Florida A&M University
IRB & Investigator Manual

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PREFACE

The policies and procedures relating to human subjects research contained in this manual, comprise the basic minimum procedures that the Florida A&M University (FAMU) Institutional Review Board (IRB) uses in its review processes. These guidelines are written in accordance with the Department of Health and Human Services regulations governing research involving human subjects at 45 CFR 46, and are in compliance with the principles of the 1979 Belmont Report, which specifies the ethical principles for the protection of human subjects (See Appendix D for the Belmont Report and Appendix E for 45 CFR 46). Both the membership of the IRB and any prospective researchers who intend to use human subjects in their research projects are reminded that this document establishes the basic minimum of policies and procedures and does not include every possibility for the variation in research protocols involving human subjects.

The FAMU IRB will apply the policies and guidance in this guidebook for all research involving human subjects that is conducted at FAMU and that is sponsored by this institution, conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involves the use of this institution’s non-public information to identify or contact human research subjects or prospective subjects, regardless of sponsorship.

The purpose of this guidebook is twofold: to assist the IRB in reviewing research involving human subjects and to assist and provide guidance to researchers planning to conduct research involving human subjects.

The review of human subject’s research at the FAMU is a collaborative process intended to result in mutually acceptable research procedures that protect the rights and welfare of research participants while aiding investigators in accomplishing their scientific objectives. Every effort is made to adopt creative administrative and other means to reduce administrative burdens and maximize attention to the most important ethical issues. To this end, the IRB tries to be as flexible as possible and reviews each project as a separate case rather than simply imposing rigid requirements, and every attempt is made to take into account all factors in determining the outcome of the review. The IRB encourages consultation at all stages of the research process.
FREQUENTLY ASKED QUESTIONS

How do I know if I am conducting research with human subjects?

Federal regulations define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” The regulations further specify “activities which meet this definition constitute research … whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.” (45 CFR 46.102(d))

Human subjects are living individuals “about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” The following additional guidance is included in the regulations to aid in determining whether the research involves human subjects: Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.” (45 CFR 46.102(f))

Only projects meeting both definitions (research and human subjects) come under the purview of the IRB.

Why is my research subject to review?

The University has negotiated a Federal wide Assurance (FWA) with the Federal Office for Human Research Protections (OHRP). According to the terms of this assurance, it is the University’s responsibility to reasonably ensure that the rights and welfare of human subjects are adequately protected in research conducted under its auspices. In addition, federal laws require this protection. In order for the University to fulfill its responsibility, all human subjects research conducted under its auspices must receive appropriate review and approval.

Who will review my research?

The University has authorized the IRB to review and approve human subject’s research from the University. The IRB committee is comprised of faculty researchers, administrators and at least one non-institutional member and one member whose primary interests are non-scientific.
How do I submit my research for review by the IRB?

All applications now must be submitted online via email at irb@famu.edu. A hard copy with the original signature by the principal investigator, must also be submitted to the Office of Animal Care & Research Compliance, Room 130 Dyson Building, Tallahassee, FL 32307.

When do I submit my research for review by the IRB?

When submitting projects, sufficient time should be allowed for adequate review. A schedule of the IRB meetings and submission deadlines are posted on the Division of Research Office of Animal Care and Research Compliance website. The IRB meets at least once monthly during the academic year and as needed at other times. IRB proposals must be submitted two weeks prior to the scheduled meeting in order to be placed on the agenda of that meeting. Projects eligible for less intensive review procedures may be submitted at any time and will generally be reviewed within two weeks. Please contact the IRB office or consult the IRB website for additional information.

How will my research be reviewed?

The review of human subject’s research is confined solely to procedures affecting the ethical treatment of human subjects. The review focuses on such issues as minimizing risk to subjects, ensuring voluntary participation, and protecting privacy and confidentiality.

Where can I get assistance?

The FAMU IRB Staff acts as liaison between the University’s research community and the IRB. They are available to answer any questions concerning your application.

What happens if I do not comply with the University policy and Federal regulations regarding human subject’s research?

If non-compliance is alleged, the IRB Chair will initiate an investigation. The researcher will be informed of the allegations and given ample time to respond. The IRB Chair will then review the relevant information and make a Report to the Institutional Official, including recommendations. Non-compliance can have serious consequences for both the researcher and the University: approval for the project may be terminated and the University could be placed at risk of losing Federal or other funding related to research activities. The IRB Chair is required to report cases of non-compliance directly to the appropriate Dean, with a copy to the Institutional Official who has executive responsibility for enforcement the University’s FWA. If the Institutional Official determines the non-compliance to be either serious or continuing, it must be reported to OHRP and if sponsored, to the sponsoring agency.
PROCEDURES

Getting Started: Planning a Research Project and Applying for IRB Review

When an investigator plans to conduct research involving human subjects, s/he may want to consider contacting the FAMU IRB Staff as early in the process as possible.

To aid in determining whether a project is subject to IRB review (and federal regulations governing human subjects research more generally), the federal Office for Human Research Protections (OHRP) has produced a set of decision charts. These may be found at: http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm. These charts are guidance documents only. The FAMU IRB and the federal regulations themselves should be consulted in cases where the decision charts are unclear about the need for IRB review.

The following checklist may also prove helpful when planning a research project:

Declare your project considered to be “research” under the federal regulations?

*Research* is defined in the Federal regulations as “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46.102(d))

In general, research that involves data gathered solely for internal, on-going campus use (e.g., course evaluation or institutional research), or is part of a classroom project that will not be presented outside the classroom does not need to be reviewed by the IRB. If, however, the results of this research will be disseminated publicly in any way, then the research is subject to review by the IRB. If no dissemination is planned at the time the data is gathered, but the possibility of future dissemination exists, the researcher is advised to submit the project for IRB review and approval before initiating the research.

Does your project involve “human subjects”?

A *human subject* is defined in the Federal Regulations as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.” (45 CFR 46.102(f), emphasis added)

The initial determination as to whether a research project should be considered human subjects research should be made by the investigator based on the above referenced definition. If the researcher has any questions or is unsure about whether the research involves human subjects, s/he should consult the IRB Staff. Final authority for making this determination rests with the IRB.

If you are using existing/archival data, do you still need to obtain IRB approval?

Only if the study meets the definitions of both “human subjects” and “research” noted above. If no identifiers exist in the data set, then the research may be exempt from review by the IRB (See the exemption decision chart in Appendix G). Additionally, if identifiers exist but the investigator will not record them as part of the research, the research may be

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1 See the section below on Student Research & Class Projects for additional information.
 exempt from review by the IRB. If the data could be considered “educational records”, additional rules from the US Department of Education – The Family Educational Rights Privacy Act (FERPA) – may also be applicable (See Appendix O for FERPA information). The requirement for IRB review also applies to identifiable records a researcher may have access to in their daily duties either at work or school (i.e., a teacher has access to student grades but cannot use those records for research without IRB approval).

**Public Use Data Sets**

Although some research involving public use data sets or archives may be either outside the purview of the IRB (i.e., not involving human subjects) or exempt from the HHS regulations at 45 CFR 46, the IRB often requires submission of the research in order to make such a determination. In an effort to reduce the burden on investigators whose research relies solely on public use data, the IRB has determined that research involving the following public use data sets and archives meet the exemption requirements at 45 CFR 46.101(b)(4) (research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects) and so does not require review and approval by the IRB:

- Inter-University Consortium for Political and Social Research (ICPSR)
- U.S. Bureau of the Census
- National Center for Health Statistics
- National Center for Educational Statistics
- National Election Studies

Investigators whose research involves solely the use of one of these data sets/archives do not need to submit a formal proposal to the IRB, since the IRB has already determined that these data sets/archives meet the requirements for exemption at 45 CFR 46.101(b)(4).

