Standard Operating Procedure (SOP) for the Handling of Allegations of Non-Compliance with Human Subject Protection Laws, Regulations and Policies

I. Introduction:

This document describes the process that Florida International University (FIU) Institutional Review Board (IRB) for the protection of human subjects follows for allegations and findings of non-compliance with policies and regulations governing research involving human subjects.

The FIU IRB is responsible for review and approval of all investigations involving human subjects in accordance with 45 CFR Part 46 and 21 CFR Parts 50 and 56. The primary concern of the IRB is the protection of the rights, welfare, and safety of human subjects.

All members of the research community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional policies and procedures governing the conduct of research involving human subjects.

The IRB encourages those who are aware of, or concerned about the potential non-compliance by researchers, to report their concerns to the IRB as set forth in this SOP.

II. Applicability:

This SOP applies to all faculty, staff, and students conducting human subject research.

III. Definitions:

Allegation of non-compliance: An unconfirmed report of non-compliance with applicable federal, state, or local laws or regulations, IRB SOPs, or with an approved IRB protocol.

Complainant: The individual who presents an allegation of non-compliance. Such an allegation of non-compliance must be made in good faith and with a reasonable basis for believing that the non-compliance occurred.

Continuing non-compliance: Non-compliance that has been previously reported and that re-occurred after the non-compliance individual was provided with education on the non-compliance. Also, a pattern of non-compliance that suggests a lack of understanding of human subjects' protection requirements.

Finding of non-compliance: A determination of non-compliance pursuant to this SOP.

HIPAA: Health Insurance Portability and Accountability Act.

***Inquiry Committee*:** The committee tasked with reviewing allegations of non-compliance which is comprised of the following members: the Health Sciences-IRB Chair, the Social and Behavioral-IRB Chair, and the Director of Research Integrity. The Inquiry Committee will also be comprised of the following alternate members: the IRB Co-Chair and the Associate Director of Research Integrity. Additional members may be appointed by the Institutional Official (or his/her designee) if specialized knowledge or additional representation is required to resolve an allegation of non-compliance. The Compliance Officer and Legal Counsel shall serve in an advisory capacity as needed.

Institutional Official: The individual at an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of research with human subjects. The FIU Institutional Official is the Vice President for Research.

***Non-compliance*:** The failure (intentional or unintentional) to comply with applicable federal, state, or local laws or regulations, IRB SOPs, or with an approved IRB protocol.

OHRP: The Office of Human Subjects Research Protection of the U.S. Department of Health and Human Services. This is the U.S. regulatory body providing oversight of human subject research in the biomedical and social-behavioral fields.

ORI: The Office of Research Integrity within the Office of Research and Economic Development (ORED). This is the office overseeing research compliance at FIU.

Respondent: The person against whom an allegation of non-compliance has been made.

Serious non-compliance: Non-compliance that has the potential to increase the risks to subjects or to adversely affect the subject's(s') rights or wellbeing.

Subject: A human participant in a research project at FIU which requires the approval of the IRB.

IV. Non-Compliance:

Non-compliance may be minor or serious, sporadic or continuing. The degree of non-compliance is evaluated on a case-by-case basis, taking into account considerations such as to what degree the subjects were harmed or placed at an increased risk and the willfulness of the non-compliance.

Examples of non-compliance include, but are not limited to the following:

- Conducting human subjects research without a proper IRB exemption or approval in place;

- Failing to follow the requirements of an approved IRB protocol in conducting human subjects research, including but not limited to, failure to maintain required documents of the study;
- Failing to cooperate with the IRB in fulfilling protocol application and reporting requirements;
- Failing to timely respond to requests for information and documentation from the IRB
- Enrolling subjects in a study who fail to meet inclusion or exclusion criteria of the approved IRB protocol;
- Enrolling subjects in a study after study approval has lapsed;
- Modifying an IRB-approved protocol without approval from the IRB;
- Willfully or negligently placing human subjects in a situation which could lead to serious harm to any subject in a manner that was not addressed in the approved IRB protocol and in the informed consent form signed by the subject;
- Applying coercion or undue influence to recruit or keep subjects in a study;
- Breaching subject confidentiality;
- Failing to report adverse event(s) or unanticipated problems within the required time frames; or
- Intentionally misleading subjects, other investigators, study sponsors, or any others.

Only the IRB and/or the Institutional Official may make the determination of non-compliance based on the recommendation of the Inquiry Committee. If a finding of non-compliance is determined to be serious and/or continuing, the same shall be reported to the OHRP as stated below.

V. Reporting Allegations of Non-compliance*:*

Allegations of non-compliance may be made known to FIU in several ways, including but not limited to:

- Reported by the OHRP to FIU;
- During post-approval monitoring of the research project by ORI;
- Reports from collaborators, study personnel, employees, subjects and/or their family members or community members; or
- Complaints from anonymous sources.

The following are the preferred methods to report allegations of non-compliance in human subject research:

- Send an email to ori@fiu.edu; or
- Report via the FIU Convercent hotline (must be used if you wish to remain anonymous) https://compliance.fiu.edu/convercent.html

Allegations should include as much information as the person reporting the allegation knows, including:

- A detailed description of the allegation of non-compliance;
- Name of the principal investigator of the study involved;
- The name(s) of personnel alleged to have committed/be committing the non-compliance; and

- The title and IRB approval number of the protocol.

It is a violation for any individual to engage in retaliatory acts against any individual who reports an incident of non-compliance, or assists or participates in a proceeding or investigation relating to allegations of non-compliance.

VI. Process for Evaluating Allegations of Non-compliance*:*

A. <u>Receipt of Allegation and Potential Study Administrative Hold</u>. Upon receiving an allegation of non-compliance, the Director of ORI shall confer with the Institutional Official as to whether the allegation is of such a nature that it warrants a temporary administrative hold of the study at issue pending review by the Inquiry Committee. If so, the Director of ORI (or his/her designee) shall advise the PI of the allegation of non-compliance and that continuation of the study is on hold pending completion of the Inquiry Committee review. The PI may submit to the Director of ORI any documentation the PI wishes be provided to the Inquiry Committee as part of its review.

B. <u>Inquiry Committee</u>. ORI will promptly assemble the Inquiry Committee to review all material provided by the complainant (and the PI of the study, if any documentation has been provided). The Inquiry Committee may determine that it is necessary to interview the complainant, if the complainant is known, in which case ORI shall arrange for such interview. The Inquiry Committee shall also review the approved IRB protocol for the study as well as any other documents the Inquiry Committee deems appropriate. No member of the Inquiry Committee may have an actual or potential conflict of interest as relates to the allegation of non-compliance being reviewed. Each member of the Inquiry Committee must disclose to the Director of ORI or to the Institutional Official, as appropriate, any conflict as soon as the member becomes aware of it. Any member with a conflict with reference to an allegation of non-compliance shall be excused from service on the Inquiry Committee reviewing that allegation.

C. <u>No Investigation Warranted/Can be Pursued</u>. If the Inquiry Committee determines that the allegation has not received sufficient information to determine whether non-compliance has occurred and/or has no basis in fact, no further investigation will be required. The Inquiry Committee shall notify the complainant, if known, of the reasons for the decision. If the allegation was made via the University's Convercent hotline, the Director of ORI (or his/her designee) shall notify the complainant on Convercent so that the complainant may provide additional information if such exists. If no additional information is provided after a reasonable period of time, the in inquiry shall be closed.

D. <u>Research Misconduct</u>. If the Inquiry Committee determines the allegation constitutes possible research misconduct, the allegation shall be reviewed in accordance with the ORED Research Misconduct policy, # 2370.070 as relates to the research misconduct allegation.

E. **HIPAA Violations.** If the allegation constitutes a possible HIPAA violation, the Compliance and Privacy Official for Health Affairs will be promptly notified.

F. **Inquiry Committee finding that additional investigation is warranted regarding allegation of IRB non-compliance.** If the Inquiry Committee determines that further investigation is warranted relating to potential IRB non-compliance, the Inquiry Committee shall notify the Institutional Official (or his/her designee) in writing. ORI will then notify the Respondent, if the respondent has not been notified previously during the administrative hold of the study. The notification shall advise the respondent that: 1) an allegation of non-compliance has been made involving him/her and of the specific nature of the allegation; 2) an inquiry has determined that an investigation is warranted and will be conducted regarding the allegation; and, 3) the respondent will have an opportunity to respond to the allegations as part of the investigation.

