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Policy Statement
The Institutional Review Board (IRB) will ascertain the acceptability of ALL proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB will be primarily concerned with the protection (level or risk) of human subjects in research. The IRB will conduct its activities, according to and as required by FDA guidelines (21CFR-Part 56).

In order to increase the effectiveness of the IRB, copies of the IRB Manual will be made available to the Office of Sponsored Programs, Deans, Department Chairs and active principal investigators. The Manual is available on the web at www.famu.edu/research.

Definitions
Adverse event – An undesirable and unintended, although not necessarily unexpected, result arising during the course of a research protocol.

Adverse Event Report – Report to appropriate institutional officials about adverse events.
Advertising – One mechanism or method used by researchers to recruit subjects for research studies.
Alternatives – Options that exist for a subject who is thinking about participating in research.
Assent – Agreement by an individual not competent to give legally valid informed consent to participate in research (e.g., a child).
Assurance – A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with regulations governing the protection of human subjects in research. Assurance is the word used in the Federal Policy (Common Rule).
Belmont Report – A statement of basic ethical principles governing research involving human subjects issued in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
Beneficence – An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
Benefit – A valued or desired outcome; an advantage.
Certificate of Confidentiality – A Certificate of Confidentiality protects the compelled release of identifiable information about research subjects in any
legal proceeding. These documents are issued by the DHHS and can be requested for all research, regardless of funding source [42 USC 241(d)].

Appendix I Certification – The human subject regulations, in certain parts require the Institutional Review Board (IRB) to provide a “certification” to the government. For example, see the prisoner regulations at 45 CFR Part 46, Subpart C.

**Chair** – The person who leads the activities of the IRB.

**Children** – Persons who are minors as defined by law.

**Clinical Investigation** – Any experiment that involves a test article and one or more human subjects that is subject to Food and Drug Administration (FDA) requirements for research or marketing permits [21 CFR Part 50.3(c) and 56.102(c)].

**Clinical Trial** – A controlled study involving human subjects designed to contribute to generalizable knowledge about the safety and/or effectiveness of an intervention or treatment.

**Coercion** – The act of inducing or pressuring an individual to consent to participate in research or to stay in research.

**Cognitive Impairment** – Some disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished.


**Compensation** – Refers to payment or other benefits that will be given to subjects who volunteer to participate in research protocols.

**Competence** – The capacity to act on one’s own behalf; the ability to understand information presented; to appreciate the consequences of acting or not acting on that information, and to make a choice.

**Confidentiality** – Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

**Consent** – Agreement to do something. Informed consent is agreement to do something based upon a complete understanding of that task.

**Control** – Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of the study.

**Continuing Review** – The regulatory requirement that the Institutional Review Board (IRB) review research at intervals not greater than one year. The IRB may review research at more frequent intervals [45 CFR 46.109(e); 21 CFR 56.109(f)]. Appendix I

**Data and Safety Monitoring Board (DSMB)** – A group of people who monitor a clinical trial for adverse events and other trends. The Data and Safety Monitoring Board looks for any information that might warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