However, researchers do need to register their research by submitting the following information to the IRB: (1) researcher’s name, title, and department; (2) title of the research study; and (3) name of data set/archive that will be used. This information should be sent to the IRB via email at IRB@famu.edu.

Note that additional data sets and archives may qualify for inclusion on this list. Researchers who wish to have a specific data set or data archive considered for inclusion on this list must submit the following information to the FAMU IRB:

The name of data set or data archive;
The URL for the data set/archive or other specific information on how to obtain the data set; and
An abstract that describes the content and potential uses of the data set/archive.

**Note:** Research projects that merge more than one data set/archive are not covered by this policy, and require review and approval by the FAMU IRB.
Review and Approval Process

How will your application be reviewed and how long will the process take?

There are three (3) levels of review for research involving human subjects: administrative, expedited and full board. Each of these is described below.

All submissions undergo administrative review by the IRB Staff. The IRB Staff can request additional information about the research and/or request modifications to the application form, protocol, and/or informed consent documents prior to review by a member of the IRB. The IRB Staff also makes recommendations to the Chair and IRB members about the level of review (expedited or full board) a given project should undergo.

Projects that meet exemption requirements undergo administrative review by the IRB Staff and review by the IRB Chair.

New and continuing projects may be eligible for expedited review if they both involve no more than minimal risk to subjects and meet one of nine specified categories. After a preliminary determination as to the appropriate level of review, the IRB Director, Associate Director, or IRB Chair will assign a designated expedited reviewer to review the submission and makes a final determination about the research.

Projects that involve more than minimal risk or do not fit into one or more of the categories for expedited review must be reviewed by the full board at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary interests are non-scientific. The IRB Director, Associate Director, or IRB Chair will assign a primary and a secondary reviewer for those projects scheduled for full board review. These members are responsible for presenting the research to the committee at the convened meeting. Although these primary and secondary reviewers are responsible for the presentation of the research at the meeting, all members receive a copy of the complete submission, including the application, protocol, informed consent documents, and instruments, and are expected to participate in the review and discussion of the research at the meeting. The IRB Chair may invite ad hoc reviewers to assist in the review of research where additional expertise may be necessary. In order for a given project to be approved, it must receive the approval of a majority of those members present at the meeting.

The following time estimates apply for submissions that are complete and for which no additional information or modifications are required:

Administrative Review  5-7 days
Expedited Review  10-14 days
Full Board Review  14 days – 28 days
You have determined that your project involves both “research” and “human subjects”. Now what?

Additional Materials
The following items, when applicable, must accompany your IRB application:
- A copy of any recruitment scripts or materials that will be used in the research;
- A copy of all informed consent scripts or documents that will be used in the research;
- A copy of all questionnaires, surveys, and/or interview questions or guides that will be used in the research;
- A description of the research methodology; and
- Letters of support or approval from performance sites (i.e., some research requires school district or organization permission) on appropriate letterhead

NOTE: Letters of support or approval can be submitted following IRB review, but final approval will be contingent on receipt of these materials.

Note that NIH-funded researchers must receive NIH human subjects’ research certification. NIH offers a computer-based training program at [http://ohsr.od.nih.gov/cbt/cbt.html](http://ohsr.od.nih.gov/cbt/cbt.html)

IRB Training is required for Principal Investigators and Co-Investigators on IRB projects. CITI Program’s online course in the Protection of Human Research Subjects [http://www.citiprogram.org](http://www.citiprogram.org) and register under FAMU.

Has the risk related to this project been clearly assessed and described in the application?

When answering questions about risk on the application, please consider the following types of risk or discomfort:

**Physical Risks:** These risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. These risks are not commonly encountered in social and behavioral science research.

**Psychological Risks:** Psychological risks may be experienced during participation in the research and/or afterwards as a result of participating in the research. These risks include anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, and/or altered behavior.

**Social/Economic Risks:** Economic risks include alterations in relationships with others that are to the disadvantage of the subject, and may involve embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject's opportunities and status in relation to others. These risks include payment by subjects for procedures, loss of wages or income, and/or damage to employability or insurability.

**Legal Risks:** Legal risks include risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally liable.

**Loss of Confidentiality:** Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks from breach of confidentiality include invasion of privacy, as well as the social, economic and
legal risks outlined above. Loss of confidentiality is the most common type of risk encountered in social and behavioral science research.

What does the IRB look for when deciding whether or not your project will be approved?

In order for the IRB to approve a given research project, it must make the following determinations:

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

◆ **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 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 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.

◆ **Selection of subjects is equitable**. In making this assessment the IRB 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.

◆ **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.²

◆ **Informed consent will be appropriately documented**, in accordance with, and to the extent required by 45 CFR 46.117.³

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

◆ When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

◆ 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, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

How will you know when your application has been reviewed and approved?

² Note that provisions for an alteration or waiver of informed consent are specified at 45 CFR 46.116 [see 46.116(d)].

³ Note that provisions for a waiver of signed consent are specified at 45 CFR 46.117 [see 46.117(c)].
If additional information or changes are requested based on the administrative review, the principal investigator will be notified as such by the FAMU IRB staff via email. Once the IRB has reviewed the application, the researcher will be notified by email of the IRB’s decision. If changes are required or requested, an email detailing these changes will be sent to the investigator. If the research is approved, a letter of the approval will be sent to the investigator as well as a paper copy of the approval notice through standard mail.

**Conditions of Approval**

Approval of a project by the IRB applies only to the procedures included with the submission. Investigators must secure prior approval from the IRB for any changes in the approved submission procedures or documents. Investigators must also report to the IRB in a timely fashion any problems that arise in connection with the involvement of human subjects.

Approval is not granted until all conditions or contingencies required by the IRB have been satisfied.

Approval for projects is valid only until the expiration date. All research projects must be reviewed no less than annually. The approval period is determined by the IRB and is based on the level and degree of risk involved in the research.

**IRB approval of your research will expire before you finish your project. What do you need to do to maintain IRB approval?**

With the exception of projects that are determined to be exempt from the regulations, the IRB is required to conduct continuing review of research at intervals appropriate to the degree of risk but not less than once annually. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. The approval notification from the IRB will specify the date of the expiration of approval.

The FAMU IRB will send all investigators a request for continuing review, including a link to the Continuing Review Request, several months prior to the expiration date for approval of the research. Two reminder requests will also be sent to the investigator if the FAMU IRB has not received the required information.

**You want to change something in your project. Do you have to submit everything to the IRB again?**

All changes in the project that deviate from the original submission must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subjects.

Changes in recruitment procedures and/or consent procedures must be explained in detail. Changes to data collection instruments such as questionnaires must also be submitted. These changes cannot be implemented without IRB approval.
The funding agency requires proof of IRB approval before they will release funds, but the money is needed to develop the instruments and procedures. What do you do?

