	SOP: Noncompliance				
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1 PURPOSE

1.1 All researchers conducting human subjects research are expected to comply with the provisions of the HREB-approved study, SUNY New Paltz HREB Policies, and all related federal regulations, college policies, and state and local laws. If any allegations of noncompliance are made to the SUNY New Paltz HREB, then those allegations must be investigated and it must be determined whether the allegation has a basis in fact or not. The procedures for this investigation and the outcome of the investigation are described below.

1.2 SUNY New Paltz personnel, including investigators, research team, faculty, staff, administration, or students are responsible for reporting to the HREB suspected or actual noncompliance with the provisions of an HREB-approved study as well as with any applicable human research regulations. Reports of noncompliance may come in the form of a complaint or from the result of an audit.

1.3 HHS regulations at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents related to research conducted under an OHRP- approved assurance are promptly reported to OHRP:

1.3.1 Any unanticipated problems involving risks to subjects or others;

1.3.2 Any serious or continuing noncompliance with this policy or the requirements or determinations of the HREB; and

1.3.3 Any suspension or termination of HREB approval.

1.4 Some accrediting bodies also require the reporting of research misconduct.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 Definitions

3.1 Noncompliance: Failure (intentional or unintentional) to comply with applicable federal regulations, state, or local laws, the requirements or determinations of the HREB, or university policy regarding research involving human subjects. Some examples of noncompliance include, but are not limited to:

3.1.1 Failure to obtain approval for research prior to initiating the research activities,

3.1.2 Continuing research activities beyond the expiration date without obtaining continuing review approval,

3.1.3 Failure to obtain informed consent when required,

3.1.4 Failure to file an adverse event report,

3.1.5 Implementing changes to the protocol without prior approval,

3.1.6 Performance of research at an unapproved site, or

3.1.7 Failure to adhere to the approved protocol.

3.2 Non-serious or minor noncompliance: Noncompliance that does not increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human research protection program. Examples of minor noncompliance may include, but are not limited to the following:

3.2.1 Lapses in continuing HREB approval,

3.2.2 Minor changes in or deviations from an approved protocol, or

3.2.3 Administrative errors.

3.3 Serious noncompliance: Noncompliance that increases risk to research participants, compromises participants' rights or welfare, or affects the integrity of the research/data or the human research protection program. Examples of serious noncompliance may include, but are not limited to the following:

3.3.1 Human subjects research conducted without HREB approval,

3.3.2 Failure to obtain exempt determination before exempt research involving human subjects is conducted,

3.3.3 Conducting or continuing non-exempt human subjects research without HREB approval;

3.3.4 Lack of legally effective informed consent from research participants;

3.3.5 Failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or

3.3.6 Inappropriate oversight of the research to ensure the safety of human subjects and the integrity of the research/data.

3.4 Continuing noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention. Examples of continuing noncompliance may include, but are not limited to the following:

3.4.1 Repeated incidents of not getting HREB approval or modifying a study without HREB approval,

3.4.2 Repeated failures to provide or review progress reports resulting in lapses of HREB approval,

3.4.3 Inadequate oversight of ongoing research, or

3.4.4 Failure to respond to or resolve previous allegations or findings of noncompliance.

3.5 Allegation of noncompliance: An unconfirmed report of noncompliance.

3.6 Finding of noncompliance: An occurrence or determination of noncompliance that does not require further confirmation or investigation (e.g., failure to respond to the HREB within established deadlines, allegation of noncompliance determined by the HREB to be true).

4 RESPONSIBILITIES

4.1 The HREB Chair in consultation with the Human Protections Administrator carries out these procedures.

4.2 The campus Signatory Official makes all final determinations.

5 HANDLING ALLEGATIONS AND FINDINGS OF NONCOMPLIANCE

5.1 Allegations of noncompliance should be forwarded to the HREB Chair (hrebchair@newpaltz.edu), the Human Protections Administrator (hpa@newpaltz.edu), and the HREB Coordinator (hrebcoordinator@newpaltz.edu). Allegations of noncompliance will remain confidential to the extent permitted by Federal and New York State law, consistent with the need to conduct an adequate investigation.

5.2 Actions undertaken in response to an allegation or finding of noncompliance will be completed in a timely manner, based on the circumstances and seriousness of the potential noncompliance. Under federal regulations, the HREB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the HREB's requirements or that has been associated with unexpected serious harm to subjects. The HREB Chair, the full HREB board, Human Protections Administrator, or Signatory Official may suspend or terminate approval of an investigator's research and/or secure critical documents at any time during or following an inquiry or investigation if necessary to assure the protection of research participants.

5.3 Initial HREB Review of Allegations of Noncompliance

5.3.1 The HREB Chair or Associate Chair will make an initial determination as to whether the allegation:

5.3.1.1 Has possible basis in fact, but is not serious and not continuing noncompliance.

5.3.1.2 Has possible basis in fact, and is serious and/or continuing noncompliance.

5.3.1.3 Has no basis in fact.

5.3.1.4 Has a possible basis in fact and is of such a nature that the safety, rights and welfare of subjects are at immediate risk or hazard.

5.3.1.5 Possible Outcomes of Initial Review,

5.3.1.5.1 Dismissal of the allegation (i.e., unsubstantiated),

5.3.1.5.2 Referral to other appropriate university process,

5.3.1.5.3 No further action required (i.e., for minor violations),

5.3.1.5.4 Corrective action(s) recommended (i.e., for minor violations)

5.3.1.5.5 Review by convened HREB required (i.e., noncompliance may be serious and/or continuing but further investigation is not needed),

5.3.1.5.6 Referral to the HREB Board, or

5.3.1.5.7 Further investigation required.

5.3.2 Full Board Review of Allegations of Noncompliance

5.3.2.1 If the HREB Chair or Associate Chair determine that noncompliance has occurred, the case will be forwarded to the full board for investigation.

5.3.2.2 Full Board Review Process

5.3.2.2.1 The reported noncompliance or allegation of suspected noncompliance and appropriate review materials will be distributed to the primary reviewer(s) and all HREB Committee members approximately one week prior to the meeting, time permitting.

5.3.2.2.2 Appropriate review materials may include but are not limited to the following: inquiry correspondence (to and from investigator or to the appropriate person at the institution), study protocol, current approval notice, current approved informed consent document, and other pertinent documents.

5.3.2.2.3 The HREB may request additional information from the Principal Investigator in order to facilitate a thorough review before a final determination is made.

5.3.2.3 During a meeting of the full HREB board, the following possible determinations will be made:

5.3.2.3.1 For allegations of noncompliance:

5.3.2.3.1.1 There is no basis in fact.

5.3.2.3.1.2 There is a basis in fact, but the noncompliance is neither serious nor continuing.

5.3.2.3.1.3 There is a basis in fact and the noncompliance is serious and/or continuing.

5.3.2.3.1.4 There is basis in fact and the noncompliance constitutes an unanticipated problem.

5.3.2.3.2 For reported noncompliance:

5.3.2.3.2.1 The noncompliance is neither serious nor continuing.

5.3.2.3.2.2 The noncompliance is serious and/or continuing.

5.3.2.3.2.3 The noncompliance constitutes an unanticipated problem.

5.3.2.3.3 The HREB will consider which of the following actions are required. This consideration may include but is not limited to the following:

5.3.2.3.3.1 Require no further action;

5.3.2.3.3.2 Accept and approve the Principal Investigator’s proposed corrective action plan or changes;

5.3.2.3.3.3 Require that the Principal Investigator modify the protocol to minimize risk;

5.3.2.3.3.4 Require the interval at which continuing review is conducted to be modified to less than one year as appropriate to the degree of risk;

5.3.2.3.3.5 Require that the Principal Investigator modify the recruitment or consent documents;

5.3.2.3.3.6 Require that currently enrolled subjects be reconsented with the additional relevant information provided;

5.3.2.3.3.7 Require notification of previously enrolled subjects of new information;

5.3.2.3.3.8 Require notification of currently enrolled subjects of new information, as such information may relate to a subject’s willingness to continue participation in the research;

5.3.2.3.3.9 Require observation of the research or the consent process;

5.3.2.3.3.10 Require submission of status reports on a defined set schedule to the HREB;

5.3.2.3.3.11 Require additional education and training for the investigators and support staff;

5.3.2.3.3.12 Require additional monitoring of the research;

5.3.2.3.3.13 Recommend sanctions to the campus Signatory Official to achieve compliance or prevent recurrence of noncompliance

5.3.2.3.3.14 Suspend any or all components of the research (i.e., new enrollment, treatment, follow up and data analysis) until a corrective action plan can be developed and implemented or until additional review can occur; and/or

5.3.2.3.3.15 Terminate the research;

5.4 Outcome of the HREB Meeting

5.4.1 The HREB's meeting will be documented within the minutes.

5.4.2 The HREB Chair will forward the HREB's decision to the Human Protections Administrator along with the HREB's recommended actions. A copy of this letter is also forwarded to the Principal Investigator.

5.4.3 The Human Protections Administrator will then forward their recommendations to the campus Signatory Official along with an explanation for why they support or do not support the HREB's recommended actions. A copy of this letter is forwarded to the HREB Chair and the Principal Investigator.

5.4.4 Ultimately, the campus Signatory Official will make the final determination on any recommended actions outside of the HREB's purview.

5.4.5 The Signatory Official will ultimately be responsible for reporting any cases of noncompliance to the Office of Human Research Protections per their guidelines.

6 REFERENCES (SOP is based on the following documents)

6.1 The Ohio State University – Noncompliance Policy

6.2 Guidance on Reporting Incidents to OHRP

6.3 HHS Guidance on Reporting Incidents to OHRP (2011)

6.4 OHRPP Policy: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research

6.5 The University of Texas – Noncompliance Policy