**Deception** – Intentionally misleading with respect to a research protocol.

**Declaration of Helsinki** – A code of ethics for clinical research approved by the World Medical Association. It has been widely adopted by medical associations worldwide and has been revised numerous times.
DSMB – Acronym for Data and Safety Monitoring Board.
Emancipated Minor – Defined by law, this refers to the legal status of a person who has not yet attained the age of legal competency but who is entitled to adult status for certain matters.
Embryo – Early stages of a developing organism, broadly used to refer to stages immediately following fertilization of an egg through implantation and very early pregnancy.
Exemptions – The Federal Policy for the Protection of Human Subjects contains six exemptions. Research falling under one of these exemptions is not required to undergo IRB review and the investigator is not required to abide by the requirements for obtaining information consent [See 45 CFR 46.101(b)]. FDA regulations contain an exemption from IRB review requirements for the emergency use of a test article [21 CFR 56.104(c)] and for certain taste and food quality evaluations and consumer acceptance studies [21 CFR 56.104(d)].
Expedited Review – Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire convened IRB. Federal regulations permit expedited review for: (1) certain kinds of research involving no more than minimal risk and that fall within a category listed on the November 9, 1998 Federal Register [63 FR 60364]; and, (2) for minor changes in previously approved research [45 CFR 46.110; 21 CFR 56.110].
Experiment – Generally, this refers to an intervention or interaction that is unproven and not yet scientifically validated.
FDA – Acronym for the Food and Drug Administration, a component of DHHS.
Federal Policy – Another short reference, along with the phrase “Common Rule,” for the Federal Policy for the Protection of Human Subjects in Research [56 FR 28003]. Federal Register – The government’s publication in which final and proposed rules or notices are published. Appendix I
Fetus – The product of conception from the time of implantation until delivery. Refer to Subpart B of 45 CFR Part 46 for specific findings that are required for research involving fetuses.
FR – Acronym for Federal Register.
Full Board Review – Review of proposed research at a convened meeting of the IRB, at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in a nonscientific area [45 CFR 46.109; 21 CFR 56.108].
Grant – Financial support provided for a research study designed and proposed by the principal investigator.
Guardian – An individual who is authorized under applicable state or local law to give permission on behalf of another person to participate in research.
Helsinki Declaration – See “Declaration of Helsinki.” Human in Vitro Fertilization – Any fertilization involving human sperm and ova that occurs outside the human body.
Human Protections Administrator – An individual who has responsibility for day-to-day operation and implementation of the institution’s program for
protecting human subjects. The institutional title and duties of the Human Protections Administrator may vary widely from institution to institution. For example, an institutional compliance officer, head IRB administrator, or some other individual might fill this role, depending upon the nature of the institution. In any case, the Human Protections Administrator should have detailed knowledge of institutional protection mechanisms and be readily available for consultation with federal officials and institutional personnel. The IRB Chairperson should not serve as the Human Protections Administrator.

**Human Subject** – An individual who is the object of study in a research project. Under the Federal Policy (Common Rule), human subject means a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [45 CFR 46.102(f)]. Under FDA regulations, “human subject” means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient [21 CFR 50.3(g) and 56.102(e)].

**IDE** – Acronym for Investigational Device Exemption.

**IEC** – Acronym for Independent Ethics Committee. Incapacity – Refers to a person’s mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Appendix I

**Inclusion Criteria** – The criteria that establish whether a person is eligible to participate in a clinical trial.

**Incompetence** – A legal term meaning inability to manage one’s own affairs.

**IND** – Acronym for Investigational New Drug Application.

**Independent Ethics Committee (IEC)** – The equivalent of an IRB under the International Conference on Harmonisation Guidelines for Good Clinical Practice.

**Informed Consent** – A person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

**Institution** – Any public or private entity or agency (including federal, state, and other agencies) [45 CFR 46.102(b); and, 21 CFR 50.3(h) and 56.102(f)].

**Institutional Review Board (IRB)** – A review body established by regulation to protect the welfare of human subjects recruited to participate in research.

**Institutional Official** – The individual at an institution who is responsible for ensuring the effective administration and implementation of the institution’s system for the protection of human subjects.

**Investigational Device Exemption (IDE)** – Exemptions from certain regulations found in the FDA, Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations [21 CFR 812.20].

**Investigational New Drug Application (IND)** – An application to conduct a clinical investigation involving a drug not yet determined by the Food and Drug Administration to be safe and effective for a particular use in the general population and not yet licensed for marketing [21 CFR 312.1].

**Investigator** – The individual who actually conducts a research investigation [21 CFR 50.3(d) and 56.102(h)].
**IRB** – Acronym for Institutional Review Board. IRB Forum (formerly known as “McWIRB” – An IRB Listserv that is widely used and can be found at [http://www.irbforum.org](http://www.irbforum.org).

*Justice* – An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly. Appendix I

**Legally Authorized Representative (LAR)** – The person authorized by law to consent to something on behalf of another person. For research purposes, only select states permit a LAR to consent for research participation [45 CFR 46.102(c); 21 CFR 50.3(e)].

**Member** – A person who is listed on the roster of an IRB as a voting participant in IRB deliberations and actions.

**Minimal Risk (Federal Policy, DHHS Subpart A, and FDA)** – 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 [45 CFR 46.102(i); and, 21 CFR 50.3(k) and 56.102(j)].

**Minimal Risk (DHHS Subpart C - prisoners)** – 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 [45 CFR 46. 303(d)].

**Monitoring** – A mechanism for keeping track of any part of the research process: data analysis, recruitment of subjects, informed consent process, to ensure its compliance with Institutional Review Board dictates and the federal regulations.

**National Bioethics Advisory Commission (NBAC)** – A Presidentially appointed commission that issues reports and makes recommendations relating to the protection of human subjects in research.

**NIH** – Acronym for National Institutes of Health.

**Non-Affiliated Member** – Member of an IRB who has no ties (and whose immediate family members have no ties) to the parent institution, its staff, or faculty. This individual is usually from the local community [45 CFR 46.107(d); and 21 CFR 56.107(d)].

**Non-Scientist** – Member of an IRB who does not have a scientific background, but may be affiliated with the institution [45 CFR 46.107(c); and, 21 CFR 56.107(c)]. At least one nonscientist member must be present at convened meetings to approve research [45 CFR 46.108(b); and, 21 CFR 46.108(c)].

**Normal Volunteers** – Volunteer subjects in a research study who do not have the condition under study. The 1993 Office for Protection from Research Risks (OPRR) Guidebook defines normal volunteers as follows: “Normal” may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the “normals” in a study of diabetes complicated by heart disease [OPRR IRB Guidebook, 1993, G-9].

**Notice of Proposed Rule-Making (NPRM)** – Pursuant to the Administrative
Procedure Act, the government must typically issue a notice of a proposed rule before it issues the final rule. This affords the public the opportunity to comment on contemplated government action. Appendix I

**Nuremberg Code** – A code of research ethics developed during the trials of Nazi war criminals following World War II and widely recognized as a standard during the 1950s and 1960s for protecting human subjects.

**Oral Consent** – Typically refers to informed consent that is obtained from a subject without use of a written informed consent document.

**Office for Human Research Protections (OHRP)** – An office within the DHHS that was created in June of 2000. OHRP is responsible for the implementation of the DHHS regulations [45 CFR Part 46] governing the protection of human subjects in research. Office for Protection from Research Risks (OPRR) – Until June 2000, this office was within the DHHS as part of the National Institutes of Health (NIH). OPRR was responsible for the implementation of the DHHS regulations [45 CFR Part 46] governing research involving human subjects. The Office for Human Research Protections supercedes OPRR. Parental Permission – The agreement of one or both parents or a guardian to research involving a minor [45 CFR 46.402(c)].

**Public Health Service (PHS)** – A division within the DHHS. PHS agencies include the National Institutes of Health, Centers for Disease Control, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration.

**Placebo** – In biomedical research, a chemically inert substance given in the guise of medicine for its psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than the actual power of a drug. In social and behavioral research, a condition that mimics the experimental context but does not include the experimental manipulation under study. As in biomedical research, the control condition is used to confirm that observed effects are the result of the experimental manipulation rather than the research context itself.

**Pregnancy** – The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test [45 CFR 46.203(b)]. This confirmation may be in error, but, for research purposes, investigators must presume that a living fetus is present until evidence to the contrary is clear. Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

**Principal Investigator (PI)** – The person with primary responsibility for design and conduct of a research project. Public Responsibility in Medicine and Research (PRIM&R) – A non-profit organization that organizes conferences, workshops, and other activities to further the protection of human subjects in research. Appendix I

**Prisoner** – An individual involuntarily confined or detained in a penal
institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution; or (4) incarcerated in a penal institution [45 CFR 46.303(c)].

**Prisoner Representative** – A member of an IRB who has appropriate background and experience to represent the interests and concerns of an individual who is involuntarily confined to an institution [45 CFR 46.304(b)].

**Privacy** – Concealment from others of information about oneself. **Protocol** – The formal design or plan of an experiment or research activity. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**Random Assignment** – Assignment of subjects to different treatments, interventions, or conditions according to chance. **Recruitment** – The process of enrolling human subjects in research protocols.

**Research** – Under the Federal Policy and the DHHS Subpart A, research is a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)]. Under FDA regulations, “research” is synonymous with “clinical investigation” [21 CFR 56.102(c)].

**Respect for Persons** – A principle enunciated in the Belmont Report stating that (1) individuals should be treated as autonomous agents, and (2) persons with diminished autonomy are entitled to protection.

**Risk** – The probability of harm or injury occurring as a result of participation in a research study. **Secretary** – In the context of the federal regulations pertaining to the protection of human subjects in research, refers to the head of a federal agency [45 CFR 46.102(a)].

**Site Visit** – Typically refers to a visit from a federal office to ensure the entity is complying with federal regulations.

**Sponsor** – Typically refers to the entity that initiates a clinical investigation but does not actually conduct the investigation [21 CFR 50.3(e) and 56.102(j)]. **Sponsor-Investigator** – An individual who both initiates and actually conducts a clinical investigation [21 CFR 50.3(f) and 56.102(k)].


**Surveys** – Studies designed to obtain information from human subjects through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures. **Suspension** – Typically used in the context
of a federal agency taking action against an institution. For example, the Office for Human Research Protections can suspend an Assurance, preventing the institution from continuing to conduct studies supported with federal funds.

**Test Article** – Any drug, biological product for human use, medical device for human use, human food additive, color additive, electronic product subject to FDA regulations under 42 USC 262, 263b-263N [21 CFR 50.3(j) and 56.102(e)].

**Tuskegee** – Often used erroneously to refer to the U.S. Public Health Service Syphilis Study in Tuskegee, Alabama.

**Undue Influence** – This refers to a prohibition in the Common Rule that investigators not use unfair measures or influence to enroll persons in research [45 CFR 46.116].

**Unaffiliated Member** – See “Non-affiliated member.”

**Unanticipated Problems Involving Risks to Subjects or Others** – This is a regulatory phrase which requires reporting of this event to the IRB and to the government [45 CFR 46.103(d)(5); 21 CFR 56.108(b)].

**Voluntary** – Free of coercion, duress, or undue influence.

**Vulnerable population** – This is a regulatory phrase which refers to a group of people who have some condition or situation that makes them more susceptible to coercion or undue influence [45 CFR 46.107(a)].

**Waiver of Informed Consent** – An action taken by the IRB permitting the investigator to pursue research involving human subjects without obtaining informed consent [45 CFR 46.116(d)].

**Composition of the Institutional Review Board**

The Florida A&M University IRB includes members that have expertise in a wide range of medical and social research areas, familiarity with applicable regulations and laws and with relevant standards of professional conduct and practice, and knowledge of vulnerable or special populations such as children, prisoners, pregnant women, and disabled persons. The committee strives for a balance of men and women with representation from minority populations.

The following criteria apply to the IRB:

1. The IRB board is composed of at least five members with varying backgrounds. Every nondiscriminatory effort is made to assure that the board is composed entirely of either men or women.
2. At least one member (the Community Representative) has no affiliation, other than IRB membership, with the University and is not an immediate family member of anyone affiliated with the University. Whenever the primary Community Representative is unable to attend an IRB meeting, every attempt is made to appoint an alternate Community Representative to serve.
3. Typically, at least one IRB board member has primary professional expertise in a scientific field relevant to the type of research reviewed, and at least one member has primary concerns in a nonscientific field.

**Appointment and Length of Service Terms**

In the selection new members, the Director of the Animal Care and Research Compliance works with department heads and other University officials to seek candidates for nomination with consideration for maintaining the diversity and specialty requirements of the board. Each appointee outside of the community member must be a tenure track faculty at the University.

When an appropriate candidate is found, an invitation letter is sent requesting confirmation of intention to serve. The formal appointment of new members is made by the designated Institutional Official for Human Subject Protection (Vice President for Research).

Each member is appointed to a three-year renewable term.

