42 U.S.C. 241 (d). Under this Act, the Secretary of HHS may authorize persons engaged in research to protect the privacy of subjects by withholding from all persons not connected with the conduct of the research, the names or other identifying characteristics of the
subjects. This means that researchers may not be compelled in any federal, state or local civil, criminal, administrative, legislative, or other proceedings to identify their subjects.

3. The protection is available only when the research is of a sensitive nature where protection is judged necessary to achieve the research objectives.

4. Research can be considered sensitive if it involves the collection of information in the following categories:

   a) Information relating to sexual attitudes, preferences, or practices;
   b) Information relating to the use of alcohol, drugs or other addictive products;
   c) Information pertaining to illegal conduct;
   d) Information that if released could reasonably be damaging to an individual’s financial standing, employability, or reputation within the community;
   e) Information that would normally be recorded in a patient’s medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
   f) Information pertaining to an individual’s psychological well-being or mental health;
   g) Genetic information.

5. Note that the Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects from compelled disclosure of identifying characteristics by the researcher. Researchers, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject’s threatening violence to self or others. However, if a researcher intends to make such voluntary disclosures, the consent form should clearly indicate this.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.111
Florida State University Policy 7-IRB-29

Title of Policy: Recruitment of Subjects

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

Revised ____________

I. INTRODUCTION

This policy explains that the IRB must review the methods and materials used to recruit subjects to protect the rights and welfare of research subjects.

II. POLICY

1. The IRB must ensure that appropriate safeguards exist to protect the rights and welfare of research subjects. In fulfilling these responsibilities, the IRB must review the methods and materials that investigators propose to use to recruit subjects. For example, the Investigator must obtain IRB approval for all television, radio, videotape, or print advertisements, email solicitations, Internet websites, and other recruitment methods and materials.

2. Advertising or soliciting for study subjects is part of the informed consent and subject selection process. Thus, advertisements must be reviewed and approved by the IRB as part of the package for initial review. When the Investigator decides after the initial approval to advertise for subjects or to change the advertisement, the advertising is considered an amendment to the ongoing study. The IRB will review the advertisement to assure that it is not unduly coercive and does not promise a certainty of cure or other benefits beyond what is outlined in the consent and the protocol. This is especially critical when a study may involve subjects who are likely to be vulnerable to undue influence.

3. The IRB must review the information contained in an advertisement and the mode of communication. The IRB must review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the IRB must review the final audio/video tape.
4. Any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. Advertising materials should not include the following:

   a) claims, either explicitly or implicitly that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
   b) claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention.
   c) terms such as “new treatment”, “new medication” or “new drug” without explaining that the test article is investigational;
   d) promises of “free medical treatment”, when the intent is only to say that subjects will not be charged for taking part in the investigation.

5. Receptionist Scripts. The first contact prospective study subjects make is often with a receptionist who follows a script to determine basic eligibility for the specific study. The IRB must review the script and procedures to ensure protection of rights and welfare of prospective subjects, and that any information collected about prospective subjects will be appropriately handled.

6. Student Subjects. The IRB has oversight of the use of students as subjects in research. The IRB must ensure that the consent for participation is sought only under circumstances which minimize the possibility of coercion or undue influence, and that genuinely equivalent alternatives to participation are available (i.e. term papers).

7. Inclusion of Women, Children, and Minorities. The inclusion of both women and men and of minorities in research is important, both to ensure that they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. Moreover, for purposes of generalizing research results, investigators must include the widest possible range of population groups.

8. NIH supported investigators must provide to the IRB details of the proposed involvement of humans in their research protocols, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any subpopulation. If ethnic, racial, and gender estimates and continuing review numbers are not included in the background data for a protocol, the investigators must provide a clear rationale for exclusion of this information.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.103
I. INTRODUCTION

This policy states that it is the responsibility of the IRB to review the timing of payments, the amount of payments and alternative payments given to research subjects. The policy also explains that payment is not considered a benefit, but rather compensation for time and inconvenience or a recruitment incentive. This policy also includes the requirements for reporting payments to the IRS.

II. POLICY

1. The IRB must determine that the risks to subjects are reasonable in relation to anticipated benefits and that the consent document contains an adequate description of the study procedures as well as the risks and benefits. Payment to research subjects for participation in studies is not considered a benefit. Rather, it should be considered compensation for time and inconvenience or a recruitment incentive. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence.

a) **Timing of Payments.** Credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. The subject should be paid in proportion to their time and inconvenience as a result of participation in the research study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be paid at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.

b) **Completion Bonus.** While the entire payment should not be contingent upon
completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable, provided that such incentive is not coercive. The amount paid as a bonus for completion should be reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.

c) Disclosure of Payments. All information concerning payment should be set forth in the informed consent document.

d) Advertisement of Payments. Advertisements may state that subjects will be paid or compensated, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type.

2. Alterations in Payments. Any alterations in human subjects research payment or payment schedule must be reported to the IRB prior to the implementation as an amendment to the protocol.

3. Reporting Payments to the IRS. The Internal Revenue Service requires that FSU (or whomever is paying the subjects for their participation) report payments in excess of $600 per calendar year on Form 1099 Misc. The filing of these forms necessitate that the name and social security number of the subject be collected on a Form 1099 and released to the Office of Research and FSU Comptroller’s Office to process the Form 1099-Misc. The collection and release of this information must be addressed thoroughly in the informed consent document so that it is clear to the subject that his or her identity will be released for the purpose of payment and reporting.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116
Florida State University Policy 7-IRB-31

Title of Policy: Compensation or Medical Treatment If Injury Occurs

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy explains that all subjects must be provided explanation as to whether any compensation or any medical treatments are available if injury occurs.

II. POLICY

1. If applicable, all subjects must be provided an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

2. For commercially sponsored studies, the Informed Consent document must contain one of the following three choices and the following paragraph (given the provisions of the agreement with the sponsor), unless specifically waived by the IRB:

   a) Any costs for the treatment of research related adverse events will be paid for or reimbursed by the sponsor (Note: This is the preferred language).
   b) Any costs for the treatment of research related adverse events will be charged to you or your insurance carrier. However, if for any reason these costs are not covered by insurance, they will be paid for or reimbursed by the sponsor. (Note: Use of this option requires that it matches the agreement to be approved by the Office of Research).
   c) Any costs for the treatment of research related adverse events will be charged to you or your insurance carrier. However, if for any reason these costs are not covered by insurance, they will be your responsibility. (Note: Use of this option requires that it matches agreement to be approved by the Office of Research).

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116
Florida State University Policy 7-IRB-32

Title of Policy: IRB Office Educational Activities – Investigator Training

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New

Revised

I. INTRODUCTION

This policy describes the responsibility of the IRB to provide information and training materials to each individual who conducts or reviews human subjects research.

II. POLICY

1. The IRB office will provide information to each individual who conducts or review human subjects research where he/she may review or obtain a copy of the FSU Federalwide Assurance, the Belmont Report, 45 CFR Part 46, guidelines/policies of federal regulations or agencies related to human subject research, and user-friendly forms for providing information to the IRB. The IRB (Human Subjects Committee) website will contain these documents in downloadable formats, and will also provide links to various agencies and resources for easy access to information (such as National Institute of Health, Food and Drug Administration, Office for Human Research Protections, National Bioethics Committee, etc.).

2. Principal Investigators and key personnel are encouraged to participate in training to ensure the protection and rights of human subjects. The IRB will provide investigator training by two methods for the convenience of the Investigator: 1) an on-line tutorial and NIH certification and 2) participation in an FSU training seminar. Investigators are responsible for ensuring that appropriate support staff associated with human subjects are adequately trained on the protection of human subjects.

3. Periodic training seminars will be provided on specific topics relating to the IRB process and federal guidelines.
4. The IRB Reference Library contains information on assorted topics related to issues and regulations on human subject research. These tools may be checked out upon request.

The IRB website will provide a “Frequently Asked Questions” section to aid in educating Investigators in an informal manner.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m)
Florida State University Policy 7-IRB-33

Title of Policy: General Requirements for Informed Consent

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy describes the requirements for informed consent. The policy also explains the responsibility of the IRB and the investigator to obtain legally effective informed consent from each subject or the subject’s legally authorized representative.

II. POLICY

1. Except as provided elsewhere in 45 CFR 46.116, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. Informed consent is a process that takes place between the Investigator and the prospective subject.

2. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

3. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, in the institution or its agents from liability for negligence.

4. The IRB must ensure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject’s legally authorized
representative. There are limited circumstances under which the regulations give the IRB authority to waive the required informed consent. Documentation of informed consent must be obtained unless alternate procedures are approved by the IRB. The IRB must review all informed consent documents and assure the adequacy of the information contained in the consent document.

5. Each subject or his/her authorized representative must sign, date, and receive a copy of the current IRB approved consent form prior to enrollment or any participation in any phase of the study, unless the requirement is waived by the IRB.

6. A “legally authorized representative” means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure involved in the research. Example: A parent or a minor child or a legal guardian may be a legally authorized representative.

7. The IRB may approve a consent procedure in which a surrogate consents on behalf of a subject who is unable to give informed consent and for whom the proposed intervention reasonably appears to offer a therapeutic gain. The surrogate is deemed to be a legally authorized representative. A surrogate consent can only be used when the subject faces a high likelihood of death or serious bodily injury from standard of care alone and the window or opportunity for employing the investigational agent would be too brief to allow obtaining consent by an alternative legal representative. In such circumstances, if the IRB otherwise approves the protocol and a surrogate consent document, the approval recommendation will be forwarded after committee review and before final approval to the Associate Vice President for Research or IRB Chair for administrative approval of the use of surrogate consent. The person acting as a surrogate must execute the document in the presence of a witness who should also execute the consent document.

8. Studies involving subjects who are decisionally impaired may take place over an extended period. Therefore, the IRB shall consider whether periodic reconsenting of individuals should be required to ensure that a subject’s continued involvement is voluntary. The IRB may require that investigators reconsent subjects after taking into account the study’s anticipated length and the condition of the individuals to be included (such as subjects with progressive neurological disorders), and whether or when to require a reassessment of decisionmaking capacity.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116
I. INTRODUCTION

This policy states that according to 45 CFR 46.116, specific elements must be included in all informed consent documents unless waived by the IRB.

II. POLICY

1. 45 CFR 46.116 requires that specific elements be contained in all informed consent documents unless waived by the IRB. Required elements of informed consent may not be omitted and there shall be no inconsistencies between the IRB application and the informed consent document regarding the purpose, risks, and benefits of the research.

2. In seeking consent, the following information shall be provided to each subject and are the fundamental basic elements of consent:

   a) a clear statement that the study involves “research”;
   b) an explanation of the purposes of the research;
   c) the expected duration of the subject’s participation;
   d) a complete description of the procedures to be followed;
   e) an identification of any procedures which are experimental;
   f) a description of any reasonably foreseeable risks or discomforts to the subject;
   g) a description of any benefits to the subject or to others which may reasonably be expected from the research;
   h) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
   i) a statement describing the extent, if any, to which confidentiality of
records identifying the subject will be maintained;

j) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

k) an explanation of whom to contact for answers to pertinent questions about the research and the research subjects’ rights (such as the IRB office); and

l) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

a) a statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

b) anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

c) any additional costs to the subject that may result from participation in the research;

d) the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e) a statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and

f) the approximate number of subjects involved in the study.

4. The informed consent document should not contain any unproven claims of effectiveness or certainty of benefit, either express or implied.

5. The informed consent document must be communicated in a language that is understandable to the subject, and should not be complex, so that it can be comprehended by all subjects. Technical and scientific terms should be adequately explained using common or lay terminology.

6. The informed consent document shall not contain any exculpatory language through which the subject is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence.
7. If research involves test articles regulated by the US Food and Drug Administration (FDA), the informed consent document must include a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116
Florida State University Policy 7-IRB-35

Title of Policy: Documentation of Informed Consent

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003
Revised __________

I. INTRODUCTION

This policy outlines the procedure in obtaining informed consent from each research subject. The policy explains that the IRB has the authority to waive the documentation of informed consent in certain circumstances.

II. POLICY

1. Except as provided in paragraph (3) of this policy, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy of the consent form shall be given to the person signing the form. Consent form pages shall be consecutively numbered inclusively.

2. Except as provided in paragraph (3) of this policy, the consent form may be either of the following:

   a) A written consent document that embodies the elements of informed consent required by IRB Policy. This form may be read to the subject or the subject’s legally authorized representative, but in any event the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed, and the form should utilize language understandable to the subject; or

   b) A short form written consent document stating that the elements of informed consent required by IRB Policy have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. The person obtaining consent may not be the witness to the consent. Also, the IRB shall approve a written summary (script) of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. Where informed consent is documented using the short form for
non-English speaking subjects, the oral presentation and the short form consent form must be in a language understandable to the subject, and the witness shall be fluent in both English and the language of the subject.

c) The IRB committee must receive all foreign (non-English) language versions of the written consent form or short form documents as a condition of approval.

3. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

   a) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

   b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Note: “Minimal Risk” is defined to mean that the probability and the magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

   c) In cases in which the consent documentation requirement has been waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

4. The IRB may approve that the written informed consent document be delivered to the potential subject or legally authorized representative by mail or by facsimile, and to conduct the consent interview by telephone provided the potential subject or the legally authorized representative can read the consent document as it is discussed. Note: All other applicable requirements for documentation of informed consent must be met when using this delivery procedure.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.117
Florida State University Policy 7-IRB-36

Title of Policy: Waiver of Informed Consent

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy explains the authority of the IRB under certain circumstances to waive or allow modification of some elements of informed consent.

II. POLICY

1. The IRB must ensure that provisions are made to obtain legally effective informed consent prospectively from each research subject or the subject’s legally authorized representative. However, the regulations do permit an IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent entirely provided the IRB finds and documents that:

   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; and
   d) whenever appropriate, the subjects be provided with additional pertinent information after participation.

2. Additionally, as documentation of informed consent, an IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all subjects if it finds either:

   a) that the only record linking the subject and the research would be the consent
document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject shall be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

b) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Note that “minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3. When the IRB approves a procedure which alters or waives the requirement for informed consent, the minutes of the IRB meeting shall document that the Committee made the required findings as set out above, and should document discussion of the risks and benefits of the research as required by regulation.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116, 117
Florida State University Policy 7-IRB-37

Title of Policy: Approval and expiration dates informed consent document and stamping

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy states the responsibilities and procedure the IRB follows for approving and dating informed consent documents.

II. POLICY

1. The IRB Office shall affix the approval and expiration dates to all IRB approved informed consent documents. Copies of the current, dated documents are the ONLY versions that shall be used by investigators in obtaining consent. This procedure helps to ensure that only the current, approved informed consent documents are presented to subjects and also functions as a reminder to the investigators of the need for continuing review.

2. For projects approved by expedited review, the approval date for the informed consent document shall be the same as the date of the initial notice letter approving the protocol. The expiration date shall be one year (365 days) from the date of approval minus one day. Thus, as an example, if the initial approval notice letter is dated as approved on June 1, 2003, then the expiration date shall be May 31, 2004. No research may continue unless the appropriate request for renewal has been timely received and the project has received continuing review and approval. Any changes to the consent form during the course of the initial 365 day term shall still set to expire on the same date as the original expiration date. Upon renewal and approval, the current consent form shall be extended for another year term.

3. For projects approved by full committee review, the approval date for the informed consent document shall be the same as the date of the monthly full committee meeting at
which the protocol was reviewed and approved. The date of approval of the protocol should match the date of approval of the informed consent document. The expiration date shall be one year (365) days minus one day. As an example: A protocol is reviewed at full committee and approved at the June 1, 2003 meeting. The approval date for the project shall be June 1, 2003, and the expiration date for the consent document shall be May 31, 2004. Any change to the consent form during the course of the initial term shall not modify the existing expiration date.

Once an approval is granted, the Program Coordinator assigned to full committee projects or the Program Associate assigned to expedited/exempt review projects, shall add a footer or stamp the lower right corner of the informed consent document. The footer or stamp shall reflect the approval date, the Human Subjects internal number, (example if 2003, then project would be number 03.001 consecutively, and if the project is a renewed project that received continuing review and approval, the number shall be followed by an “R”), and the expiration date, noted as “Void After”.

4. The student assistant shall copy the date stamped informed consent document and the final approval letter for the file, and transmit the documents to the Investigator. A copy of both should be retained in the IRB files. The investigator is notified in the final approval letter that only current informed consent documents with the date of the IRB approval and expiration are to be copied and used for obtaining informed consent from subjects.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116, 46.117
Florida State University Policy 7-IRB-38

Title of Policy: Assent of Subjects

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy summarizes the responsibility of the IRB to review whether assent is required, if adequate provisions are made for soliciting the assent of the subject, and if the subject is capable of providing assent.

II. POLICY

1. Whenever a subject is not legally capable of giving informed consent (such as a minor child) or where the subject is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the subject when in the judgment of the IRB, the subject is capable of providing assent.

2. “Assent” means a subject’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as an assent.

3. In determining whether subjects are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the subjects is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well being of the subject and is available only in the context of the research, the assent of the subject is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable
of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116.

