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Approved By:	Institutional Review Board	Approval Date: October 13, 2020

PURPOSE

To describe the reporting requirements related to adverse events, serious adverse events, unanticipated problems, and non-compliance.

DEFINITIONS

Adverse event - An unfavorable medical occurrence, which may include abnormal signs (for example, abnormal physical exam or laboratory finding), symptoms, or disease, temporally associated with, but not necessarily considered related to, the subject's participation in the research study. Not all adverse events meet IRB reporting guidelines.

Continuing non- compliance - Non-compliance that has been previously reported or a pattern of ongoing non-compliance that, in the judgment of the University IRB, significantly adversely affects the rights and welfare of participants or significantly compromises the quality of the research data (i.e., negatively impacts the ability to draw conclusions from the study data).

External adverse event - An adverse event that occurs at a site external to the authority of the University IRB and is reported to the University investigator.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

Internal adverse event - An adverse event that occurs at a site that falls directly under the authority of the University IRB.

Investigator - any individual who is involved in conducting human subjects research studies.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Non-compliance: Failure on the part of the investigator or any member of the study team to follow the terms of University IRB approved protocol or to abide by applicable laws or regulations, or University IRB policies. This includes protocol deviations.

Incidents of non-compliance on the part of research participants which do not involve risk need not be reported to the IRB.

Possibly Related to the Research Intervention: In the opinion of the principal investigator, there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

Probably Related to the Research Intervention: In the opinion of the principal investigator, the incident, experience or outcome more likely than not was caused by the procedures involved in the research.

Serious Adverse Event or Suspected Adverse Reaction: An adverse event or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor, it results in any o2(ul)2.6(t)4.3(s)-2( )]TJ 0 -hany]TJ 0 w -4.152 s .6(nt)-6(o111.2(t)-6D5(m)-8.9(p)-0 -1.1)1.141 TD [to tDot

threatening problem or death caused by, or associated with, a device, if that effect, or problem, or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unantic

External Adverse Events

- External Adverse Events which are Unexpected, Serious AND suggest that the research places subjects or others at greater risk than was previously recognized and Related to the Research Intervention will be reported to the University IRB within 5 working days of their receipt by the University or the investigator.
- Ideally, adverse events occurring in subjects enrolled in a multicenter study should be submitted to a monitoring entity for review and analysis.
- The report of the adverse event to the University IRB should include confirmation as to whether the external site reported the event to their IRB and to a monitoring entity.
- The University IRB may act with regard to the local study in response to the external adverse event (e.g., suspend the local study enrollment, but will not report the event to a federal agency or sponsor, unless required by the local action).

General Reporting Requirements for Unanticipated Problems Involving Risk to Subjects or Others and Non- compliance

1. Unanticipated problems which meet the following definition of "any accident, experience or outcome" that meets <u>all three</u> of the following criteria must be reported:

- unexpected in terms of nature, severity, or frequency;
- related, or possibly related, to a subject's participation in 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.

Examples of types of unanticipated problems that must be reported to the IRB include:

- any accidental or intentional deviation from the IRB-approved protocol that involves risks (e.g., missed safety labs, incorrect dosing or labeling);
- any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a given research subject;
- any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected increase in the risk to benefit ratio of the research;
- any complaint of a subject that indicates an unanticipated risk or which cannot be resolved by the research staff;
- any other untoward event that affects the welfare or the privacy, confidentiality or other rights of research subjects or members of their family (e.g. lost or stolen research data);
- any other untoward event that presents a risk to investigators and research staff involved in the conduct of the research.

2. Incidents of non- compliance, which meet the following must be reported:

- Failure on the part of the investigator or any member of the study team to follow the terms of University IRB approved protocol or to abide by applicable laws or regulations, or University IRB policies that:
    - adversely affect that rights and welfare of human subjects, or
    -

IRB approval;

- Implementing protocol modifications without obtaining prospective IRB approval;
- Initiating research activities prior to obtaining consent;
- Altering from the informed consent process as described in the IRB approved protocol
- Having research activities performed by individuals who are not sufficiently trained or credentialed to perform the task;
- Obtaining consent using an outdated consent form, when the new consent form contained new information that may have caused the subject to change their mind about participating;
- Conducting research during a lapse in IRB approval;
- Not adhering to inclusion/exclusion criteria;
- Enrolling more subjects than were approved in the protocol of a greater than minimal risk study;
- Failing to [illegible]

NEIU IRB
University of Pittsburgh, Policies and Procedures, Chapter 17, "Reportable New Information."

Contact Information
Please direct questions or concerns about this policy to:

Contact	Phone	E-Mail
IRB Office	773-442-4675	irb@neiu.edu
Dean of the College of Graduate Studies and Research	773-442-6012	gradstudies@neiu.edu

Disclaimer
The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.