**Duties and Responsibilities**

A member of the IRB has the primary duty of protection of the rights and welfare of individuals who serve as the subjects of research. The members are serving as a link between the investigator and the research subjects.

**A. Regular Members**

Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a scientific area is required to assess if an application adequately protects the rights and welfare of subjects.

**B. Nonscientific Member**

Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Example: Nonscientific members who are lawyers should present legal views of specific areas that may be discussed.
C. Community Representative

Community representatives are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

D. IRB Chairperson

In addition to the above duties, the chairperson is responsible for chairing the meetings. The IRB Chairperson performs, or delegates to appropriate voting IRB members authority to perform, expedited and exempt review when appropriate. The IRB chairperson is also empowered, pending IRB review to suspend the conduct of a study if he/she determines that an Investigator is not following IRB requirements. The IRB Chairperson may also delegate to the IRB Vice Chairperson to assist or act on behalf of the IRB Chairperson at IRB meetings.

IRB Members – Convened Meeting

The IRB is charged with protecting research subjects from risks in experimental studies. Principles codified in the Nuremberg Code, the Declaration of Helsinki, Belmont Report, and existing federal regulations are employed to provide a framework for ethical considerations and assessment of risk and benefit in individual studies. The decisions made by the IRB are guided by these principles, but the IRB can only be successful if members are free of conflict of interest (COI).

Prior to discussion of protocols at a convened meeting, the IRB Chair will ask if any member has a COI with any protocol being discussed at that meeting. A conflict of interest may include financial interests of the IRB member or immediate family members (spouse, domestic partner, and dependents) without any de minimus, as well as nonfinancial issues. A financial interest exists when the member has financial relationship with the sponsor, product or service being tested.

Should an IRB member declare involvement in any way in a research protocol under review by the IRB, or state a COI with the research protocol the following is required:

1. IRB member is excluded from discussion and voting except to provide information requested by the IRB.
2. IRB member leaves the meeting room during discussion and voting.
3. IRB member is not counted towards quorum.

IRB members with a conflict are documented in the minutes as being absent with an indication that a conflict of interest was the reason for the absence.

**Designated Reviewers for Expedited Review**

IRB members (including experienced IRB staff members) who have been designated by the IRB Chair as reviewers for initial or continuing review of research protocols, reports of noncompliance, protocol deviations, unanticipated problems, and amendment requests that qualify for expedited review will self-identify any COI that they may have with the research or PI. In such cases, the review responsibility will be reassigned to another experienced IRB member.

**Conflicts of Interests (COI) for IRB Members**

**Examples of IRB Member COI**

IRB members are considered to have a conflict of interest if they:

1. Are involved in the design, conduct, or reporting of the research study.
2. Have direct administrative powers over the investigators or the study.
3. Have a financial and/or ownership interest of any amount in or related to the research and the value can be readily determined.
4. Have a financial and/or ownership interest in or related to the research but the value cannot be readily determined.
5. Received or will receive compensation and/or have ownership interest of any amount with value that may be affected by the outcome of the study.
6. Have received in the past year, currently are receiving, or will receive from the sponsor of the study, honoraria, payments, or compensation of any amount.
7. Have a proprietary interest in the research, including but not limited to a patent, trademark, copyright, or licensing agreement.
8. Serve as directors, board members, scientific advisors or hold other decision-making positions in the entity sponsoring the research.
9. Are not an investigator, co-investigator, or consultant on a study, but are closely associated with the investigators on the study being reviewed, or other studies.
10. Have personal, familial, or intimate relationships with the principal investigator.
11. For any reason, believe they cannot be objective concerning a study.

In order to avoid real or perceived conflicts of interest in the conduct of IRB business, any IRB member must recuse themselves from the application review and approval process of any research protocol in cases where the IRB
member has a significant financial interest in the sponsor of the research, or is involved in the design, conduct, or reporting of the research, or has any other interest that may reasonably be considered to interfere with an objective review of the research.