4. If the IRB determines that assent is required, it shall also make a determination as to whether and how the assent must be documented.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116, 46.117, and 46.402
Florida State University Policy 7-IRB-39

Title of Policy: Membership of IRB Committee

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New June 1, 2006

I. INTRODUCTION

This policy explains the requirements needed for staffing the IRB Committee and the appointment length and responsibilities of Committee members.

II. POLICY

1. Each IRB Committee shall include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area, and one member who is not affiliated with Florida State University (i.e. not a family member or spouse or an employee, not an alumnus).

2. Each IRB Committee is required to have a minimum of five members each, with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the Institution (Florida State University).

3. Formally appointed alternates may vote in place of a missing regularly appointed member. Each alternate member must have qualifications similar to the member he/she replaces. The Vice President for Research formally appoints alternates for two year renewable terms. Alternate members will be notified and provided with all materials in advance of a meeting they will attend in place of the regular member, and will have full voting status at the time of the meeting. The minutes must document when an alternate member replaces the appointed member.
4. The IRB Committee membership must be sufficiently qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel, and able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The composition of membership must be adequate in light of the anticipated scope of FSU’s research activities, the types of subject populations likely to be involved, and the size and complexity of FSU.

5. IRB members are formally appointed to a two year renewable term by the Vice President for Research at Florida State University. When the IRB and/or the Vice President for Research determine that a new member is necessary for the functioning of the IRB, the current membership shall suggest possible candidates for consideration by the Vice President for Research. The IRB Chair and the Associate Vice President for Research shall review the qualifications of the candidate and make a recommendation for appointment to the Vice President for Research.

6. FSU must assure that the IRB is able to function in an independent and credible manner. Only tenured faculty may be appointed to serve as faculty IRB members, unless specifically authorized by the Vice President of Research.

7. IRB Chair is appointed to an open ended term by the Vice President for Research, votes as an active member of the Board, and should possess the following qualifications:

   a) The individual should have experience on the IRB and be a member in good standing.
   b) The individual should have a good understanding of the Code of Federal Regulations as they apply to the protection of human subjects in research and the policies and procedures of the IRB.
   c) The individual should have enough time at his/her disposal to perform the duties and responsibilities of the Chair.

8. IRB members are expected to attend the majority of meetings and notify the IRB Office or Chair of any absence. If an IRB member fails to attend a minimum of 50% of the IRB meetings, that member can be removed from active membership. No voting by proxy is permitted.

9. IRB members may be monetarily compensated by FSU for their time and efforts, as determined by the Office of Research.
10. The IRB shall not have a member participating in initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

11. To remove a member from the IRB, there must be just cause shown of that member’s inability or unfitness to serve on the Board. Just cause for removal may be lack of minimum attendance, lack of participation at meeting as judged by the IRB Chair, misconduct, or unresolved conflict of interest.

12. The Vice President for Research is authorized to remove an IRB Chair for cause only.

13. An IRB Committee considering a protocol involving children as subjects should assess its needs for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities and consider inclusion of one or more individuals who are knowledgeable and experienced in working with children. To fulfill this requirement, the IRB may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members.

14. The IRB membership is required to be modified if it is to review research involving prisoners. Therefore, if there will be a review of research involving prisoners, at least one member of the IRB Committee shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

15. On a case by case basis, the IRB may request review by an individual (consultant) with competence in an area not represented by the IRB membership.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.107
Florida State University Policy 7-IRB-40

Title of Policy: Compensation of the IRB Members

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New June 1, 2006

Revised July 17, 2007, June 19, 2014

I. INTRODUCTION

This policy details the compensation of the IRB Committee Members for service. The policy also explains stipulations associated with the Committee member compensation.

II. POLICY

1. FSU has committed by an assurance to provide adequate resources and support for the Institutional Review Board in the discharge of its responsibilities for protecting the rights and welfare of human subjects. In furtherance therefore, the Office of Research shall compensate IRB Committee members for their service on the IRB as described in the following described manner:

