NEOMED RESEARCH POLICY	Policy No: 3349-R-656
RESEARCH POLICY TITLE: Reporting Unanticipated Problems, Adverse Events, and Noncompliance in Human Subjects Research	EFFECTIVE DATE: 8/1/2019
RESPONSIBLE DEPARTMENTS: V.P. for Research/ORSP	Approval Authority: V.P. for Research Responsible Office:

(A) PURPOSE

The purpose of this policy is to define and provide a framework for responding to unanticipated problems, adverse events and noncompliance with federal, state, or local laws and regulations; institutional policies governing the protection of human subjects; or the requirements of Northeast Ohio Medical University Institutional Review Board (NEOMED IRB).

The Department of Health and Human Services (DHHS) requires that institutions have "written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this guidance or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval" (45 CFR 46. 103(b)(S)).

(B) SCOPE

This policy applies to all NEOMED employees, volunteers, and students who engage in human subjects research, including investigators (professional and student), administrators, and staff.

(C) DEFINITIONS

(1) ***"Adverse Events"***, as defined by the Office of Human Research Protections (OHRP) of the Department of Health and Human Services (HHS), refers to:

(a) Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

(b) Encompass both physical and psychological harms, and can be in the context of biomedical or social and behavioral research.

(2) ***"Unanticipated Problems"*** generally refers to any incident, experience, or outcome that meets all of the following criteria:

(a) Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.

(b) Related or possibly related to participation in the research (for this policy, "possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

(c) The research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

(3) ***"Noncompliance"*** refers to minor or serious violations of any institutional, state, and federal regulation that governs human subject research, which may compromise the integrity of scientific research and/or the safety and welfare of human subjects and includes any unanticipated problems or adverse events not reported to the NEOMED IRB in accordance with this policy.

(a) Minor noncompliance issues or events may include administrative protocol deviations, and/or any event that may pose minimal risk to the safety and welfare of human subjects.

(b) Serious noncompliance issues or events compromise the integrity of scientific research and may include minimal or more than minimal risks

to the safety and welfare of human subjects and yields automatic reporting to OHRP.

(c) Continuous noncompliance is a series of more than one noncompliant issue or event that further prompts the need for the evaluation of the procedures and processes used to protect human subjects, and yields automatic reporting to OHRP.

(D) POLICY STATEMENT

(1) Any person who suspects or discovers an incident of Noncompliance may report the incident to the IRB Chair or the Human Protections Administrator (HPA), or, alternatively, complete an Unanticipated Problem/Serious Adverse Event/Noncompliance Reporting Form and submit the form to the IRB Chair or Coordinator for processing.

(2) Reporting Adverse Events and Unanticipated Problems

(a) When an Adverse Event is serious, unexpected, related or possibly related to the research and place subjects or others at greater risk of harm, it must be reported by the Principal Investigator within 5 working a days to the NEOMED IRB.

(b) When an Adverse Event is expected, was contained in the approved IRB protocol and mentioned in the informed consent, reporting may be done annually at the time of a study's continuation.

(c) All Unanticipated Problems must be reported to the NEOMED IRB within 10 working days by a study's Principal Investigator by completing an Unanticipated Problem/Serious Adverse Event/Noncompliance Reporting Form.

(3) The IRB is responsible for investigating and reporting to appropriate Institutional Officials and federal agencies: any Unanticipated Problems involving risks to

human subjects or others; any serious or continuing noncompliance with this guidance or the requirements or determinations of the IRB; and any suspension or termination of IRB approval.

(4) All reported Noncompliance issues or events will be thoroughly investigated and considered suspected or possible Noncompliance until a final determination is made by the IRB Chair and HPA, or by the convened IRB committee.

(5) The individual reporting Noncompliance shall:

(a) Schedule an appointment with the IRB Chair or HPA to discuss the suspected or identified incident of Noncompliance.

(b) Complete an Unanticipated Problems/Serious Adverse Event/Noncompliance Reporting Form to document all suspected problems or acts of noncompliance; and

(c) Submit the completed form to the IRB Chair with contact information; names are held in confidence unless there are regulatory or legal requirements to disclose.

(6) The individual(s) suspected of Noncompliance shall:

(a) Be notified by the IRB Chair or HPA in writing of the suspected incident;

(b) Schedule a meeting with the IRB Chair and/or HPA to review the reported incident; and

(c) Provide the IRB Chair and HPA with any requested information during the investigation.

(7) The IRB Chair and/or HPA shall:

(a) Document the details of the reported incident of Noncompliance during a scheduled meeting, or review the completed Unanticipated Problems/Serious Adverse Event/Noncompliance Reporting Form.

(b) Notify the individual(s) suspected of Noncompliance;

(c) Gather additional information for purposes of a thorough investigation;

(d) The IRB Chair and HPA will convene to review all collected information and make a determination as to whether a Noncompliance event or issue occurred, and the extent to which the Noncompliance negatively impacted the integrity of the research and the safety and welfare of the human subjects;

(e) For those Noncompliance issues that are serious or continuous the IRB committee will be convened;

(f) Determine a course of action; and

(g) Notify the IO, either verbally or in writing, of the unanticipated problem or incident of noncompliance. With regard to human subjects research, the IO is the Vice President for Research.

(8) Determinations and Consequences of Noncompliance

(a) If the incident or issue is determined to be ***Minor Noncompliance:***

(i) The IRB Chair and/or HPA may determine that the Noncompliance is minor, and in such instances, a corrective action plan is required that is agreed upon by the Chair and the investigator(s).

(ii) The corrective action plan should identify those steps that will be completed to correct the Noncompliant incident, as well as steps to prevent future incidents.

(iii) Minor Noncompliance events that do not include Adverse Events will be reported to the IRB committee, the principal investigator, the department chair or supervisor of the principal investigator, and the IO.

(iv) The IO may choose to report the Noncompliance event to others whose position and authority may dictate further action beyond the purview of the IRB (e.g., Dean).

(v) A hard copy letter detailing the investigative findings of the Noncompliance issue or event, and the request for a corrective action plan, will be provided to the principal investigator, the HPA, the department chair or supervisor of the principal investigator, and the IO through the IRB office. Copies may be made by the IO to be distributed confidentiality to others on a need to know basis.

(b) If the incident or issue is determined to be serious or continuous Noncompliance:

(i) The OHRP will be notified in addition to the IRB committee and the IO.

(ii) The IO may choose to report the Noncompliance event to others whose position and authority may dictate further action beyond the purview of the IRB.

(iii) In the event of a serious or continuous Noncompliance issue or event, the IRB Chair will immediately bring the issue to the IRB committee at the earliest possible time to determine whether the protocol should be suspended or terminated in whole or in part.

(iv) All members of the IRB committee will be provided with a summary of the issue or event prepared by the IRB Chair and HPA, as well as current investigative findings. The IRB committee reserves the right to ask the investigator(s) to attend the committee meeting to further explain the issue or event.

(v) lnvestigator(s) will be required to submit a corrective action plan based on the committee's recommendations, as well as a written report responding to all issues and questions raised by the IRB Chair and/or IRB committee.

(9) Final Outcome Notification

(a) Upon successful completion of a corrective action plan, the principal investigator(s) submitting the plan will be notified in writing of the final outcome of the incident.

(b) The reporter may contact the IRB Chair or HPA to discuss the final outcome of the incident.

(c) The final report will be distributed to the IO, and will be maintained in the IRB office.

(d) The I0 will report any unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance, and any suspension or termination of IRB approval to OHRP.

(e) In the event of reporting a serious or continuing noncompliance issue or event, the OHRP may require additional investigations and sanctions.

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REFERENCES

FORMS

Unanticipated Problems/Serious Adverse Event/Noncompliance Reporting Form

CROSS-REFERENCE

http://www.hhs.gov/ohrp/policy/advevntguid.html#Q1

REVISION HISTORY

RULES PROMUGLATED UNDER

LEGAL