Many times funding is needed to develop and finalize the instruments and procedures that will be used in a study. This presents a dilemma regarding the responsibility to thoroughly review human subject research submissions prior to awarding of funding. In accordance with 45 CFR 46.118 (and all correlating federal subparts distinct to each “Common Rule” agency), the following procedure will be used:

When an investigator plans to involve human subjects in a research project, but has not yet developed the instruments and/or procedures that will be used in the research, an IRB application should be submitted that includes all relevant information known at that time. The investigator should indicate that approval is being sought for the purposes of development only. The submission will then be reviewed by the IRB Staff and Chairperson, and may be approved for the purposes of development only, with the stipulation that no human subjects may be involved in the proposed research until the instruments and procedures that will be used have been reviewed and approved by the IRB.
POLICIES

Research that is Exempt from the HHS Regulations at 45 CFR 46

The HHS regulations at 45 CFR 46.101(b) specify six categories of research that are exempt from the policy. All human subject research that is exempt under this section will be conducted in accordance with the Belmont Report. Research in which the only involvement of human subjects is in one or more of the following categories is exempt:

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

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that 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.

Researchers who believe their research meets one or more of the categories for exemption can contact the IRB staff and the chair will determine whether the research meets the exemption
requirements when they review the application. The FAMU IRB Staff and Chair will determine whether the research meets the exemption requirements when they review the online protocol.

**Research that is Eligible for Expedited Review Procedures**

The HHS Regulations at 45 CFR 46.110 specify conditions under which research may be reviewed by the IRB under expedited review procedures. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

Research activities that meet both of the following two conditions may be reviewed under expedited review procedures:

1. The research presents no more than minimal risk to human subjects, and
2. The research involves only procedures listed in one or more of the allowed categories (see below).

The expedited review procedure may not be used for:

1. Research 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 subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
2. Classified research involving human subjects.

Research that involves no more than minimal risk and in which the only involvement of human subjects is in one or more of the following categories is eligible for expedited review:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and

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4 HHS regulations define "minimal risk" at 45 CFR 46.102(i) as “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”.

5 The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research
remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The expedited review procedure may also be used to review minor changes in previously approved research during the period for which approval is authorized. (45 CFR 46.110)

Research Requiring Review by the Full Board

All research that does not meet exemption requirements or is not eligible for expedited review procedures will be scheduled for review by the full board at a convened IRB meeting at which a majority of the membership of the IRB is present, including at least one member whose primary interests are non-scientific. Disapprovals may only be made by the convened IRB.

Examples of projects requiring review by the full board include the following:
- Research involving greater than minimal risk.
- Research that does not fit into expedited categories.
- Research involving prisoners.
- Research involving pregnant women/fetuses.

Continuing Review

The HHS regulations require that the IRB conduct continuing review of all human subjects research at intervals appropriate to the degree of risk, but not less than once per year [45 CFR 46.109(e)].

Continuing review must be substantive and meaningful, and must be conducted by the convened IRB, unless the research is otherwise appropriate for expedited review. Ordinarily, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. Continuing review must include determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting continuing review, the IRB will review, at a minimum, the protocol and any amendments as well as a status report on the progress of the research, including (a) the number of subjects accrued; (b) a description of any adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research; a summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research; and (d) a copy of the current informed consent document. Review of the currently approved consent document must ensure that the information is still accurate and complete. Any significant new

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Note that there are specific conditions that must be met in order for continuing review of research that was previously reviewed and approved by the convened IRB to be reviewed under expedited procedures. See expedited categories 8 and 9 above.
findings that may relate to the subject’s willingness to continue participation should be provided to the subject.

**Amendments**

Investigators must report to the IRB any planned changes in the conduct of their research, since these may affect the protection of human subjects. Minor changes proposed for previously approved research may be reviewed in an expedited manner prior to the scheduled continuing review date (45 CFR 46.110). When a proposed change in a research study is not minor, then the IRB must review and approve changes at a convened meeting before changes can be implemented. The only exception is the rare circumstance in which a change is necessary to eliminate apparent immediate hazards to the research subjects. In this case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with protection of human subjects.

Unanticipated risks to subjects or new information that may affect the risk/benefit assessment also must be promptly reported to, and reviewed by, the IRB to ensure adequate protection of human subjects. Examples of “minor changes” include changes in recruitment materials, changes in research team members, and minor changes in surveys or other research-related instruments.

**Scientific Review of IRB Proposals**

The IRB is responsible for the scientific review of protocol submissions within the context of assessments of risks and benefits associated with participation in research. IRB members are assigned to review protocols based on relevant disciplinary and regulatory knowledge and experience with study contexts and populations. By applying this expertise during the review process, IRB members document the extent to which study design manifests the ethical principles of the Belmont Report and related institutional, local, state and federal regulations and policies governing the conduct of research involving human subjects. In cases where study procedures are determined to unnecessarily increase direct or indirect risks or burdens to study participants, the IRB may require modifications to these procedures as a condition of approval. In the event the IRB lacks the appropriate expertise to assess scientific merit and the research is judged by the IRB to have greater than minimal risk, the IRB may seek outside expertise to assist its evaluation of the proposed research.

As part of the scientific review process, student researchers are required to identify a member of the University faculty as the PI for their IRB protocols. Review of new protocol, continuing review, and amendment submissions for student research projects (including M.A. and PhD theses and dissertations) is not initiated until the IRB receives an endorsement of the submission from the PI. Further, copies of departmental thesis proposals are required components of IRB submissions for students from departments that require such proposals.

**Student Research and Class Projects**

All student researchers must have a member of the faculty (usually the student’s advisor or dissertation chair) act as the principal investigator for the research. This individual is responsible for ensuring that the student researcher complies with all of the conditions of the approval, and must sign the assurance form certifying that the project is under his/her supervision.

**Class-related activities**
The collection of information from respondents for the purpose of class discussion or for the purpose of training in research or research methods generally does not require IRB review, with the exceptions noted below. In this situation, care should be taken to protect the rights and welfare of the individuals who act as participants.

Class-related projects
The following class-related projects require review and approval by the IRB:
- All theses and dissertations that involve human subjects.
- All projects for which findings may be published or otherwise disseminated outside of the classroom.
- Class-related projects for which the data are collected and archived for any purpose other than administrative evaluations.

Selection of Subjects
Defining the appropriate population of subjects for a research project involves a variety of factors, including scientific design, susceptibility to risk, likelihood of benefit, practicability, and considerations of fairness. The IRB requirement to make a specific determination that the selection of subjects is equitable is based on the principle of justice, and helps ensure that the burdens and benefits of research will be fairly distributed. The Belmont Report recommends that, as a matter of social justice, there should be an order of preference in the selection of classes of subjects: adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized persons. In addition, those individuals who may already be burdened (e.g., by disabilities or institutionalization) should not be asked to accept the burdens of research unless there is the possibility of direct benefit, or if other appropriate subjects cannot be found (i.e., if the research concerns their particular disability or circumstance). The IRB will consider the extent to which a proposed subject population may already be burdened by poverty, illness, or chronic disabilities in deciding whether they are a suitable subject population.

Incentives
Although there are no specific regulations governing subject incentives, incentives should not be of an amount or kind that they might impede a potential subject’s ability to choose freely whether to participate in the proposed research. In making its determination about the appropriateness of a given incentive, the IRB will consider who the subjects will be, what incentives are being offered, and the conditions under which the offer will be made. Informed consent documents should include a detailed account of the terms of the incentive, including a description of the conditions under which a subject might not receive the full incentive.

