Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 5: MANAGING NONCOMPLIANCE IN HUMAN RESEARCH PROTECTION PROGRAM

1. Subject of Policy & Procedure

Noncompliance occurs when research involving human participants is conducted in a manner that disregards or violates federal regulations, the policies or procedures of the Institutional Review Board (IRB), or institutional policies governing human research. Noncompliance with respect to human research participant protection violates Cornell's Federalwide Assurance Registration (FWA). Even in the absence of intent, an unapproved or otherwise noncompliant research activity may place a research participant at unnecessary risk.

This policy sets forth the definition and examples of noncompliance; the procedures for reporting an allegation of noncompliance to the IRB; and the procedures for the IRB's management of such allegations, and if appropriate, of confirmed noncompliance.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell University faculty, staff, or students or by anyone conducting a research activity supported by Cornell University or where Cornell is considered to be engaged in the research.

3. Terms and Definitions

Allegation: An assertion made by a party which has not yet been proven or supported by evidence.

Confirmed Noncompliance: An allegation of noncompliance that has been verified as a result of an investigation and/or a for-cause audit.

Continuing Noncompliance: A repeated pattern or un-rectified instance of noncompliance by an individual investigator or research staff member either on a single protocol or multiple protocols.

Noncompliance: Failure to comply with federal regulations; the policies or procedures of the IRB; or institutional policies governing human research. Examples of noncompliance include: (1) conducting human participant research without IRB approval (*e.g.*, before approval; after expiration of approval and in the absence of a continuation application submitted to the IRB; during a suspension of IRB approval; after termination of IRB approval); (2) disregarding or otherwise violating IRB-approved informed consent procedures (*e.g.*, failing to obtain consent/assent, using unapproved or outdated consent, assent, and information sheets, missing signatures, failing to document consent process); (3) deviating from the protocol approved by the IRB; (4) modifying an approved protocol without IRB consent; (5) failing to report or tardily reporting unanticipated problems; (6) failing to maintain adequate records; (7) failing to

train research team members in the proper procedures; and (8) failing to follow recommendations by the IRB to ensure the safety of research participants. Noncompliance may constitute or may result in unanticipated problems, which should be addressed in accordance with SOP 4: Unanticipated Problems Involving Risk to Human Research Participants or Others.

Serious Noncompliance: Noncompliance involving one or more of the following: (1) bringing harm to research participants; (2) exposing research participants to a significant risk of substantive harm; (3) compromising the privacy and confidentiality of research participants; (4) causing damage to scientific integrity of the research data that has been collected; (5) engaging in willful or knowing noncompliance; (6) impacting ethical principles adversely.

In addition, all parties to whom this policy applies (*e.g.,* faculty, students, staff, IRB members) should consult the IRB Glossary.

4. Attachments

All parties to whom this policy applies should also consult:

1. Cornell University Federalwide Assurance Registration

5. Regulations Applicable to Managing Noncompliance

5.1. 45 CFR 46.109; 21 CFR 56.109: IRB Review of Research, mandating IRB review and approval of human participant research.

5.2. 45 CFR 46.103(b)(5)(i), mandating compliance with "[w]ritten procedures to ensure prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of…any serious or continuing noncompliance with [45 CFR 46(A)] or the requirements or determinations of the IRB... ."

5.3. 21 CFR 56.108(b)(2), mandating compliance with "[w]ritten procedures to ensure prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of…any serious or continuing noncompliance with [21 CFR 56(C)] or the requirements or determinations of the IRB... ."

6. Addressing Allegations of Noncompliance

6.1. The IRB or the Office of Research Integrity and Assurance (ORIA) may become aware of an allegation of noncompliance or of circumstances indicating noncompliance (*see* Section 3, Terms and Definition, Noncompliance) upon the receipt of a complaint from a participant, researcher, Cornell employee, or member of the public; from the interpretation of information received during a Continuation, Amendment, Unanticipated Problems Review; or from the findings of a random or for-cause audit or other quality control activities.

6.2. Once it has received an allegation of noncompliance, ORIA will request the alleger to submit a Noncompliance Report Form to ORIA. In the case of an anonymous complaint or a request for confidentiality, ORIA will submit this form. ORIA will forward the form to the IRB Chair and the Director of ORIA. The IRB Chair and the Director of ORIA will make the following initial determinations: (a) whether noncompliance is alleged; and (b) whether the allegation indicates that an immediate action such as suspension by the IRB is warranted. If it is determined that immediate action by the IRB is warranted (*e.g.,* suspension), then the IRB Chair will initiate

those proceedings in accordance with SOP 6: SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols, Section 8.2, Suspensions by the Chair of the IRB. ORIA will then initiate an investigation of the circumstances alleged in the Noncompliance Report Form. ORIA may elect to investigate informally by reading relevant documents and communicating with the affected parties. If ORIA and the IRB Chair determine that the allegation is not credible or is unsubstantiated, then the inquiry ends. ORIA will document this finding in a written report; place the report in the study file; and notify the IRB of the finding on the agenda of the next available meeting. If, however, the inquiry yields evidence that noncompliance has occurred, then ORIA will present this information to the IRB Chair and submit a corresponding report to the full IRB for discussion at the next available meeting.

7. Confirming and Resolving Noncompliance

7.1. If it is determined that the noncompliance is neither serious nor continuing (*see* Section 3, Terms and Definitions), the IRB Chair and ORIA will devise a corrective plan, which generally will involve immediate remediation (*e.g.*, obtaining signature of Protocol PI on submissions, providing missing documentation) and/or remedial education with the ORIA Education Coordinator.

7.2. If it is determined that the noncompliance is serious or continuing, ORIA will conduct a for-cause audit. If it is determined that an unanticipated problem has occurred, ORIA and the IRB Chair will address it in accordance with SOP 4: Unanticipated Problems Involving Risk to Human Research Participants or Others. The Protocol PI may request a meeting with the IRB Chair or the AVPRC regarding their determination of serious or continuing noncompliance. As stated in SOP 6: SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols, Section 7.4, a Protocol PI may decide voluntarily to suspend or terminate some or all of the research activities that may be under current review or investigation. The Protocol PI should inform ORIA of this action, so that ORIA can notify the IRB Chair and place the protocol on the agenda for the next available IRB meeting. The IRB will address the suspension or termination in accordance with SOP 6.

7.3. ORIA will distribute its for-cause audit report to the Protocol PI, the IRB Chair, the members of the IRB, and, if appropriate, the Institutional Official and/or appropriate Dean and/or Chair of the Protocol PI's Department. The Protocol PI may submit a response to the audit report in writing and/or may request to speak to the IRB at a convened meeting. ORIA will place the report and any written response from the Protocol PI as discussion items on the agenda of the next available IRB meeting. The IRB will make a final determination as to whether the evidence supports a finding of serious or continuing noncompliance and, if so, will determine a corrective plan, including timeframe for correction, and will, if necessary, initiate suspension or termination proceedings in accordance with SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols.

7.4. In reviewing information to make a final determination of serious or continuing noncompliance, the IRB should consider:

(a) Whether the audit report and any other available information sufficiently supports a determination of non-compliance
(b) Whether the audit report and any other available information supports suspension or termination of research in order to protect human participants or others

(c) Additional actions to protect the rights and welfare of currently enrolled participants
(d) Whether procedures for withdrawal of enrolled participants account for their rights and welfare
(e) Whether participants should be informed of the noncompliance and/or any of the corrective actions

7.5. The IRB may invite the Protocol PI to a portion of the meeting to answer questions and to discuss the issue of noncompliance. If the Protocol PI requests, or is requested, to be present at the IRB meeting, he or she may be accompanied by a faculty representative, legal counsel, or another member of his or her department. The role of these individuals is limited to providing information and support to the Protocol PI; they will not participate in the discussion between the Protocol PI and the IRB.

7.6. The Protocol PI must implement the corrective plan within the required timeframe. ORIA will monitor the Protocol PI's implementation of the corrective plan. A failure to implement the corrective plan on time will be reported by ORIA to the IRB Chair and the Director of ORIA for further action, including initiation of procedures for suspension or termination of IRB approval of the research protocol, in accordance with SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols.

7.7. Upon full implementation of the corrective plan, ORIA will draft a final noncompliance report for discussion by the IRB at the next available meeting. After the report is finalized by ORIA and the Director of ORIA, ORIA will distribute this report to the following parties:

(a) Protocol PI
(b) Institutional Official
(c) Department Chair, Center Director, and/or College Dean of the Protocol PI
(d) Cornell's Office of Sponsored Programs, when applicable
(e) Sponsoring agency, when applicable
(f) OHRP, when applicable

7.8. While the IRB has the authority to take appropriate action concerning a research protocol, neither the IRB nor ORIA has the authority to take disciplinary action against any individual relating to a finding of confirmed noncompliance. Instead, disciplinary action shall be the responsibility of the institution. The Director of ORIA shall report any termination of research to the appropriate institutional officials, and the Director of ORIA and the IRB Chair will, if requested, assist in any disciplinary action process taken by the appropriate academic unit.

8. Corrective Actions in Response to Noncompliance

8.1. The actions taken to correct noncompliance vary and depend on the nature and seriousness of the noncompliance. The IRB, in consultation with the Director of ORIA, may take any of the following actions:

8.1.1. Take no action
8.1.2. Request a protocol and/or consent form modification
8.1.3. Require that all participants be re-consented
8.1.4. Require previous participants to be informed of any changes to the protocol and/or consent procedures

8.1.5. Require observation of consent procedures
8.1.6. Require more frequent review of the conduct of the research
8.1.7. Require additional training for the research team
8.1.8. Require follow-up audit(s)
8.1.9. Suspend the research: *see* SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols, Sections 8.1, 8.2, 8.3
8.1.10. Terminate the research: *see* SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols, Sections, 8.1, 8.4, 8.5
8.1.11. Refer issues to other institutional entities (*e.g.*, Institutional Official, Dean, Legal Counsel)
8.1.12. Any other action deemed appropriate by the IRB to protect the rights and welfare of research participants

8.2. Informed by any audit reports, corrective plans, and final noncompliance reports, the Senior IRB Administrator will develop and administer required and optional educational programs, as specified in corrective plans for the Protocol PI and for the research community generally.

9. Documentation Relating to Reporting and Resolution of Noncompliance

All documents relating to noncompliance will be maintained by ORIA for a period of not less than 5 years.

These documents include but are not limited to: Noncompliance Report Forms; correspondence with the Protocol PI; and documentation of implementation of corrective plans.