2. For each FSU faculty member appointed to serve on the IRB, the Office of Research shall provide a $1,000 Research & Creative Activity grant. These grants will be awarded at the beginning of the fiscal year for continuing IRB members or at the time of appointment of new members. New members appointed prior to January 1 of each year shall receive the full $1,000 grant amount; and those members appointed after January 1 of each year shall receive a reduced percentage of the $1,000 grant as determined by the Office of the Vice President of Research. The grant will be administered through the Office of the Vice President for Research, and procedures for access and use of these funds will be disseminated to Committee members. The funds for this grant will be derived from SRAD revenues and are intended to support scholarly activity, broadly defined as follows:

   a) Expenses tied to specific research and creative activities which include items such as supplies, travel to meetings or research venues, professional society memberships, books, journals, items of equipment supporting scholarly activity and student stipends; or

   b) If the IRB member has sufficient funds available from this award, he/she may, with the approval of his/her Supervisor (Dean, Chair or Director), have his/her department identify an adjunct or graduate student to teach one (1) of his/her courses during the regular academic year. If approved, the department will make the
appointment and the OVPR will transfer available funds not to exceed $1,000 from the member’s account to the department for the cost of the appointment. Note that this does not constitute a course “buy-out” in the traditional sense.

3. It will not be necessary for Committee members to make a decision as to how to use the funds at the beginning of the fiscal year. Unexpended funds will carry over from fiscal year to fiscal year.

4. The Chair and Vice Chair of the IRB will receive compensation as negotiated on a case by case basis.

5. In the event that the faculty member serving on the IRB shall no longer be able to serve, for whatever reason, the Department Chair shall promptly recommend another qualified faculty member for consideration to the IRB Chair for service on the IRB.

6. Community or other consulting members appointed to the IRB are volunteers as described by Section 110.501-05 and 768.28, Florida Statutes and University policy. Monetary compensation for volunteer service shall be provided in the following manner:

   a) The Office of Research shall pay to the community or consulting members a nominal fee in the amount of $1000 per year, as well as reimbursement for meals, lodging or transportation, at University rates.

   b) The payments to the appointed community or consulting members of the IRB shall be made annually by the Office of Research.

   c) In the event that the community or consulting member serving on the IRB shall no longer be able to serve, for whatever reason, a prorated payment amount for service shall be paid, as determined by the Office of Research.

   d) Each community or consulting member serving on the IRB shall sign a Record of Volunteer Service and a Memorandum which will reflect this policy, and the payment provisions described herein.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.107
Title of Policy: Local Research Context

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003
          Revised ____________

I. INTRODUCTION

This policy describes the local context requirements and implements the IRB authority to rely on other IRBs to avoid duplication of efforts.

II. POLICY

1. The IRB must fulfill its responsibilities under its Assurance with the federal government regardless of the IRB’s geographic location relative to the Institution and the research. This is particularly important when the research involves greater than minimal risk to subjects or vulnerable categories of subjects.

2. When the IRB is geographically removed from the local research context, the IRB must demonstrate that it has obtained necessary information about the local research context through compliance with one of the following standards. These standards reflect minimum levels of adequacy. More stringent standards may be required depending upon the nature of the proposed research or the relevant research context.

   a) **Minimal Risk.** Where the research involves minimal risk to subjects, the IRB should demonstrate that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants.

   b) **Greater than Minimal Risk.** Where the research involves greater than minimal risk to subjects but the local research context involves no intervention or interaction with subjects and the principal risk associated with the local research context is limited to the potential harm resulting from a breach of confidentiality, the IRB should demonstrate that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants. Examples of information may include anticipated scope of research activities, types of subject populations involved, institutional commitments and regulations, standards of professional conduct, equitable selection of subjects, protection of confidentiality and privacy of subjects,
language understood by prospective subjects, and other safeguards to protect the rights and welfare of vulnerable subjects.

c) **Greater than Minimal Risk.** Where the research involves greater than minimal risk to subjects and paragraph (b) does not apply, the IRB should demonstrate that it has obtained necessary information about the local research context through one or more of the following mechanisms, or through other mechanisms deemed appropriate by OHRP or the proposed research and the local research context.

- Personal knowledge of the local research context on the part of one or more IRB members, such knowledge having been obtained through extended direct experience with the research institution.
- Participation by one or more appropriate consultants in convened meetings of the IRB. Such consultant(s) should have personal knowledge of the local research context, such knowledge having been obtained through extended, direct experience with the research institution.
- Prior written review of the proposed research by one or more appropriate consultants in conjunction with participation by the consultant(s) in convened meetings of the IRB, when such participation is required by the consultant(s) or the IRB.
- Systematic, reciprocal, and documented interchange between the IRB and elements of the local research context. Such interchange should include periodic visits to the research site by one or more of the IRB members in order to maintain knowledge of local research context, periodic discussion with appropriate consultant(s) about local research context, regular interaction with one or more designated institutional liaisons, and review of relevant written materials.

3. When the IRB desires to avoid duplication of effort, the IRB may rely on the review of another OHRP Assurance holding institution. The review arrangement must be approved in writing by OHRP and by appropriate officials of the institutions involved. When relying on another IRB’s review, the FSU IRB must ensure that the particular characteristics of the local research context are considered, either through knowledge of the local research context by the reviewing IRB (see paragraph 2 above), or through subsequent review by appropriate designated institutional officials.

**III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY**

BOG 1.001(3)(m), 45 CFR 46.103
Florida State University Policy 7-IRB-42

Title of Policy: IRB Office Records

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003
Revised ____________

I. INTRODUCTION

This policy states the requirements of how IRB Office records should be maintained and retained.

II. POLICY

1. The IRB Office files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports.

2. The IRB Office must retain all records regarding an application (including those which did not receive approval) for at least 3 years. For all applications that are approved and the research initiated, the IRB Office must retain all records regarding that research for at least three (3) years after completion of the research. Records may be archived as provided by State Law.

3. The IRB Office must make all records available for inspection and copying by authorized representatives of the sponsoring Department or Agency at reasonable times and in a reasonable manner.

4. The IRB Office must prepare and/or maintain the following documents:

   a) Applications - copies of all research applications reviewed, scientific evaluations, approved sample consent documents, data safety monitoring
board reports, progress reports submitted by investigators, and reports of injuries or adverse events to subjects.

b) Minutes - the complete minutes of all IRB Committee meetings.

c) Continuing Review - records of continuing review activities.

d) Correspondence with Investigators - copies of all correspondence between the IRB and the investigators.

e) Listing of IRB Committee Members - A list of the membership identified by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, sufficient to describe each member’s chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and FSU, such as full or part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Note that changes to IRB Committee membership need to be updated periodically with OHRP by the IRB Office.

f) Written policies and procedures which the IRB Office and the IRB Committee will follow for:

- conducting initial and continuing review of research and for reporting its finding and actions to the Investigator and the institution (FSU);
- determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review.
- ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;
- ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval.

g) Statements of any new significant findings developed during the course of the research which may relate to the subject’s willingness to continue participation provided to subjects.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.115
Florida State University Policy 7-IRB-43

Title of Policy: IRB Committee Meeting Agenda – Contents

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy summarizes what information should be included on each IRB Committee Meeting Agenda.

II. POLICY

1. New IRB proposals submitted for review. At convened meetings, the IRB shall review all newly proposed human subject research. This excludes those projects that either meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) or one or more of the expedited categories as authorized in 45 CFR 46.110.

2. Continuing review applications. At a convened meeting, the IRB shall review all continuing human subjects research at intervals appropriate to the degree of risk, but not less than once per year. This excludes those projects that either meet one or more of the exemption categories as provided by 45 CFR 46.101(b) or one or more of the expedited categories as authorized by 45 CFR 46.101(b)(8) or (9).

3. Expedited review determinations. When a determination regarding a review conducted utilizing expedited review procedures has been made, this must be documented in the agenda provided to the full Committee for the next possible convened meeting as authorized in 45 CFR 46.110. The documentation must include a citation to the specific permissible category justifying the expedited review, and must advise all committee members of research proposals that have been approved under the expedited review procedure.
4. **Major amendments.** At a convened meeting, the IRB shall review substantial, major proposed changes to approved human subjects research. This excludes those projects that either meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) or one or more of the expedited categories as provided in 45 CFR 46.110.

5. **Notification of approvals by Chair and Minutes.** The agenda will include a section on Notification of Approvals by the Chair such as expedited approvals, exempt approvals, and the previous month Committee minutes.

6. **Noncompliance.** The IRB Office shall report promptly to the IRB Committee members any serious or continuing noncompliance with the regulations or requirements of the IRB by including an item on the next official IRB Committee meeting agenda.

7. **Serious and unexpected adverse events.** The IRB shall review serious, unexpected adverse events. Factors that help determine the need for review at the convened meeting are the seriousness of the event, whether the event is described in the study protocol and informed consent document, whether the event occurred at a location for which the IRB is the IRB of records, and the Investigator’s recommendation as to whether the adverse event was a direct result of a subject’s participation in the research study.

8. **Audits and monitoring.** The results of any audit or monitoring by the IRB should be reported to the Committee on the agenda of the next regularly scheduled meeting. However, if information gathered during the audit or monitoring process indicates that a subject of a research project is or has been exposed to unexpected serious harm, the IRB may suspend or terminate the research project prior to the next regularly scheduled meeting.

9. **Monthly education for IRB members.** At each convened meeting, a member of the IRB or the IRB Office shall educate and update the IRB members in regard to current federal regulations, local polices and procedures, changes to federal regulations, human subject research news or topics, or any other relevant items as requested by the IRB.

**III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY**

BOG 1.001(3)(m), 45 CFR 46.115
Florida State University Policy 7-IRB-44

Title of Policy: Documentation of IRB Committee Meeting Minutes

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted – January 1, 2015

Revision History: New August 13, 2003

I. INTRODUCTION

This policy describes the IRB minutes format and inclusion requirements.

II. POLICY

1. The minutes of all IRB Committee meetings must be in sufficient detail to show:

   a) Attendance at the meetings, including whether an alternate is voting, when a member leaves the room, when a member absents themselves during the vote due to a conflicting interest, and the initial and continued presence of a majority of the members, including at least one nonscientist member.

   b) For each protocol discussed, the actions taken by the IRB Committee, the vote on these actions including the number of members voting for, against, and abstaining, in the following format: Total 14, Vote: for-13, Opposed- 0, Abstained-1 (Name). This method demonstrates the continued existence of a quorum at the meeting.

   c) When a protocol is approved, the minutes should reflect that the IRB Committee determined that the risks to subjects are minimized and reasonable in relation to the anticipated benefits, that the selection of subjects is reasonable in relation to anticipated benefits, that informed consent is appropriately documented, and that there are provisions for safety monitoring of the data, protections to ensure the privacy of subjects and confidentiality of data, and appropriate safeguards for vulnerable populations.

   d) When protocol revisions are requested or a proposal is disapproved, the basis for doing so should be recorded.

   e) A written summary of the discussion of controversial issues and their resolution.

   f) Expedited and exempt application review and approvals for the previous
2. The minutes of the IRB meetings should reflect the Committee’s determination regarding which protocols require continuing review more often than annually, as appropriate to the degree of risk, and the approval period if other than annually. Minutes for continuing review should reflect that the Committee determined that the risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits, that the selection of subjects continues to be reasonable in relation to anticipated benefits, and that informed consent continues to be appropriately documented. Also documented should be any provisions for the safety monitoring of data, protections for privacy of subjects and confidentiality of data, and that appropriate safeguards are in place for vulnerable populations.

3. When specific findings on the part of the IRB are required these finding should be fully documented in the minutes and should include protocol specific information justifying each IRB finding.

   a) When approving a procedure which alters or waives the requirements of informed consent, the minutes must document the findings as required.
   b) When approving a procedure which waives the requirement for obtaining a signed consent form, the minutes must document that the Committee made the findings as required.
   c) When approving research involving prisoners, the minutes must reflect that the Committee made the additional findings which authorizes the research required in the federal regulations. The recordkeeping must reference that either a majority of the IRB Committee has no association with the prison(s) involved, apart from their membership on the IRB, or at least one member of the IRB Committee is a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a research project is reviewed by more than one IRB, only one IRB need satisfy this requirement. Note: if a prisoner representative is selected to serve on the IRB Committee, the person must have a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals include present or former prisoners, prison chaplains, prison psychologists, prison social workers, or other prison service providers, persons who have conducted advocacy for the rights of prisoners, or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.
   d) When approving research involving children, the minutes must document that the Committee made the findings as required in the federal regulations. Note: When reviewing research involving children who are wards of the state or any other agency, institution, or entity, the IRB must find and document in the minutes that such research is related to their status as wards or conducted in schools, camps, hospitals, institutions, or similar settings in which the
majority of children involved as subjects are not wards.

4. Meeting minutes must document when an alternate Committee member replaces the appointed Committee member.

5. At a meeting in which Committee members participate by telephone, meeting minutes must document that each participating IRB Committee member has received all pertinent material prior to the meeting, and can actively and equally participate in the discussion of all protocols.

6. If reviewing protocols that anticipate an emergency situation, the IRB minutes must specifically record the licensed physician member’s affirmative vote.

7. Copies of the IRB Committee’s minutes should be distributed to the IRB Committee members, and the Associate Vice President of Research. The minutes shall be made available for review by the Vice President for Research.

**III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY**

BOG 1.001(3)(m), 45 CFR 46.115