Standard Operating Procedure (SOP) for the Handling of Allegations of Non-Compliance with Recombinant or Synthetic Nucleic Acid Molecules, Regulations and Policies

I. Introduction:

This document describes the process that Florida International University (FIU) Institutional Biosafety Committee (IBC) follows for allegations and findings of non-compliance with policies and regulations governing research involving recombinant and/or synthetic nucleic acid molecules.

The FIU IBC is responsible for review and approval of all investigations involving recombinant and/or synthetic nucleic acid molecules in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. The primary concern of the IBC is to ensure that the research is conducted in full conformity with the provisions of the *NIH Guidelines*.

All members of the research community involved in research involving recombinant and/or synthetic nucleic acid molecules 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 recombinant and/or synthetic nucleic acid molecules.

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

II. Applicability:

This SOP applies to all faculty, staff, and students conducting work with recombinant and/or synthetic nucleic acid molecules.

III. Definitions:

Allegation of non-compliance: An unconfirmed report of non-compliance with applicable federal, state, or local laws or regulations, IBC SOPs, or with an approved IBC 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 the *NIH Guidelines*.

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

***Inquiry Committee*:** The committee tasked with reviewing allegations of non-compliance which is comprised of the following members: the IBC Chair, the Associate Director of Research Integrity, and the 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 recombinant and/or synthetic nucleic acid molecules. The FIU Institutional Official is the Vice President for Research and Dean of the University Graduate School.

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

OBA: The Office of Biotechnology Activities manages and evaluates the current biosafety policies for NIH-supported research at institutions in the US and abroad to ensure that such research is conducted in accordance with the highest standards to protect the health of researchers, the public and the environment.

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 personnel or to adversely affect the environment.

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 of exposure and the willfulness of the non-compliance.

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

- Conducting activities that involve the use of recombinant DNA or synthetic nucleic Acid molecules or DNA or RNA derived from synthetic nucleic acid molecules without a proper IBC exemption or approval in place;

- Failing to follow the requirements of an approved IBC protocol ;
- Conducting rDNA or SNA work after study approval has lapsed;
- Modifying an IBC-approved protocol without approval from the IBC;
- Spills and accidents in BL2 laboratories resulting in an overt exposure;
- Failing to report adverse event(s) or unanticipated problems within the required time frames

Only the IBC 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 OBA 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 OBA to FIU;
- New IBC applications or continuing reviews submitted to the IBC may reflect instances of non-compliance in the conduct of previously IBC approved protocols;
- Reports from collaborators, study personnel, or employees; or
- Complaints from anonymous sources.

The following are the preferred methods to report allegations of non-compliance in research with recombinant or synthetic nucleic acid molecules:

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

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 IBC approval number of the protocol (if applicable)

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. Receipt of Allegation and Potential Study Administrative Hold. 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. Inquiry Committee. 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 IBC protocol (if applicable) 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. No Investigation Warranted/Can be Pursued. 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. If no additional information is provided after a reasonable period of time, the inquiry shall be closed.

D. Research Misconduct. If the Inquiry Committee determines the allegation also constitutes possible research misconduct or constitutes research misconduct and not an IBC non-compliance, the allegation shall be reviewed in accordance with the ORED Research Misconduct policy, # 2370.070 as relates to the research misconduct allegation.

E. Inquiry Committee finding that additional investigation is warranted regarding allegation of IBC non-compliance. If the Inquiry Committee determines that further investigation is warranted relating to potential IBC 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.

F. IBC Research Procedures and Temporary Suspension of Study. At any time during the investigation process, the Inquiry Committee may convene the applicable IBC to

determine whether research procedures should be modified or whether the study 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.

G. <u>Complete Investigation</u>. 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, and/or the complainant;
- Conducting an unannounced laboratory visit; and/or
- Reviewing research records.

H. <u>Inquiry Committee Final Report</u>. 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 as follows:

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; and/or
c. Requiring that the respondent or the PI, if appropriate, create a plan of action to remedy the non-compliance.

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

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

b. The IBC shall determine what actions to take to protect the health of

researchers, the public and environment. 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. Suspending or terminating the study;
v. Suspending all protocols of the respondent or the principal investigator (temporarily or permanently);
vi. Conducting random audits of the studies conducted by the respondent or the principal investigator and/or all research staff;
vii. Modifying the research protocol;
viii. Confiscating all data collected during the period of non-compliance
ix. Recommending, as relates to the respondent or the PI, if applicable, suspension or revoking the privilege to conduct rDNA/SNA work as a PI or Co-PI or serve as a faculty advisor of student research at FIU; and/or
x. 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 IBC must report to OBA under applicable law and regulations as noted below:
   i. Office of Biotechnology Activities – Incident Reporting (http://www.osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting)
   ii. FAQs on Incident Reporting (http://www.osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting)