



## Reporting of Non-Compliance with IRB Regulations and/or Requirements

### PURPOSE

- 1.1. The purpose of this policy is to describe the procedures the IRB office follows when a non-compliance allegation or complaint is reported.

### 1. SCOPE

- 1.1. This policy applies to all human subjects research under the oversight of Clemson University (CU) IRB, including cooperative research projects, regardless of the level of review of the study or the study status.

### 2. POLICY STATEMENT

- 2.1. CU applies the federal regulations 45 CFR 46 when research is sponsored or overseen by a federal agency. When studies do not receive funding from, or are not otherwise regulated by, a federal agency, CU has adopted policies and procedures to accommodate difference in types of research. In these instances, CU adopted equivalent protections for participants.
- 2.2. Non-compliance means conducting research involving human subjects in a manner that disregards or violates CU policies, state or federal regulations governing such research. The IRB reviews all allegations of non-compliance according to human subjects protections regulations and its own requirements.
- 2.3. Any individual or organization may submit a complaint or allegation of non-compliance regarding CU researchers or a project conducted under the oversight of CU IRB. The IRB may also initiate a complaint based on information available to the IRB (e.g., deficiencies noted in IRB records, media, or scholarly reports of research activity subject to IRB jurisdiction).
- 2.4. Non-compliance can include, but is not limited to the following:
  - a. Conducting research involving human subjects without IRB approval;
  - b. Conducting research prior to receiving IRB notification of final approval;
  - c. Initiation of substantial changes (i.e., changes to recruitment procedures, research methods, informed consent process) to the IRB application and/or protocol without prior IRB approval, including changes necessary to eliminate apparent immediate hazards to the subject;
  - d. Inclusion of vulnerable subject populations without specific IRB approval;
  - e. Conduct of research when IRB approval has expired or been closed, suspended, or terminated;
  - f. Interactions with participants or review of identifiable research data by individuals who have not completed appropriate investigator requirements (e.g., COI disclosure and CITI training);
  - g. Failure to obtain informed consent from each prospective participant according to the IRB-approved study, including obtaining consent from someone who cannot legally consent for the participant;
  - h. Conduct of research after participant decides not to participate, dissents, or withdraws from the research;
  - i. Failure to provide ongoing progress reports as requested by the IRB;
  - j. Failure to promptly report non-compliance events when required per CU IRB policies;
- 2.5. Serious and/or continuing non-compliance must be reported to the CU IRB within three (3) business days of the study team becoming aware of the event.
  - a. Serious noncompliance is a failure to adhere to the policies and/or regulations governing human subjects research that involve substantive harm or a genuine risk of substantive harm to the safety, rights or welfare of human subjects or research staff, or others.
  - b. Continuing noncompliance is a persistent failure, willful or otherwise, to adhere to the policies or regulations governing human subjects research.



### 3. SUBMISSION AND REVIEW OF NON-COMPLIANCE TO THE IRB OFFICE

#### 3.1. Allegations or complaints may be reported to the IRB office by:

- a. Submitting the Reportable Incidents eForm through the IRB online submission system, InfoEd, <https://infoed.clemson.edu>;
- b. E-mail at [irb@clemson.edu](mailto:irb@clemson.edu)
- c. Phone at (864) 656-0636
- d. Contacting the ethics/safety hotline, <https://www.clemson.edu/administration/internalaudit/ethicsline.html>

#### 3.2. Initial Review of Reportable Incidents Report

- a. The IRB Program Administrator and/or IRB Chair will review the report to determine if the incident constitutes serious or continuing non-compliance and if further investigation is required.
- b. Incidents that fall under the scope of the CU research misconduct policy will be reported to the Research Integrity Officer.
- c. The IRB Program Administrator will notify the Principal Investigator (PI) that an allegation or complaint of non-compliance was reported to the IRB office if the report was not submitted through the IRB online submission system or if the PI is not the individual reporting the incident. The name of the individual reporting the incident will not be shared with the PI.

### 4. INVESTIGATING REPORT OF NON-COMPLIANCE

#### 4.1. The IRB Program Administrator and/or IRB Chair will investigate the incident.

- a. The PI will be required to provide a written response if the incident was not submitted through the IRB online submission system or reported by the PI.
- b. The PI should provide an explanation of the noncompliance, the cause or steps leading to the noncompliance, the impact (if any) to human subjects, and proposed corrective actions in response to the noncompliance.

#### 4.2. Incidents Determined Not to be Serious or Continuing Non-Compliance

- a. The IRB Program Administrator and IRB Chair will review and accept the report without review by the convened IRB.
- b. The IRB Program Administrator will send a written response of the findings to the PI.
- c. A report of Incidents reviewed and determined not to be apparent serious or continuing non-compliance is periodically provided to the convened IRB and the Office of Research Compliance (ORC) Director.

#### 4.3. Incidents Determined to be Serious or Continuing Non-Compliance

- a. The IRB Program Administrator will notify the ORC Director and IRB members and submit the report to a convened IRB meeting for review and possible action.
- b. The PI may be requested to appear at the convened IRB meeting.

### 5. CONVENE IRB REVIEW OF NON-COMPLIANCE

#### 5.1. The convened IRB reviews the report to determine:

- a. If report constitutes serious or continuing noncompliance.
- b. If the research protocol still satisfies the requirements for IRB approval under 45 CFR 46.111. In particular, the IRB considers whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result.
- c. If the event presents an unanticipated problem involving risks to subjects or others.



d. If further investigation is warranted.

5.2. If further investigation is warranted, a subcommittee will be created to include the IRB Program Administrator and members appointed by the IRB Chair. The subcommittee will be responsible for:

- a. Reviewing the IRB protocol;
- b. Interviewing study team personnel;
- c. Consulting with appropriate CU offices, if necessary, to determine if other institutional policies and oversight is required; AND
- d. Reporting findings to the convened IRB.

5.3. Determination and Findings

- a. The convened IRB will vote to determine if:
  1. The human subjects research activities should continue with modifications to the research design and methods.
  2. Sanctions are required. Examples include, but are not limited to:
    - 5.3.a.2.1.1. New or repeated training of personnel
    - 5.3.a.2.1.2. Amending study procedures
    - 5.3.a.2.1.3. Additional monitoring or reporting to the IRB
    - 5.3.a.2.1.4. The human subjects research activities be suspended until further investigation is complete.
    - 5.3.a.2.1.5. The human subjects research activities should be terminated.
- b. The IRB Program Administrator will send a written response of the findings to the PI, ORC Director, Department Chair, the college Associate Dean of Research (ADR), and other institutions IRB office for cooperative research projects. The findings should include a summary of the allegation, a summary of the review, cite the noncompliance (policy, regulation, etc.) and recommended sanction.
- c. If the IRB determines that a report does represent an unanticipated problem involving risks to subjects or others, the determination is reported to appropriate institutional officials, federal regulatory agencies (e.g., OHRP, FDA), research sponsors and others pursuant to the CU policies.

## 6. **SANCTIONS**

- 6.1. Individuals found to be in violation of this policy may be subject to sanctions relating to their participation in research with human subjects, up to and including permanent suspension or debarment from engaging in research with human subjects at CU.
- 6.2. Additional sanctions may be placed by federal regulatory agencies and research sponsors.

## 7. **CONFIDENTIALY**

- 7.1. The IRB members and IRB staff will follow all CU confidentiality policies during the review and investigation process, including protecting the identify of individuals reporting allegations or complaints of non-compliance.

## 8. **RETALIATION**

- 8.1. The ORC Director will assist the IRB in protecting complainants from retaliatory actions.



## 9. ADDITIONAL RELATED RESOURCES

### 9.1. CU:

- a. Division of Research policies, <https://www.clemson.edu/research/division-of-research/research-policies.html>
- b. Research Misconduct Policy, <https://www.clemson.edu/research/compliance/research-misconduct/>
- c. Whistleblower and Non-Retaliation Policy, <https://www.clemson.edu/research/division-of-research/resources/policies.html>
- d. IRB Review Procedures and Other Policies, <https://www.clemson.edu/research/division-of-research/offices/orc/irb/resources/index.html>

### 9.2. U.S. Department of Health and Human Services (HHS)

- a. Office for Human Research Protections (OHRP): Reporting Incidents to OHRP (2022), <https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html>
- b. The Office of Research Integrity Policies, <https://ori.hhs.gov/ori-policies>

## 10. RESPONSIBLE DEPARTMENT/DIVISION:

- 10.1. The CU IRB program administrator should be contacted regarding questions or issues with this policy.

## 11. PUBLISHED LOCATION:

- 11.1. This policy may be accessed on the IRB webpage, <https://www.clemson.edu/research/compliance/irb/>.

## 12. APPROVAL & REVISION HISTORY

- 12.1. Last Date of Revision: 6/2023

## 13. REFERENCES

- 13.1. Title 45 Code of Federal Regulations Part 46 (45 CFR 46), Protection of Human Subjects
- 13.2. Policy adapted, with permission, from the Indiana University Human Research Protection Program (HRPP)