Special Topics: XXII. Non-Compliance				
Effective Date:	**Supersession:**		**Page**	**SOP# 22**
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A. Introduction:

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

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

46 and 21 CFR 50 and 56.

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 of non-compliance by researchers, to report their concerns to the IRB.

B. Applicability:

This SOP applies to all faculty, staff, and students conducting human subject research as defined by the UCCS IRB Standard Operating Procedures.

C. Definitions:

Complainant: The Complainant is the individual who presents an allegation of non-compliance with Human Subject Protection Regulations. The University requires any person who makes an allegation of non-compliance to proceed in good faith and with a reasonable basis for believing that non-compliance occurred.

***Executive Committee*:** The Executive Committee is comprised of the following members: the UCCS Research Integrity Officer (RIO), the IRB Chair, and an IRB member appointed by the RIO. Additional members may be appointed by the RIO if specialized knowledge is required to resolve an allegation of non-compliance. The Research Compliance Coordinator and Legal Counsel shall serve in an advisory capacity. The RIO will serve as chair of the Executive Committee.

Respondent: The Respondent is the person against whom an allegation of non-compliance with Human Subject Protection Regulations has been made.

Allegation of non-compliance: An unconfirmed report of non-compliance.

Finding of non-compliance: A determination of non-compliance (by the Executive Committee) that is determined by using the "Process for Evaluating Allegations of Non-compliance" found below.

***Non-compliance*:** Non-compliance is the failure (intentional or unintentional) to comply with relevant federal, state, or local laws or regulations, IRB SOPs, or following procedures in an approved IRB protocol.

Non-compliance may be minor or serious, sporadic or continuing. The degree of non-compliance is evaluated on a case-by-case basis and will take 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 exemption or approval.
- Failing to cooperate with the IRB in fulfilling application and reporting requirements.
- Failing to respond to requests for information and documentation.
- Enrolling research subjects who fail to meet inclusion or exclusion criteria of a protocol.
- Enrolling research subjects after study approval has lapsed.
- Substantially modifying an IRB-approved protocol without approval from the IRB and the deviation increases the risk to the subject.
- Willfully or negligently placing human subjects in a situation that could very likely lead to serious harm.
- Applying coercion or undue influence to recruit or keep human subjects in a study against their will.
- Breaching subject confidentiality.
- Failing to report an adverse event(s) or unanticipated problems within five business days of discovery of non-compliance.

Serious Non-compliance: Non-compliance that has the potential to increase the risks to participants or adversely affect research participants' rights or wellbeing. Some examples of serious non-compliance include but are not limited to the following: conducting human subjects research without IRB approval, failing to provide accurate reports on adverse events or unanticipated problems in a timely manner, and breaching subject confidentiality. If the IRB finds that the investigator intentionally misled subjects, other investigators, study sponsors, or any others, then the non-compliance is considered serious. Serious non-compliance may be reported to the Office of Human Research Protection (OHRP). Only the IRB/Executive Committee can make the determination of serious non-compliance.

Continuing Non-compliance: Non-compliance that has been previously reported, or a pattern of non-compliance that suggests a lack of understanding of human subjects protection requirements that continues after attempts to educate the Principal Investigator (PI). Some examples of continuing non-compliance include but are not limited to the following: repeated failures to renew IRB application ten working days before the protocol expires resulting in lapses of IRB review, inadequate oversight of ongoing research, or failure to respond to a request to resolve an episode of non-compliance within ten business days. Continuing non-compliance may be reported to OHRP.

D. Reporting Allegations of Non-compliance*:*

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

- Reported by the Office of Human Subjects Research Protection (OHRP);
- New applications or continuing reviews submitted to the IRB;
- Post-approval monitoring;
- Reports from collaborators, study personnel, employees, research participants and/or their family members, community members; or
- Complaints from anonymous sources.

The following are the preferred methods to report allegations of non-compliance:

- Send an email to composp@uccs.edu.
- Report via the CU Ethics line (must be used if you wish to remain anonymous) - https://secure.ethicspoint.com/domain/en/report_custom.asp?clientid=14973.

Allegations should include as much information as possible, such as:

- A detailed description of the allegation or indication of non-compliance***;**
- Name of the investigator;
- The name(s) of personnel alleged to have committed/be committing non-compliance; and
- The title and number of the protocol.

*****Required when reporting an allegation of non-compliance.

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.

E. Process for Evaluating Allegations of Non-compliance:

1. Upon receiving an allegation of non-compliance, the RIO and IRB Chair will determine if there is a need for the Executive Committee to be established. Once formed the Executive Committee will review all material provided by the complainant to determine whether an investigation is warranted. This may include interviewing the complainant, if known, and reviewing any other documents the Executive Committee deems appropriate. The Executive Committee shall make reasonable efforts to avoid real or apparent conflicts of interest on the part of those involved in the inquiry phase.

2. If the Executive Committee determines that there is not sufficient information to determine whether non-compliance has occurred and/or has no basis in fact, no further investigation will be required. The Executive Committee shall notify the complainant, if known, of the reasons for the decision.

3. If the Executive Committee determines the allegation constitutes possible research misconduct, the allegation shall be referred to the Research Misconduct Committee. No further investigation will be required of the Executive Committee.

4. If the Executive Committee determines an investigation is warranted for matters other than research misconduct, the Executive Committee shall notify the respondent in writing, stating:

a. The specific nature of the allegation;
b. An investigation will be conducted; **and**
c. The respondent will have an opportunity to respond to the allegations as part of the investigation.

5. At any time during the investigation process, the Executive Committee may convene the IRB to determine whether research procedures should be modified or whether the research or study enrollment should be suspended while investigating the allegation.

6. The Executive Committee shall conduct a thorough investigation to determine whether the allegation is serious and/or continuing non-compliance. The investigation may include, but is not limited to:
   a. Requesting a written response from the respondent regarding the allegations;
   b. Interviewing members of the research team, the respondent, the complainant, and/or subjects;
   c. Conducting an unannounced laboratory visit; **and**
   d. Reviewing research records.
7. Upon conclusion of the investigation, the Executive Committee shall prepare a written report detailing the investigation process that includes summaries of all interviews conducted, and the evidence reviewed. The report will also document the conclusions of the Executive Committee, including whether there was non-compliance and, if so, whether the non-compliance is serious and/or continuing as determined by a majority vote.

If the Executive Committee determines a finding of non-compliance, the type of non-compliance will be identified and the procedures in either section F or G will be followed, according to which is appropriate for the type of non-compliance identified.

F. Non-Compliance Determined not to be Serious or Continuing Non-Compliance Procedure:

1. If the non-compliance is determined to be neither serious nor continuing, the Executive Committee may decide what actions to take and report the outcome to the full IRB at the next convened meeting.

2. The actions may include, but are not limited to:
   a. Sending a letter of reprimand to the PI (copy to the department chair, dean, institute and/or center director, faculty advisor (student research) and research compliance coordinator);
   b. Educating the PI, department, institute, center, or staff; and/or
   c. Requiring that the PI create a plan of action to remedy the non-compliance.

G. Non-compliance Determined to be Serious or Continuing Non-compliance Procedure:

1. If the non-compliance is determined to be serious or continuing, the finding is brought to the full IRB at a convened meeting for consideration of actions to be taken.

2. The following information is distributed to the IRB:
   a. A copy of the approved IRB protocol;
   b. Minutes from the relevant IRB meeting, if the protocol warranted a full review;
   c. The title and abstract of the research project and/or grant proposal in which the non-compliance occurred;

d. The number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
e. A copy of the original submitted non-compliance allegation (if available);
f. A detailed description of the research/investigation performed by the Executive Committee; **and**
g. Any other relevant materials that were reviewed by the Executive Committee during their investigation.

3. The IRB shall determine what actions to take to protect the rights and welfare of the human subjects. These actions may include, but are not limited to:
   a. Obtaining more information pending a final decision;
   b. Requesting a corrective action plan;
   c. Educating the investigator and/or all research staff;
   d. Suspending or terminating the research;
   e. Suspending all protocols of the investigator (temporarily or permanently);
   f. Conducting random audits of the investigator and/or all research staff;
   g. Modifying the research protocol;
   h. Confiscating all data collected during the period of non-compliance;
   i. Notifying current participants (required when such information may relate to participants' willingness to continue to take part in the research);
   j. Requiring current participants to re-consent to participate;
   k. Modifying the continuing review schedule;
   l. Suspending or revoking the privilege to conduct human research as a PI or Co-PI or serve as a faculty advisor of student research at UCCS; **and**
   m. Submitting the allegation to the Research Misconduct Committee.

4. The Executive Committee shall report serious or continuing non-compliance with regulations and the action(s) taken, or in progress, to regulatory and supporting agencies, as required, the IRB, the department chair, dean, institute and/or center director, faculty advisor (student research), research compliance coordinator, and other institutional officials as appropriate.

5. The IRB must report to OHRP, under 45 CFR 46.103(a) and 46.108(a) or FDA, under 21 CFR 56.113. See the following for what must be reported:
   a. Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to
      i. Subjects or others - http://www.hhs.gov/ohrp/policy/advevntguid.html;
   b. Any serious non-compliance;
   c. Continuing non-compliance with IRB requirements; or
   d. Any suspension or termination of IRB approval -
      i. http://www.hhs.gov/ohrp/compliance/reports/index.html.

Applicable Regulations/Guidance:
21 CFR 50.25(b)(5), 21 CFR 56.108(b)(2), 21 CFR 56.112, 21 CFR 56.113, 21 CFR 56.115(b), 45 CFR 46.108(a)(3)(i), 45 CFR 46.111(b)(5), 45 CFR 46.112, 45 CFR 46.113, 45 CFR 46.115(b), "Guidance on Reporting Incidents to OHRP" (06/20/11)