G. **IRB Research Procedures and Temporary Suspension of Study.** At any time during the investigation process, the Inquiry Committee may convene the applicable IRB to determine whether research procedures should be modified or whether the study enrollment should be suspended while investigating the allegation. In addition, the Director of ORI (or his/her designee) and/or the Institutional Official (or his/her designee) reserve the right to place an administrative hold on the study at any time pending the final outcome of the allegation investigation.

H. **Complete Investigation.** The Inquiry Committee shall conduct a thorough and timely investigation of whether there was/is, in fact, a situation of non-compliance and whether it was/is serious and/or continuing. The investigation may include, but is not limited to:

- Requesting a written response from the respondent regarding the allegation;
- Interviewing members of the research team, the respondent, the complainant, and/or any subjects;
- Conducting an unannounced laboratory visit; and/or
- Reviewing research records.

I. **Inquiry Committee Final Report.** Upon conclusion of the investigation, the Inquiry Committee shall prepare a final written report to the Institutional Official detailing the investigation process and its findings and recommendations. The report will also document the recommendation of the Inquiry Committee regarding whether there is/was non-compliance and, if so, whether the non-compliance is/was serious and/or continuing as determined by a majority vote of the Inquiry Committee. If the Inquiry Committee determines that there was/is non-compliance, the Inquiry Committee shall also recommend the actions to be taken, which may include, but are not limited to:

1. For Non-Compliance that is determined not to be Serious or Continuing:

a. Sending a letter of reprimand to the respondent and the PI, if appropriate,

(copied to their respective department chair, dean, institute and/or center director, faculty advisor (student research) and research compliance coordinator);

b. Educating the respondent and the PI, if appropriate, as well as the department, institute or center staff;
c. Requiring for researchers to complete training courses/seminars;
d. Requiring that the respondent or the PI, if appropriate, create a plan of action to remedy the non-compliance;
e. Modifying the research protocol;
f. Notifying current subjects of the non-compliance (required when such information may relate to subject' willingness to continue to take part in the study); and/or
g. Requiring current subjects to re-consent to participate in the study;

2. For Non-Compliance that is determined to be Serious or Continuing*:*

a. A meeting of the IRB shall be convened to review:
    i. A copy of the approved IRB protocol;
    ii. The minutes of the relevant IRB meeting, if the protocol warranted a full IRB review;
    iii. A copy of the Inquiry Committee Final Report; and
    iv. Any other relevant materials.

b. The IRB shall determine what actions to take to protect the rights and welfare of the subjects. These actions may include, but are not limited to:
    i. Obtaining more information pending a final decision;
    ii. Requesting that the PI provide a corrective action plan;
    iii. Educating the respondent and the PI, if applicable, and/or all research staff;
    iv. Requiring for researchers to complete training courses/seminars;
    v. Suspending or terminating the study;
    vi. Suspending all protocols of the respondent or the principal investigator (temporarily or permanently);
    vii. Conducting random audits of the studies conducted by the respondent or the principal investigator and/or all research staff;
    viii. Modifying the research protocol;
    ix. Confiscating all data collected during the period of non-compliance
    x. Notifying current subjects of the non-compliance (required when such information may relate to subject' willingness to continue to take part in the study);
    xi. Requiring current subjects to re-consent to participate in the study;
    xii. Modifying the IRB's continuing review schedule for the study;
    xiii. Monitoring of the research or the consent process;
    xiv. Recommending, as relates to the respondent or the PI, if applicable, suspension or revoking the privilege to conduct human subject research as a PI or Co-PI or serve as a faculty advisor of student

research at FIU; and/or

xv. Referral to other organizational entities (e.g., General Counsel, Human Resources).

c. As required by applicable law, regulation or FIU policies and procedures, the Institutional Official shall report, in writing, the finding of serious or continuing non-compliance and the action(s) taken by FIU to address such non-compliance, to regulatory agencies and to the study sponsor, and to the applicable department chair(s) and/or dean(s), institute(s) and/or center director(s), the faculty advisor(s) (for student research), and other FIU officials as appropriate.

d. The IRB must report to OHRP or FDA, under applicable law and regulations as noted below:

   i. Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or others (http://www.hhs.gov/ohrp/policy/advevntguid.html);

   ii. Any serious or continuing non-compliance with IRB requirements;

   iii. Any suspension or termination of IRB approval (http://www.hhs.gov/ohrp/compliance/reports/index.html) (http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm).