

EVENT REPORTING GUIDANCE

REPORTING TIMELINES FOR FREQUENTLY USED IRBS OF RECORD:

National Jewish Health IRB:	Within 7 working days after site becomes aware
Western IRB (WIRB):	Within 5 working days after site becomes aware
Advarra IRB:	Within 10 working days after site becomes aware
COMIRB:	Within 5 working days after site becomes aware
Single Academic IRBs:	Under the SmartIRB reliance agreement, various academic IRBs may be utilized as the singleIRB of Record. The approval letter will list the specific reporting timeline of the SingleIRB. <i>Please contact HRPP for assistance in reporting.</i>

Unless specifically required by the IRB of Record, the NJH HRPP Office does not accept interim event reports of adverse events and IND Safety Reports that do not meet the definition of a UPIRTSO. NJH HRPP/IRB does not require reporting a Protocol Deviation unless it involves risk to subjects or compromises data integrity. Note: Adverse events in clinical trials must be reported to the sponsor in compliance with FDA regulations and sponsor requirements.

Track adverse events and protocol deviations that do not meet the above criteria in logs provided by sponsor or NJH HRPP (available on NJH HRPP/IRB) website. Please submit logs at the time of continuing review.

DEFINITIONS:

Noncompliance is defined as the failure to follow federal, state, or local regulations governing human subject research, institutional policies related to human subject research, or the requirements or determinations of the IRB. Noncompliance may be minor or sporadic or it may be serious or continuing. Only Serious and Continuing Non-compliance are promptly reportable:

Protocol Deviation is a kind of Noncompliance. Protocol Deviation means any variation from the IRB approved research plan that happens without prior review and approval of the IRB

Serious Non-Compliance: is defined as noncompliance that, in the preliminary opinion of the investigator, creates an increase in risks to subjects, adversely affects the rights, welfare, or safety of subjects, or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious noncompliance. Examples include:

- **Enrollment or continued inclusion of vulnerable populations without prior IRB approval**
- **Conducting non-exempt human subjects research without IRB approval**
- **Conducting non-exempt human subjects research without obtaining informed consent, without an IRB-approved waiver of informed consent**

Continuing Non-Compliance: is defined as a pattern of noncompliance that, in the preliminary opinion of the investigator, suggests a likelihood that instances of noncompliance will continue unless the IRB or institution intervenes.

Adverse event is an untoward or unfavorable occurrence in a human subject temporally associated with the subject's participation in the research study.

Serious Adverse Event is a medical occurrence with a study participant that results in death, is life threatening or places the participant in immediate risk of death from the event as it occurred, requires hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects or is another condition which investigator judges to represent a significant hazard

UPIRTSO must meet all three of the following criteria to be promptly reportable:

- **Unexpected event**, as it relates to unanticipated problems, means that the incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied.
- **Related** means that it is at least possibly related to participation in the research
- **Greater Risk of Harm** indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized