

Florida State University

Institutional Review Board

Policies and Procedures

Table of Contents

IRB AUTHORITY AND COMMITMENT	4
001 Institutional Oversight of Ethical Principles Regarding Research Involving Humans as Subjects	4
002 Institutional Review Board Jurisdiction/Applicability	5
003 Policy and Procedures Development	10
IRB REVIEW PROCEDURES	
004 Exempt Research Activities	11
005 Expedited Review	14
006 Full Committee Review	18
007 Procedures for reviewing expedited, exempt, and full committee applications	20
008 Initial Application Materials to be Reviewed at Full Committee	22
009 IRB Quorum Requirement for Full Committee Review	25
010 Final Action by the IRB Committee	27
011 Amendments to Previously Approved Applications	29
012 Cooperative Project/Multi-site projects – IRB Review	30
013 IRB Continuing Review (Renewals)	31
014 IRB Audits and Monitoring	35
015 Reporting of Unanticipated Problems Involving Risk or Adverse Events	37
016 Suspension or Termination of IRB Approval for Cause	41
017 Use of Consultants by Institutional Review Board	42
018 Non-member Investigator and Other Non-member Attendance at IRB Meetings	43
019 Procedure for Human Subject Database Information	44
GENERAL IRB POLICIES	47
020 Prompt Reporting of Serious or Continuing Noncompliance	47
021 Investigator Qualifications	48
022 General Responsibilities of Investigator	49
023 Investigator Checklist	51
024 Research Involving Pregnant Women, Human Fetuses and Neonates	54
025 Special Categories of Research: Children in Research	58
026 Special Categories of Research: Prisoners as Research Subjects	63
027 HIV Testing	68
028 Certificate of Confidentiality	70
029 Recruitment of Subjects	72
030 Payment to Subjects	74
031 Compensation or Medical Treatment If Injury Occurs	76
032 IRB Office Educational Activities – Investigator Training	77

INFORMED CONSENT PROCESS	78
033 General Requirements for Informed Consent	80
034 Basic Elements of Consent	81
035 Documentation of Informed Consent	82
036 Waiver of Informed Consent	84
037 Approval and expiration dates informed consent document and stamping	85
038 Assent of Subjects	87
IRB MEMBERSHIP	88
039 Membership of IRB Committee	88
040 Compensation of the IRB Members	90
041 Local Research Context	92
RECORDS AND DOCUMENTATION	95
042 IRB Office Records	95
043 IRB Committee Meeting Agenda – Contents	97
044 Documentation of IRB Committee Meeting Minutes	99

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 001
SECTION: IRB AUTHORITY AND COMMITMENT
REVIEW RESPONSIBILITY:
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.101,103

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

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.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 002
SECTION: IRB AUTHORITY AND COMMITMENT
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.101,102,103

SUBJECT: Institutional Review Board Jurisdiction/Applicability

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.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 003
SECTION: IRB AUTHORITY AND COMMITMENT
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103

SUBJECT: Policy and Procedures Development

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.
4. 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.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 004
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.101

SUBJECT: Exempt Research Activities

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 two IRB members 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.

4. 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.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 005
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.110

SUBJECT: Expedited Review

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 two 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 paragraph numbered 4 below. The categories on the list apply regardless of the age of subjects, except as otherwise noted.
 - 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 on 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 reviewers 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 reviewers 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 reviewers 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.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 006
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IKMPLEMENTED: 45 CFR 46.103,108, 111

SUBJECT: Full Committee Review

1. The IRB has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction.
2. The decisions and requirements for modifications by the IRB shall be timely conveyed to investigators in writing by the IRB Office. If a protocol is disapproved by the IRB, the written notification from the IRB Office will be accompanied by the IRB Committee's reasons for the decision and an invitation for an opportunity for reply by the investigator, either in person or in writing.
3. 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.
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.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 007
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103

SUBJECT: Procedures for reviewing expedited, exempt, and full committee applications

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, and promptly stamped with a date stamp and provided to the Secretary of the IRB for facial compliance review and determination as to eligible categories of review (full, exempt, expedited). After review by the Secretary, the applications are provided to the student assistant for logging into the human subjects database and 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 Administrative Assistant (AA) serving the IRB, and who facilitates the review process. The AA promptly selects two

committee members based on background and experience and assigns a project for review and comment. The application proposal is sent to the reviewers and to the Chair of the Committee. The review notes, modification requests, or recommended approval from the reviewers are maintained in the project file. Upon receipt of such communication from the reviewers, the AA generates a form cover letter to the Chair, and copies of the other two reviewers notes or approvals are sent to the Chair for his/her review and approval.

- b) The Chair reviews the application, and any changes or modifications are communicated by the AA or Chair to the researcher. Once all modifications are made by the researcher, and the Chair determines the project is ready for approval, the Chair faxes or emails his/her approval and any comments back to the AA to generate an 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 mail or otherwise transmit 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 and stamped. The date of approval for the consent form is the same date as the approval letter, the application number is written on the approval stamp and the expiration (void) date 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.

8. The IRB office notifies, in writing, 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 subjects application number on the project file. Projects are reviewed for renewal in the same manner as their original review, i.e. exempt projects are reviewed by the Chair and two 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 written 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 provided to the Vice President for Research at FSU.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 008
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103,109, 115

SUBJECT: Initial Application Materials to be Reviewed at Full Committee

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.

