# IRB SOP 601 Unanticipated Problems and Adverse Event Reporting

# **Purpose**

The purpose of this standard operating procedure (SOP) is to ensure that adverse and serious adverse events are defined, recorded, reported evaluated as required by the USA Institutional Review Board (IRB).

## Scope

This SOP applies to all research wolving human subjects that is inducted at USA or any of its affiliate institutions. Application of this SOP starts at the time the subject signs the initial Informed Consent Formand continues through 30 days after the subject completes the active part of the study, unless otherwise stated.

# **Policy**

Investigators are responsible for protoreporting to the IRB of "any unanticipated problems involving risks to participants or others (45CFR46.103.b (5)) he IRB maintains responsibility for initial assessment of the risk/ benefit ratio in a research activity involving human participants. During the course of the project, investigators are required to promptly inform the IRB of any unanticipated negative effect or undesirable experience that is possibly, probably or definitely related to study procedure(s).

Adverse events are not necessarily physical in nature; attention must be paid to psychological harm (such as depression, thoughts of suicide), ethereats to privacyor participant safety. An event is considered serious and must be reported when the participant experiences an unusuallystrong response, recurring problems, and/or death.

## **Definitions**

Adverse Event: The University's policies on adverse events are based on Food and Drug Administration regulations. According to the FDA<u>saribus</u>adverse drug experience" with respect to human clinical experience includes "any experience that suggests a significant

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- g. significant overdose or protocol error; or
- h. certain medical events that may not result in death, bettifteeatening, or require hospitalization, may also be considered a serious adverse whent appropriate medical or surgical intervention is necessary to prevent one of the outcomes listed above.

Observational Studies Submission of adverse events on observational studies, which is research on materials collected for nonesearch purposes These studies do not involve intervention from the study physician, and the subject only provides authorization for the usec 450 Td

Updates or followup reports are not required unless the nearious event becomes a serious adverse event or unless otherwise stated by the Board. If this upgrade in severity occurs the procedures in section 3.0 should be followed.

### 3.0 Serious Adverse Event Reporting

All serious adverse events that are unexpectedly associated with the study procedures must be reported to the sponsor and the IRB immediately, but no later than 7 working days upon learning of the event using the USA Adverse Event Report Form.

Serious adverse events, unless otherwise stated in this policy, should be reported from the time of informed consent through 30 days after the end of study participation.

SeriousAdverse Event Reporting	
TYPE OF EVENT	Report to IRB
SeriousANDunexpectedAND related, possibly related, or	5 working days
probably related	

Updates or followup reports are not required unless the serious adverse event ends with a death or unless otherwise stated by the Board. If this upgrade in severity occurs than procedures in section 3.1 should be followed.

#### 3.1 Death

Deaths judge to be the result of progressive cancer disedsenot need to be reported. All other deaths, whether or not they are directly related to study procedures, must be reported Deaths must be submitted to the IRB within three working days from the time the first member of the study team is aware of the event.

Deaths must be reported throughout the subject's participation on a study including the active and followup period.

Death Reporting Property of the Property of th	
TYPE OF EVENT	Report to IRB
Death	3 working days

### 4.0 UnanticipatedProblems

Unanticipated problems in a study which might affect subject risk benefit analysis, confidentiality, or subjects' willingness to continue in a project are to be reported to the IRB.

The IRB will consider the effect of the problem on the study camb subjects already enrolled.

In some instances, revisiting the consent process with previously enrolled subjects may be necessary. If the problem prompts a change in the study, the consent process and documentation may require alteration for future study subjects. The investigator should use his/her own judgment when determining if an event is considered reportable beyond the scope of this policy.

### Examples of unanticipated problems include:

- An accidental or unintentional change to the IRB approprotocol that placed one or more participants at increased risk, or has the potential to occur again.
- A change to the protocol made without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- Interim findings and/or a safety monitoring report that indicate an unexpected change to the risks or potential benefits of the research in terms of severity or frequency.
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information if followup or clarification is needed. The full committee has the right to request additional information from the investigator, note the occurrence of the adverse event bet tak no action, ask the investigator to modify the protocol or the informed consent or suspend or terminate the project.

The IRB is responsible for continuing review of all human subject research. This **tisrdogle** the annual renewal process required for any ongoing study. Thus, all reported adverse events should also be described in detail in the Annual Renewal Report Form when a renewal application is submitted for the study, so that the IRB may consider renewal of the protocol in light of such information.

5.0 Safety Alerts, IND Safety Reports, MED Watch Reports

During the course of a study, IND Safety Reports or other adverse event reports are provided from the sponsor. The IRB does not require submission of these reports. The reported information will be inserted into an updated investigator's brochure. The investigator's responsibility is to ensure that the risk/benefit relationship of the research remains acceptable.

## Related Federal Regulations

45 CFR 46.130(b)(5); 21 CFR 56.108(b); 21 CFR 812.3(s)

#### **Related Guidelines**

FDA-Adverse Event Reporting to IRBsmproving Human Subject Protection

OHRP <u>Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks & Adverse Event</u> <u>Guidance</u> 2007

**HISTORY** 

Effective Date: RevisionsOctober, 2018

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