For research that requires subjects to undergo only minor inconvenience or discomfort, a modest payment will usually be adequate. Reimbursement for travel, babysitting, and so forth may also be provided. In more complex research projects, IRBs tend to base their assessment on the prevailing payment practices within their institution or general locale. Volunteers are often compensated for their participation according to an established fee schedule, based upon the complexity of the study, the type and number of procedures to be performed, the time involved, and the anticipated discomfort or inconvenience. Because payments may vary according to a number of factors, the IRB will be familiar with accepted standards within the community as well as the anticipated discomforts and inconveniences involved in a particular study to judge the appropriateness of payments.
Please note that while payments or incentives to subjects are allowable and appropriate, FAMU does not allow financial incentives or bonuses (including gifts) to be paid or awarded to investigator or any member study staff as an incentive to recruit subjects to a study or meet any special enrollment targets.

**Informed Consent**

Informed consent is a process that is generally documented with a consent form. Because subject understanding is a necessary component of informed consent, information must be presented in a language and at a level that is appropriate for the population. In general, consent documents should be written in lay language at a 6th - 8th grade level. Consent documents generally are more understandable if they are written in the second person. Writing in the second person also helps communicate to the potential subject that there is a choice to be made, whereas use of the first person may be interpreted as presumption of subject consent by the investigator.

The following information should be included in the informed consent document [45 CFR 46.116(a)]:

- A description of the purpose of the research.
- A description of the procedures that subjects will be asked to participate in or undergo. This includes an estimate of the amount of time required to
- A description of any reasonably foreseeable risks, discomforts, or inconveniences that may be associated with the research activity.
- A description of any benefits (if any) subjects may reasonably expect to receive, as well as a description of the importance of the knowledge that may be gained from the research. Note that payments to subjects are not considered benefits and should not be listed as such in the consent document.
- A description of the procedures in place to maintain confidentiality and the extent to which subjects’ identifiable private information will be kept confidential.
- Names and contact information for individuals (usually the PI or members of the research team) who would be knowledgeable to answer questions about the research.
- A statement that subjects can contact the FAMU IRB with any questions about their rights as research subjects. The mailing address, telephone number and email address for the FAMU IRB should be provided at the end of the document.
- The statement reminding subjects that participation is voluntary and that they have the right to withdraw at any time without penalty (or loss of benefits or services, where appropriate).

The following information should be included when appropriate:

- A description of any alternatives to participating in the research project.
- In those cases where the research involves more than minimal risk and research-related injury (i.e. physical, psychological, social, and financial) is possible, the consent document must include a statement as to whether compensation and/or treatment will be provided. Note that the consent document cannot contain exculpatory language that waivers or appears to waive subjects’ rights.
Documentation of Informed Consent

The IRB may approve procedures for documentation of informed consent that involve either (i) a written consent form signed by the subject or the subject’s legally authorized representative (LAR), (ii) short form written consent form with oral presentation, or (iii) a waiver of signed consent.

Written Consent Form Signed by Subject or the Subject’s Legally Authorized Representative

In most circumstances, the IRB will require that informed consent be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's LAR [45 CFR 46.117(b)(1)]. This document may also be read to the subject or the subject’s LAR. The investigator should allow the subject or LAR adequate opportunity to read and discuss the consent document before being asked to sign. A copy of the consent document must be given to the person signing the form. Subjects who do not speak English should be presented with an informed consent document that is written in a language understandable to them. In cases where the investigator can anticipate the need for translated consent documents, these documents should be included with the IRB submission packet together with the English versions of the consent documents.

Waivers and Alterations

Waiver of Documentation of Written Informed Consent

An investigator may request and/or the IRB may grant a waiver of the requirement for the investigator to obtain signed consent for some or all subjects if either of the following two conditions are met:

1. The only record linking the subject and the research would be the signed consent document and the principal risk would be potential harm resulting from a breach of confidentiality. When written consent is waived under this section, each subject must be asked if they would like to sign a consent document and the subject’s wishes will govern. [45 CFR 46.117(c)(1)]; OR
2. 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. [45 CFR 46.117(c)(2)]

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Waiver or Alteration of Informed Consent

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration would not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Telephone Surveys**

The requirement for written consent often can be waived in cases where a telephone survey methodology is used. If the research involves no more than minimal risk and does not involve any procedures for which written consent is required outside the research context, consent may be obtained via telephone. The investigator should submit a copy of the script that will be used to seek consent from subjects. The consent script should include at least the following information:

- The purpose of the research
- The researcher's name, contact information, and association with Florida A&M University.
- A description of how confidentiality of their responses will be maintained.
- A statement that participation is voluntary and the participant can refuse to answer any questions or terminate their participation at anytime without penalty.
- Information about how to contact the FAMU IRB if subjects have questions about their rights as research subjects.

The IRB may determine that additional items may be required based on the subject matter and risks to subjects.

**Third Party Consent**

When an investigator conducting research obtains identifiable private information about a living individual, that individual becomes a research subject, regardless of whether that person is the individual with whom the investigator is having an interaction. For example, if the research involves asking the primary subject to provide identifiable private information about a third party, that third party then becomes a subject in the research. As such, all of the regulatory requirements for protecting that individual obtain.

The IRB can determine whether informed consent needs to be sought from third party subjects, or whether it can be waived. In making this determination, the IRB relies on both the requirements for a waiver (noted earlier in this section) and the importance of the information to the research. Investigators whose research may involve so-called secondary subjects are encouraged to contact the IRB Staff to discuss how to best protect the rights and welfare of these subjects in a given project.

**Privacy and Confidentiality**

Investigators sometimes want access to existing records in order to identify potential subjects, or in order to conduct research. If the investigator will record subjects’ names (either for further record review or for personal contact), this activity requires IRB review. The IRB will determine whether the consent of subjects should be sought before the researcher gains access to the records (in some cases, a waiver can be granted – see section on waivers). In determining whether it is appropriate to waive the requirement to obtain consent from these subjects, the IRB considers the sensitivity of the information being recorded, the vulnerability of the subject population, and the purpose for which the investigator wants access to the information.
In some cases, consent cannot be waived. For example, the Buckley Amendment [the General Education Provisions Act (20 USC 1232) – see Appendix O], also known as FERPA, requires written parental permission for release of records or identifiable information about children in public schools.

For the majority of social and behavioral science research, ensuring confidentiality is the most important procedure to minimize risk. Most researchers are familiar with the minimum standard precautions that should be taken to maintain the confidentiality of data, including coding data, separating face sheets and consent documents from survey instruments, properly disposing of computer sheets and other papers, limiting access to identifiable data, educating the research staff about the importance of protecting confidentiality, and storing records in secured locations. More elaborate procedures may be appropriate for research involve sensitive data that may involve a greater risk should confidentiality be breached. In some cases, the investigator may want to seek a Certificate of Confidentiality to protect the data from subpoena (see Appendix N). Research in which the primary risk to subjects is from breach of confidentiality, and in which no identifiable information will be recorded save the consent document, is eligible for a waiver of signed consent (see above).

Special Populations: Additional Safeguards

If the proposed research involves a population that may be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards should be included in the study to protect the rights and welfare of these subjects.

Students

Universities afford investigators with a ready pool of research subjects: students. One problem with student participation in research conducted at the University is that their agreement to participate may not be truly voluntary. For example, students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty in general (i.e., by seeming "uncooperative," not part of the scientific community). When recruiting students, investigators should be aware of the possibility that students may feel pressured to participate in research and should make every effort to make clear that participation in research is voluntary and their decision whether to participate will not affect their academic standing or their relationship with the researcher or faculty.

Offering participation in research as a way to receive course credit (or extra credit) is also controversial. There are two important issues to address when this is done: (1) participation in the research must be only one of a number of options; and (2) the other options must be roughly equivalent in terms of the amount of time and effort required. For example, participation in a 30-minute survey should not be offered as an alternative to completing a 10-page term paper.

Another issue raised by the involvement of students as subjects is confidentiality. As with any research involving human subjects, the researcher should make every effort to protect the confidentiality of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol. This is especially important for research involving students, since other
students are often members of the research team and may be involved in data collection and/or analysis. Researchers should ensure that their research staff understands the importance of protecting confidentiality. The FAMU IRB Staff is available to provide educational sessions and guidance on this topic.

Employees

Many of the same issues arise when recruiting employees to participate in research. Just as student participation raises questions regarding the ability of students to truly exercise free choice because they may be concerned that grades or other important factors will be affected by their decision whether to participate, employees may be concerned that their decision whether to participate may affect performance evaluations or job advancement. Also, it may be difficult to maintain the confidentiality of personal medical information or research data when the subjects are employees.

Individuals with Cognitive Impairments

The primary ethical concern in research involving individuals with psychiatric, cognitive, or developmental disorders, or individuals who are active substance abusers, is that their disorders may compromise their capacity to understand and/or appreciate the purpose and risks and benefits of the research and to participate in the consent process in a meaningful way. Investigators should provide a rationale for involving cognitively impaired subjects, and should include additional means to protect the rights and welfare of these subjects.

Some individuals with cognitive impairments may be institutionalized, and this may further compromise their ability to exercise free choice. It is also important to protect the privacy of all subjects and the confidentiality of information gathered in research exploring emotionally sensitive topics, since some individuals would not want the fact of their institutionalization divulged.

It is important to note that all adults, regardless of their diagnosis or condition, should be presumed competent to provide informed consent unless there is evidence of a serious condition that would impair their reasoning or judgment. Individuals who have a diagnosed mental disorder may be capable of providing informed consent. Mental disability alone should not disqualify a person from consenting to participate in research.

Persons who have been determined to be incompetent by a judge will have a court-appointed guardian who must be consulted and provide consent before that individual can be enrolled in research. Note that legally authorized representatives (LAR) are generally not officials of the institution in which these individuals reside, since their supervisory duties may give rise to conflicting interests. Also, it should not be assumed that family members or others financially responsible for the individual are able to provide legally authorized consent, since they too may have conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances.

Children

The regulations provide additional protections for children involved in research. The IRB may approve research involving children as subjects only if the research fits into one of four specific categories. These categories are based on the level of risk and the possibility of direct benefit
to individual subjects. In Florida, children include all those who have not yet reached their 18th birthday (e.g., 0 through 17 years old).

A. Permissible Research Involving Children as Subjects

1. **Research Not Involving More Than Minimal Risk**
   When the IRB finds that no greater than minimal risk to children is presented, 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. [45 CFR 46.404]

2. **Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subjects.**
   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 only if 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 below. [45 CFR 46.405]

3. **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 only if the IRB finds that:
   a. the risk represents a minor increase over minimal risk;
   b. intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
   c. the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' 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. [45 CFR 46.406]

4. **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 application but only if:
   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 Department of Health and Human Services, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine,
education, ethics, law) and following opportunity for public review and comment, has determined either:
(1) that the research in fact satisfies one of the conditions set forth above, or
(2) that:
   (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
   (ii) the research will be conducted in accordance with sound ethical principles; and
   (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth below. [45 CFR 46.407]

B. Requirements for Permission by Parents or Guardians and for Assent by Children

1. Adequate Provisions for Child's Assent [45 CFR 46.408(a)]
The investigator must make adequate provisions for soliciting the assent of child subjects when the children are capable of providing assent. In determining whether children are capable of assenting, the investigator should 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. 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. See Appendix E for sample assent language.

Waiver of Assent. [45 CFR 46.408(a)]
If the IRB determines either of the following to be 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
- 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 the research.

Child's Dissent
Parents may overrule their child's dissent in cases where 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 the research, at the IRB's discretion. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, 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 govern.

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7 "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
Finally, even where the IRB determines that the child subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived for adults. [See 45 CFR 46.116(d)]

C. Adequate Provisions for Parents’ or Guardian’s Permission
The investigator must make adequate provisions for soliciting the permission of each child’s parents or legally authorized representative. [45 CFR 46.408(b)]

Research Meeting Categories 46.404 or 46.405 (see A.1 and A.2 above):
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.

Research Meeting Categories 46.404 or 46.405 (see A.3 and A.4 above):
Where parental permission is to be obtained, 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.

Waiver of Parental or Guardian Permission [45 CFR 46.408(c)]
If parental or LAR permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), the investigator may request that the IRB waive the consent requirements described above, provided both (i) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and (ii) the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate 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.

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

E. 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 meeting categories 46.406 or 46.407 (see A.3 and A.4 above) only if the research is:
(i) related to their status as wards; or
(ii) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved under this authority, the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parents. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.
Pregnant Women and Fetuses

The regulations provide additional specific protections for pregnant women and fetus involved in research. The IRB may approve research involving children as subjects only if the research meets specific requirements. These requirements are based on the level of risk and the possibility of direct benefit to individual subjects.

A. Definitions

(1) **Dead fetus** means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(2) **Delivery** means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(3) **Fetus** means the product of conception from implantation until delivery.

(4) **Neonate** means a newborn.

(5) **Nonviable neonate** means a neonate after delivery that, although living is not viable.

(6) **Pregnancy** encompasses the period of time from implantation until delivery. A woman shall be assumed 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.

(7) **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.

B. Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met [45 CFR 46.204]:

1. 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;
2. 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;
3. Any risk is the least possible for achieving the objectives of the research;
4. 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 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;
(5) 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 requirements, 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 from rape or incest.

(6) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(7) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of the children's regulations (see above);

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

(9) 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

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

Prisoners

The special vulnerability of prisoners makes consideration of their involvement as research subjects particularly important. Prisoners may be under constraints because of their incarceration that 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 research involving prisoners as subjects. The IRB may approve research involving prisoners as subjects only if these special provisions are met.

A. Special Definitions Pertaining to Research Involving Prisoners

(1) Minimal Risk

For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk used for other populations. The definition for prisoners includes reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons.8

(2) Prisoner

"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.

B. When Subjects Become Prisoners During the Course of the Research

If a subject becomes a prisoner after enrollment in research, the investigator is responsible for reporting in writing this situation to the IRB immediately. Upon its review, the IRB can either:

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8 “Minimal risk” means 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.
(i) approve the involvement of the prisoner-subject in the research in accordance with this policy or
(ii) determine that this subject must be withdrawn from the research.

C. Specific Findings of IRB Required to Approve Research

When the IRB is reviewing a protocol in which a prisoner is a subject, the IRB Committee must make seven findings as follows:

1. **Research falls within at least one of four acceptable categories:**
   
   A. 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. 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;
   
   B. Research on conditions particularly affecting prisoners as a class (for example, 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
   
   C. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

2. **Any Advantage of Participation Does Not Impact Prisoner's Ability to Weigh Risks**

   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;

3. **The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;**

4. **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 principal 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;

5. **The information is presented in language which is understandable to the subject population;**

6. **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**

7. **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.**
D. Permitted Research Involving Prisoners.
   For research conducted or supported by HHS to involve prisoners, two actions must occur:
   (i) the IRB must certify to OHRP that it has reviewed and approved the research under the federal regulations; and
   (ii) OHRP must determine that the proposed research falls within one of the categories of permissible research described above.

