University of Pittsburgh

TABLE OF IRB REPORTING REQUIREMENTS

The following table is to assist investigators/study teams with the University of Pittsburgh's IRB Reporting Requirements. The table outlines the types of events/problems that must be reported and the timeframes for reporting. Events that may meet the definition of an Unanticipated Problem Involving Risk to Human Subjects or Others, Serious Non-compliance, and/or Continuing Non-compliance must be promptly reported to the IRB as Reportable New Information (RNI). If you encounter an event/problem that is not listed on this table, or you are having difficulty determining when/if an event requires reporting, consult the IRB at askirb@pitt.edu and refer to Chapter 17 - Reportable New Information.

REQUIRING SUBMISSION OF RNI WITHIN **24 HOURS**

Type of Event:	Definition(s):	Examples (not inclusive):
Fatal or Life-Threatening Adverse Event or Unanticipated Adverse Device Effect	Adverse Event: An unfavorable medical occurrence, which may include abnormal signs (for example, abnormal physical exam or laboratory finding), symptoms, or disease, that is temporally associated with, but not necessarily considered related to, the subject's participation in the research study. Unanticipated Adverse Device Effect: Any serious adverse effect on health or safety, life-threatening problem, or death caused by, or associated with, a device that was not previously identified in nature, severity or frequency in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.	• Any unexpected internal adverse events or unanticipated adverse device effects which are fatal, or life- threatening related or possibly related to the research or gene transfer intervention

REQUIRING SUBMISSION OF RNI WITHIN **10 WORKING DAYS**

Type of Event:	Definition(s):	Examples (not inclusive):
Unanticipated Problem (UAP) Involving Risk to Human Subjects or Others	UAP Involving Risk to Human Subjects or Others: Any accident, experience, new information or outcome that meets all the following criteria: 1. Unexpected in terms of nature, severity, or frequency; 2. Related, or possibly related, to research activities; and 3. Places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.	• Any serious, unexpected internal adverse event whether related or possibly related to the research intervention • Any serious, unexpected (external) adverse event that is related to the research intervention • Data Safety Monitoring Board (DSMB) report, interim result or publication in the literature describing an unexpected increase in the risk to benefit ratio.

		• Pregnancy of a subject when pregnancy testing and/or contraception is a requirement of the study • An untoward event that presents risks to investigators or research staff involved in human subject research • 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); • External adverse event report which the investigator feels raises a safety concern • Any change made to the study protocol without IRB approval when the change was made in order to eliminate an apparent immediate risk to subjects or others
Serious and/or Continuing Non-compliance	Serious Non-compliance: Non-compliance that, in the judgment of the IRB, significantly adversely affects the safety, rights or welfare of human research subjects or others, significantly compromises the quality or integrity of the research data (i.e., negatively impacts the ability to draw conclusions from the study data), or negatively affects the integrity of the Human Research Protection Program (HRPP). Continuing Non-compliance: Non-compliance that has been previously reported or a pattern of ongoing Non-compliance that, in the judgment of the IRB, significantly adversely affects the safety, rights or welfare of human research subjects or others, significantly compromises the quality or integrity of the research data (i.e., negatively impacts the ability to draw conclusions from the study data), or negatively affects the integrity of the HRPP.	• An accidental or intentional deviation from the IRB-approved protocol that involves potential serious risks (e.g., missed safety labs, incorrect dosing, or labeling) • Performing non-exempt human subject research without obtaining prospective IRB approval • Implementing protocol modifications without obtaining prospective IRB approval when the change is NOT being made to eliminate apparent immediate risks to subjects or others • Failing to follow the informed consent process as described in the IRB-approved study application • Initiating research procedures prior to obtaining written informed consent or IRB-approved verbal consent • 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 or beyond the IRB approval expiration date • Enrolling participants that do not meet eligibility criteria • Enrolling more subjects than were approved in the protocol of a greater than minimal risk study

		• Failure on the part of Human Research Protection Office (HRPO) staff involved in research review or oversight to abide by applicable laws or regulations, or HRP policies
REQUIRING SUBMISSION OF RNI WITHIN **30 WORKING DAYS**		
Type of Event:	**Definition(s):**	**Examples (not inclusive):**
Serious, Unexpected, and Related external Adverse Events	External Adverse Event: An Adverse Event that occurs at a site external to the authority of the University IRB	• A serious adverse event which occurred at an external site that are unexpected, related to the research intervention, and serious or otherwise suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously recognized or recognized
NON-COMPLIANCE/DEVIATION LOG		
Type of Event:	**Definition(s):**	**Examples (not inclusive):**
Incidents of Non-compliance which are unlikely to meet the definition of Serious and/or Continuing Non-compliance should be logged in real time	Non-compliance: Failure on the part of the Principal Investigator or any member of the study team to follow the terms of the IRB approved protocol or to abide by applicable laws, regulations, or HRP policies. *The maintenance of a non-compliance/deviation log is mandatory for greater than minimal risk studies, studies that meet the federal definition of a clinical trial, or studies for which reporting is required by the funding agency. It is recommended for all other clinical trials.*	• Obtaining consent using an outdated consent form when there were no substantive differences between the consent form that was used and the consent form that should have been used (i.e., dates in the footer) • Protocol deviations that do NOT adversely affect the safety, rights or welfare of human subjects or significantly compromise the quality or integrity of the research data (including non-compliance on the part of the subject) • Performing non-safety related research procedures outside the protocol specified window (i.e., administering a questionnaire outside of the protocol specified window)
ADVERSE EVENT LOG		
Type of Event:	**Definition(s):**	**Examples (not inclusive):**
Adverse Events or Unanticipated Adverse Device Effects which are unlikely to meet the definition of a UAP Involving Risk to Human Subjects	See above definitions *The maintenance of an adverse event log is mandatory for studies if the Principal Investigator is also the sponsor of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application, or if it is required by the funding agency. It is recommended for all other clinical trials.*	• All adverse events or Unanticipated Adverse Device Effects NOT determined to be Serious, unexpected and related or possibly related to the research intervention