**Meetings of the IRB**

The IRB meets on the third Thursday of each month to review applications and to conduct other items of business. The IRB maintains minutes of its meetings. Minutes that have been approved by the IRB are available to the public for review, upon written request to the IBC. Prior to the release of any requested minutes, the IRB with assistance from the Office of University Counsel will redact the minutes to ensure that confidential and private information is not released. Confidential and private information shall include, but not be limited to, individually identifiable health information as defined in the Health Insurance Portability and Accountability Act of 1996 and any regulations and official guidelines promulgated there under directory information, proprietary information, intellectual property information, trade secrets, and attorney-client privileged information.

**Obtaining an IRB Review**

**How do I submit my research for review by the IRB?**

All IRB applications must be submitted online via IRBNet system at [www.irbnet.org](http://www.irbnet.org). How to submit via IRBNet is listed on the [www.famu.edu](http://www.famu.edu) website under Institutional Review Board tab. The following is listed:

- How to **REGISTER** as a new user
- How to **SUBMIT** a new IRB application via IRBNet (visual tutorial).
- **STEPS TO SUBMT** a new application via IRBNET (written instructions)
- How to submit **AMENDMENTS, CONTINUING REVIEWS** or any additional information to my IRB.

If you have any questions on how to use IRBNet, please contact any of the Office of Animal Welfare and Research Integrity Staff.

- Dr. Tanise L. Jackson, Director – Phone: 850.599.3214 [tanise.jackson@famu.edu](mailto:tanise.jackson@famu.edu)
- Mrs. Sherry Kemp, Administrative Assistant – Phone: 850.412.5246 [sherry.kemp@famu.edu](mailto:sherry.kemp@famu.edu)

**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 Welfare and Research Integrity 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. All IRB applications must be placed in the IRBNet system, no later than 5:00 pm on the deadline date.

 pobl 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.

 pobl 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.

 pobl 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.

 pobl When will my application be reviewed?

If your applications along with all your research tools are placed into the IRBNet system by 5:00 p.m. on the application deadline date, you will make the meeting
for that month. However, if your application is not received prior to the deadline date you will automatically be placed on the agenda for the next month meeting.

❖ **How will I know the status of my application?**
Once your IRB application is reviewed by the Institutional Review Board (IRB) you will receive a response within 2 to 3 business days following the meeting. All correspondences will be sent via IRBNet system.

❖ **How will I receive the stamped documents to conduct my research?**
Upon approval all your stamped documents will be sent via the IRBNet system along with your approval letter.

❖ **How do I make a change in my application or survey instrument and/or how do I submit changes to an application?**
Please note that projects are **not unlocked** for revisions, the steps below will allow you to make changes to your application or survey instrument:


**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.

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.

❖ **What documentation is required at the end of my project?**
Once your research is complete and/or your project has expired, you are asked to go into the IRBNet system and complete the close-out review. Below are the instructions for selecting the close-out form:

Forms and templates
Select IRB Close-out Review 2014.doc
Complete and upload back into the IRBNet system

All principal investigators proposing to conduct research involving human participants should seek an IRB review as soon as possible in the following manner:

1. Complete the Application for IRB Review and answer all questions in the way the same information appears in the proposal.
2. Attach a copy of the Informed Consent to the IRB Review Form, when appropriate.
3. Submit one copy of the following to the IRB Administrative Office:
   a. Full proposal
   b. Informed Consent
   c. When appropriate, submit copy of all instruments to be administered and data collection sheets.
4. The IRB staff shall deliver copies of the application and Informed Consent to each member of the Board for review.
5. The project will be reviewed at the next scheduled meeting of the IRB. The principal investigator or a designee may attend the meeting to present the risk implications involved in the proposed research. If needed, principal investigators who are unable to attend the meeting should be available for a teleconference.
6. Faculty advisors to graduate students’ research shall always be listed as the principal investigator.