   If an investigator wishes to engage in non-HHS-supported research such certification is not required. However, the IRB will apply the standards of the federal regulations in reviewing the research.

E. Prisoners Who Are Minors.
   When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility a prisoner) the special protections regarding the inclusion of children as subjects also apply.

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

Special Categories of Research

Internet Research & Use of Email
   The growing popularity of the Internet has given researchers yet another medium in which to interact with subjects. Internet research does pose challenges in the application of traditional human subject regulations. The following is offered as guidance when undertaking research on the Internet:

   ▪ If documentation of consent can be waived, portals can be used to require consent (i.e., an introductory web page advising participants of the nature of the study and their rights with a button to click before allowing further access). If signed consent is required, a form must be signed and returned before access to the website is allowed.
   ▪ Participation by minors is discouraged, due to difficulties obtaining and verifying parental permission. There are several programs (e.g. Adult Check systems and Internet Monitoring software) that may be used as an aid to screen out minors.
   ▪ A variety of concerns about the ability to protect confidentiality arise:
      o Could there be inadvertent disclosure if someone mistakenly hits the “reply to all” button when utilizing email?
      o Is information stored on a web server?
      o Are “cookies” used?
      o Is this information vulnerable where hackers may deliberately access it?

   These issues become particularly important when sensitive data are being collected. Depending on the sensitivity of the information being gathered, it may not be possible to sufficiently minimize risks when using the Internet. In such cases, the Internet may not be an appropriate medium to use to conduct the research.
   When using electronic correspondence (email), subjects should be informed of confidentiality issues specific to email.
**International Research**

International research often requires additional safeguards to protect the rights and welfare of subjects. These include everything from the use of a translator if the person(s) seeking consent and/or collecting data is not fluent in the subject’s language to waiving the requirement to obtain written consent due to local custom or because of risks subjects may face due to social or political conditions. Investigators who will be conducting research internationally should provide the IRB with at least the following information:

- Information about where the research will be conducted (both the geographic location and the performance site, where applicable).
- A copy of local IRB or equivalent ethics committee approval, where possible. Depending on the local context, this may take the form of a letter of approval from a local IRB, a local university department sponsoring the research, a local institutional oversight committee, or an indigenous council. In areas where government-issued research visas are required, a copy of the visa should be submitted.
- Information about the investigator’s knowledge of the local research context, including information about the current social, economic, and political conditions. This should include a detailed description of the investigator’s personal experience conducting research (or studying or residing) in the region.
- Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context.
- The language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator fluent in this language, or whether a translator will be used. If a translator will be used, it should be clear what risks, if any, this might pose for subjects, as well as how they will be minimized.
- Copies of the translated informed consent documents and instruments, including verification of the accuracy of the translation(s).
- If the research is federally funded, information about the status of the assurance for the performance site, where applicable.

When composing an IRB protocol for an international research project, researchers should clearly demonstrate that the proposed procedures are appropriate given the culture, norms, and mores of local communities. Whenever practical, researchers should include local community representatives in the design of the research and consent processes to ensure that local concerns about research practices, goals, or uses of collective cultural or intellectual property are considered. Community collaboration in research design demonstrates concern for the ethical principles of justice (by articulating the equitable distribution of research risks and benefits in relation to community needs) and respect for persons (by recognizing the right of individuals to form groups with corporate agency).

**Third Party Subject Recruitment**

The FAMU IRB considers human subject recruitment procedures during its review of research protocols. In cases where research protocols propose recruiting research subjects through third-party organizations not affiliated with the University, the FAMU IRB adheres to the following University guidelines:

**Temporary Employment Agencies**

In accordance with University guidelines, the FAMU IRB recognizes that the recruitment of research subjects through temporary employment agencies is inherently problematic.
Temporary employment agencies are intended for employment opportunities. Participation as a human volunteer in a research project is NOT an employment opportunity. Temporary Employment agencies often attract the most disadvantaged populations, e.g. the homeless, the economically depressed. These individuals may feel compelled to accept assignments for research projects for the financial incentive alone or to maintain their relationships with temporary agencies for future placements. As such, the FAMU IRB does not consider the use of temporary employment agencies as a reasonable or ethically appropriate mechanism for subject recruitment.

**Administration and Jurisdiction of the FAMU IRB**

**Jurisdiction of the FAMU IRB**

The FAMU IRB is an administrative body established to protect the rights and welfare of human research subjects enrolled in research that is conducted in all disciplines and that is sponsored by this institution, conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects, regardless of sponsorship. The FAMU IRB 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 local institutional policy. Research that has been reviewed and approved by the FAMU IRB may be subject to further review, and may be disapproved by officials of the institution. However, those officials may not approve research that has been disapproved by the FAMU IRB. Furthermore, all approved research is subject to continuing review and approval by the FAMU IRB at least annually or as specified by the IRB.

**IRB Membership**

The HHS regulations specify that the FAMU IRB must have at least five members. The membership must represent a variety of backgrounds in order to promote complete and adequate review of the research activities commonly conducted by the institution. Also, the IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. There is no maximum limit to the number of individuals that may serve on the IRB.

In addition to possessing the professional competence necessary to review specific research activities, the FAMU IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Therefore, the FAMU IRB must include persons knowledgeable in these areas. No IRB, however, may consist entirely of members of one profession.

The FAMU IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. The nonaffiliated members of the IRB should be drawn from the local community at large, and may include
ministers, teachers, attorneys, businesspeople, prisoner representatives, and/or individuals who are members of advocacy groups such as the National Alliance for the Mentally Ill. The nonaffiliated member(s) should be knowledgeable about the local community and be willing and able to discuss issues and research from that perspective. When selecting the nonaffiliated member(s), consideration should be given to the type of community from which the institution will draw its research subjects.

The IRB must make every effort to ensure that it does not consist entirely of men or entirely of women, though appointment to the IRB should not be made solely on the basis of gender.

The FAMU IRB is encouraged to invite individuals with expertise in specific areas to assist in the review of issues that require expertise or perspective beyond or in addition to that available on the IRB. Although these individuals may attend meetings and take part in the discussion of research protocols, they may not vote.

The Vice President of Research appoints IRB members. Newly appointed IRB members receive training about how to review research and their responsibilities as members of the IRB. The Vice President for Research also appoints the IRB Chair. The IRB chairperson should be a highly respected individual from the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of ensuring that the IRB is a respected part of the institutional community will fall primarily to this individual. The IRB must be and must be perceived to be fair and impartial, immune from pressure either by the institution's administration, investigators whose protocols are brought before it, or other professional and nonprofessional sources.

Conflict of Interest (COI)

The PI is responsible for disclosure to the IRB at the time a protocol is submitted if any research personnel involved in the protocol have any outside financial conflicts of interest that are or could be perceived to be related to the proposed research protocol. If there is a known or potential conflict of interest at the time of IRB submission, a separate letter of disclosure should be included with the submission detailing the nature of the conflict. Any change to this status as related to a protocol should also be brought to the attention of the IRB. Please refer to the University Office of Technology Transfer Website. The current University policies for disclosure of individual financial conflicts of interest as well as OHRP's guidance particular to financial conflicts of interest in clinical research and other useful reference documents pertaining to financial conflicts of interest. The IRB will relay any conflict of interest disclosure to the Institutional Official and coordinate with the Official as to the appropriate measures or protections to be implemented or that may have already been implemented. Such measures typically include disclosure of the outside interest and the nature of the relationship to the proposed study in the Informed Consent form.

No IRB member may participate in the review of any project at a meeting or otherwise in which the member has a conflicting interest or in which the appearance of a conflict exists, except to provide information as requested by the IRB. In the case of such a conflict, this should immediately be reported to the IRB Chair. Except to provide requested information, members absent themselves when the IRB reviews research in which they have conflicting interests and their absence is recorded in the minutes. A conflict of interest is defined as a conflict between the private interests and the official responsibilities of a person. Examples of COI include
serving on a dissertation committee for a project being reviewed or holding stock in a company
for which the project is being performed.

Record Keeping

The FAMU IRB staff prepares and maintains adequate documentation of the IRB’s activities. In
addition to the written IRB procedures and membership lists required by the Assurance process
such documentation includes electronic copies of all research proposals (including informed
consent documents) reviewed, minutes of IRB meetings, records of continuing review activities,
copies of all correspondence between the IRB and investigators, and statements of significant
new findings provided to subjects. Minutes of the IRB meetings are kept in sufficient detail to
record the following information: attendance at each meeting; actions taken by the IRB; the vote
on actions taken (including the number of members voting for, against, and abstaining); the
basis for requiring changes in or disapproving research; and a written summary of the
discussion of controverter issues and their resolution.

IRB records are retained for at least three years; records pertaining to research that is
conducted must be retained for three years after completion of the research. All records are
accessible for inspection and copying by authorized representatives of the department or
agency supporting or conducting the research at reasonable times and in a reasonable manner.

Institutional Responsibilities

Each institution engaged in research must have an established IRB, or designated one from
another institution, to review and approve research involving human subjects performed at its
facilities. Before any human subjects research can be conducted, the institution must provide
the department or agency a written Assurance Plan that it will comply with the requirements of
the Policy; the Assurance must be approved by the department or agency; and the institution
must certify to the department or agency head that the research has been reviewed and
approved by an IRB established in accordance with the requirements of the Policy. Florida A&M
University has a Federalwide Assurance (FWA) that has been reviewed and approved by the
Office for Human Research Protections (see Appendix A). The FAMU IRB is covered under this
Assurance.

Communication

The institutional leadership must assure that open channels of communication are maintained at
all levels. It is important that staff, subjects, and other interested parties have a means of
communicating information about the conduct of a research project directly to the appropriate
institutional officials. It is vital that the IRB members, department heads, and other officials with
responsibility for oversight of research have open and ready access to the high levels of
authority within the institution. The Office Animal Care and Research Compliance, in
conjunction with The Division of Research, is responsible for ensuring constructive
communication among the research administrators, department heads, research investigators,
clinical care staff, human subjects, and institutional officials as a means of maintaining a high
level of awareness regarding the safeguarding of the rights and welfare of the subjects.

Education and Training

The IRB has an educational program that includes both initial and continuing educational
offerings. The IRB requires the CITI Course in The Protection of Human Research Subjects.
The NIH requires education on the protection of human research subjects for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Researchers whose projects are sponsored by NIH need to complete the NIH educational requirement. There are a variety of ways of completing this requirement, including on-line tutorials and other self-administered courses. Contact the IRB staff for guidance about which tutorial will best match your research interests and educational needs.

Audits and Monitoring

The Division of Research, responsible for procedural and record keeping audits on a regular basis for the purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by the institution.

In order to help ensure compliance with federal regulations and local IRB policies regarding research with human subjects, and to ensure that human subjects are adequately protected, the IRB staff and members may conduct routine, targeted or random audits of research protocol files subject to their jurisdiction. In addition, the IRB staff and members may request monitoring of approved projects that may take the form of routine, targeted, or random audits. These activities may include, but are not limited to the following:

- Request progress reports from investigators;
- Examine research records;
- Contact research subjects;
- Dispatch observers to the sites where research involving human subjects and/or the informed consent process is being conducted;
- Verify from sources other than investigators that no material changes in the study have occurred;
- Audit advertisements and other recruiting materials to confirm proper IRB approval;
- Review projects to verify from sources other than the investigator(s) that no material changes have occurred since previous IRB review; and/or
- Other monitoring or auditing activities deemed appropriate by the IRB.

Reporting of Audit Results to Full Board

The results of any targeted or random audits by the IRB members or staff will be reported to the full IRB on the agenda of the next regularly scheduled meeting. However, if the information gained during the monitoring or auditing process indicates that human subjects may be exposed to unexpected serious harm, the IRB may suspend or terminate approval of the research prior to the next regularly scheduled IRB meeting.

Policy on Non Compliance

Every noncompliance report or complaint about human research protections is taken seriously by the University. Any allegation or complaint received the University will be referred to the appropriate IRB for initial assessment and follow up. Complaints or reports of potential noncompliance that are received by Principal Investigators must be disclosed to the IRB. Each report is initially evaluated by the appropriate IRB Chair or designee and IRB administrative staff and the follow up will be documented. The IRB is responsible for assuring that the complaint or
report of noncompliance is investigated appropriately relative to its level of seriousness, taking special steps to assure that problems involving risks to health and well being of subjects have first priority. The IRB shall move quickly to suspend or terminate approval of research that is suspected of causing serious to subjects at Florida A&M University. A PI may voluntarily elect to suspend subject accrual to a protocol which an allegation of noncompliance or a complaint is investigated.

The IRB is responsible for carrying out an initial inquiry and reporting the outcome of that inquiry as detailed below.

Determine If It is Necessary to Suspend the Study

The IRB will determine if immediate suspension of the participant enrollment is required for the protocol in question as well as for other protocols with the same PI. This initial decision will be made by the IRB Chair or Vice Chair in consultation with the IRB Administrator and other institutional officials as may be appropriate. The decision will be based on preliminary information and the seriousness of the situation. The length of the suspension (no further participant enrollment) will be determined by continuing consultation and/or receipt of further information in conjunction with the protocol(s) in question.

The initial inquiry will examine information such as the nature of the study or whether or not the consent form contained inappropriate information. From this inquiry, a determination shall be made about whether continued inquiry (including suspension) is merited.

When Suspension is Not Necessary

If the IRB Chair and/or Vice Chair in consultation with the IRB Director determine the situation does not merit suspension, a report of the situation and factors considered will be prepared. The Report must include the date and signatures of the IRB officials who made the determination, with a statement of their conclusion and the subsequent actions to be taken are documented. All communication and ultimate resolution of the situation will be documented and maintained in the IRB application file.

When Suspension is Necessary

If the report indicates that suspension of the research study is merited, further steps are required:

1. Notice of suspension effective immediately will be sent to the PI, co-Investigators, department Chair, appropriate grants administration office, institutional official, and IRB Chair. The notification includes the requirement to halt further participant enrollment. When the PI voluntarily elects to suspend a study while an investigation of noncompliance or a complaint is undertaken, the IRB must notify the Institutional Official that a voluntary suspension is in place, identifying the PI, the protocol and a preliminary indication of the situation.

2. Within two working days, the IRB Chair, Vice Chair, IRB Senior Administrator, PI and other parties as may be appropriate given the circumstances, shall meet to discuss the nature of the situation and to determine if the situation merits a designation of serious or continuing noncompliance.

3. Further study of the situation including an examination of consent forms, all data related to the study, IRB protocol documentation, etc. may be necessary to determine whether a designation of serious or continuing noncompliance is warranted. The PI is required to
produce whatever records are called for by the IRB and University. The IRB may take what steps are considered appropriate and necessary to carry out its initial investigation, including the use of outside experts. Any involvement of investigation where outside expertise is solicited should not be undertaken without the knowledge and concurrence of the Institutional Office.

**Study Suspended: Determine if the Event is Serious or Continuing**

The results of the review of protocol and study records and discussions with the PI will determine whether the situation is of nonserious and noncontinuing nature.

- **Nonserious and Noncontinuing:** If the incident appears to be isolated and, for example, a miscommunication or misunderstanding of a nonserious and noncontinuing nature, the incident will remain internal to the University and the documentation will remain with the IRB. A letter from the IRB office to the PI describing a summary of the investigation of the allegation or complaint will be written. A response from the PI describing corrective actions is also required. IRB Chair/Vice Chair acceptance of the PI response and corrective action will constitute closure to the incident. Suspension of subject enrollment will be lifted.

- **If the IRB determines that the investigation (or audit of protocol records, consent forms, data, etc.) indicates that the situation should be considered serious or continuing, the IRB must notify the University Institutional Official including a copy of the investigative report no later than 48 hours after the determination of Serious or Continuing is made, no matter whether the project is externally funded or not.** If the research is not federally funded the IRB may make a recommendation as to whether the noncompliance should be reported to OHRP, recognizing that the University’s Federalwide Assurance requires federally-funded serious and continuing noncompliance to the reported to OHRP and other federal agencies as may be necessary.*

- **The institutional official coordinates review of the IRB’s investigation of a situation determined to be serious or continuing with appropriate institutional officials including the Office of General Counsel and the Office of the Provost. It is the responsibility of the institutional official to notify OHRP (or FDA, a federal agency or other required sponsor) when the University is required to make this disclosure or elects to self-report.**

- **The institutional official will make a phone call or OHRP (Or FDA or appropriate agency as may be required) to apprise the office of the incident of serious, continuing noncompliance and will be followed with a letter within two business days. The notification letter to OHRP (or FDA or other sponsor organization) will briefly describe the incident, the preliminary steps, and an indication of the time frame for full audit and full report to follow, including corrective actions for this specific incident as well as for the research program to ensure incidents will not occur again.**

- **The institutional official and the IRB Chair and IRB Director will assure that all documentation supporting the audit of the incident, any additional audits of other research conducted by the PI in question, and all communication with internal offices and other regulatory bodies at Florida A&M University as may be required are completed. It is the responsibility of the IRB to maintain all audit records of the investigation and to assure that all corrective action requirements made by the IRB and/or the University are implemented.**
Corrective Action Steps

In the course of investigation of allegations of noncompliance or complaints, corrective actions plans may be stipulated to assure that the situations giving rise to the investigation do not occur again. Examples of corrective action plans that may be initiated by the PI or imposed by the IRB and/or the University include, but are not limited to:

- Suspend the research until certain conditions are met
- Terminate the research
- Require additional training for research staff
- Impose other sanctions, such as limiting the number of subjects to be enrolled
- Require modifications/amendments to the protocol

* Under the Terms and Conditions of the Florida A&M University Federal wide Assurance, the University is obligated to report to [the federal] Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) serious or material unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval for Federally-supported research.
APPENDIX A
DEcision Tree Regarding Definition of Human Subject Research

Is the definition of “human subject met in this research activity?"

Is there an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion, but for this research?

Yes

Human Subjects are involved. You must submit the Human Subject Protocol Form to the IRB for review. No activity may begin prior to receiving IRB approval.

No

Will identifiable private data/information be obtained for this research in a form associable with the individual?

Yes

Human Subjects are involved. You must submit the Human Subject Protocol Form to the IRB for review. No activity may begin prior to receiving IRB approval.

No

Human Subjects Research Policy does not apply. You do not need to submit to the IRB.
APPENDIX B
DECISION TREE REGARDING DEFINITION OF RESEARCH

Is the definition of “research” met in this activity?

Is this activity a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?

Yes

Is this student research that will NOT lead to publication?

Yes

Is this research conducted off-campus?

Yes

This activity is considered research according to Human Subjects Research Policy. See the Human Subjects Decision Chart.

No

Human Subjects Research Policy does not apply. You do not need to submit to the IRB.

No

Is this student research that will NOT lead to publication?

No

Human Subjects Research Policy does not apply. You do not need to submit to the IRB.

Yes

Does this activity fall under GSU policy on class-related assignments criteria?

Yes

Complete “Approval for Class Projects” Form and turn in to instructor.

No

This activity is considered research according to Human Subjects Research Policy. See the Human Subjects Decision Chart.
APPENDIX C
USEFUL HYPERLINKS FOR FURTHER INFORMATION

Appendix A: Template Verbal Consent Scripts
- [English Version Informed Consent Materials](#)
- [Spanish Version Informed Consent Materials](#)

Appendix B: The Belmont Report

Appendix C: 45 CFR 46
- [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)

Spanish Translation of 45 CFR 46
- [http://www.hhs.gov/ohrp/espanol/intro.htm](http://www.hhs.gov/ohrp/espanol/intro.htm)

Appendix D: Expedited Review Categories
- [http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)

Appendix E: Human Subjects Regulations Decision Charts
- [http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm)

Appendix F: Continuing Review: Institutional Review Board Responsibilities

Appendix G: Engagement of Institutions in Research
- [http://www.cdc.gov/od/ads/docs/engage.pdf](http://www.cdc.gov/od/ads/docs/engage.pdf)

Appendix H: Informed Consent of Subjects Who do not Speak English
- [http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm)

Appendix I: IRB Knowledge of Local Research Context
- [http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm)

Appendix J: OHRP International Research Resources – Ethical Codes and Regulatory Standards
- [http://www.hhs.gov/ohrp/international/index.html#ethicalcode](http://www.hhs.gov/ohrp/international/index.html#ethicalcode)

Appendix K: Internet Research
- [http://www.aoir.org/reports/ethics.html](http://www.aoir.org/reports/ethics.html)

Appendix L: Certificates of Confidentiality
- [http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm)

Appendix M: FERPA Information

Appendix N: HIPPA Information
- [http://www.hrsa.gov/website.htm#overview](http://www.hrsa.gov/website.htm#overview)

Appendix O: NIH Researcher Computer-Based Training
- [http://ohsr.od.nih.gov/cbt/cbt.html](http://ohsr.od.nih.gov/cbt/cbt.html)

Appendix P: CITI Course in the Protection of Human Research Subjects
- [http://www.citiprogram.org/](http://www.citiprogram.org/)

RESOURCE DOCUMENTS

- Template Recruitment Flyer ([MS Word](#) or [Adobe PDF](#))
- Template Informed Consent Scripts/Forms ([MS Word](#) or [Adobe PDF](#))
- Informed Consent Checklist ([MS Word](#) or [Adobe PDF](#))
- Consent Form Requirements ([MS Word](#) or [Adobe PDF](#))