Researchers and Research Staff

The University HRPP policy requires training for all faculty, faculty mentors, researchers, and students, including researchers from other institutions who wish to conduct human subjects research at the University. All key personnel (PI, Co-PI, Faculty Sponsor), originally listed or later added to a study through an amendment, must complete the required human subjects training. In order to comply with the policy, researchers are required to complete the University’s training affiliated with Collaborative Institutional Training Initiative (CITI) (modules relating to ethics, regulations, risk assessment, informed consent and privacy and confidentiality). Completion of this training must be accomplished every three years. Protocol submissions (initial, continuing,
amendments) are checked to assure all researchers and research staff have completed training. Protocol actions are not approved until training is completed by all listed on the protocol. Webinars and local conferences are made available to the University community for additional training.

**Expedited Review Procedures**

A less than formal IRB review, expedited, can be conducted for minimal risk and for minor changes in approved research. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The procedure for an expedited review is as follows:

1. May be carried out by the IRB chairperson or one or more experienced reviewers designated by the chairperson as authorized by Section 56.110 of the FDA regulations.
2. Chairperson or the IRB member(s) may exercise all of the authorities of the full Board except that the reviewer(s) may not disapprove the research. (A majority of the IRB members is needed to disapprove a research activity).
3. All IRB members must be apprised of an expedited review.
4. FDA may restrict the use of expedited reviews by an institution when the restriction is seen as needed to protect the rights of human participants.

**Approval Notification**

Written notification of approval will be sent by the IRB secretary to the principal investigator.

1. Notifications will include, as appropriate, approval of the:
   a. informed consent
   b. protocol
   c. investigators
   d. limitations imposed by the Board
   e. dates of approval for the protocol
2. Written notification will include the following responsibility by the investigators during the research period:
   a. promptly report to the Board any changes in research activities,
   b. no changes without Board review and approval unless “apparent immediate hazard to human participants” is being eliminated
c. promptly report any unanticipated problems involving risks to the subjects or others

**Modification of Projects**

1. When modifications of pre-approved projects are necessary, the principal investigator will submit a modification form in the IRBNet system for review.

**Informed Consent**

1. All research projects will include an Informed Consent which meets FDA guidelines 21CFR-Part 50. An Informed Consent shall provide the following information:
   a) A statement that the study involves research
   b) An explanation of the purpose of the research
   c) The expected duration of the participant’s participation
   d) A description of the procedures to be followed
   e) Identification of any procedures which are experimental
2. A description of any reasonably foreseeable risks or discomforts to the participant.
3. A description of any benefits to the participant or to others, which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
6. For research involving more than minimal risk, an explanation of any compensation and an explanation of any medical treatments that are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to the participant is otherwise entitled.
9. When appropriate, one or more of the following elements of information shall also be provided in the consent.
10. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the
participant is or may become pregnant) which are currently unforeseeable.

11. Anticipated circumstances under which the participant’s participation may be terminated by the investigator, without regard to the participant’s consent.

12. Any costs to the subject that may result from participation in the research.

13. The consequence of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the participants.

14. A statement will be provided to the participant indicating findings developed during the research which may be related to participant’s willingness to continue participation.

15. The approximate number of participants involved in the study.

16. Documentation of informed consents:
   a. Written approval of the IRB must be on record.
   b. Copy shall be given to the persons signing the form.
   c. The consent that will be read to the participants or their legally authorized representatives or they shall have adequate opportunity to read the consent before it is signed.
   d. If consents are to be used with verbal explanations the Board will approve a written summary of what is said to the participant or the representative:
      1) only the form itself is signed by the participant/representative,
      2) the witness shall sign the form and a copy of the summary (person actually obtaining the consent shall sign a copy of the summary), and
      3) A copy of the summary shall be given to the participant or representative.

**Exempt Research**

§46.104  Exempt research.

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as
follows:

(1) *Subpart B.* Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C.* The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) *Subpart D.* The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a
manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the
Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

**Limited IRB Review**

Limited IRB review is a process that is required only for certain exemptions and does not require an IRB to consider all of the IRB approval criteria in §46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.
**Single IRB-of-Record (sIRB)** - IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting January 20, 2020.

**Research Request from Outside of the University**

Research that is requested from outside of the University must adhere to the following procedures:

1. Those requesting to perform research form outside of the university must first contact the IRB Administrative Office.
2. An Unaffiliated Investigator Agreement will be completed and placed in the IRBNet system.