WESTCLIFF UNIVERSITY
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Standard Operating Procedure

SOP 14	SOP 14: Adverse Event Reporting	Effective Date 1/1/2023

PURPOSE

SOP 14 ensures adverse and serious events are defined, recorded, reported, and evaluated as required by IRB.

DEFINITIONS

Adverse Drug Reaction (ADR). The World Health Organization (WHO) defines an ADR as "any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function." The IRB will deny all studies with potential ADRs per SOP 1.

Adverse Event (AE)—Unanticipated Problems Involving Risks to Participants or Others (UPIRHSO). The Office for Human Research Protections (OHRP) defines a UPIRHSO as any event or outcome that was previously unforeseen and indicates that participants or others are at an increased risk of harm. OHRP considers unanticipated problems as incidents, experiences, or outcomes meeting the following criteria:

- *unexpected* (in terms of the nature, severity, or frequency) given: (a) the description of the likely harms in the protocol, the consent form, or the other materials submitted to the IRB; and (b) the characteristics of the population;
- *related* to a subject's [participant's] participation in the research; and
- suggests that the research places participants or others at *greater risk of physical, psychological, economic, or social harm* than was previously known or recognized.

UPIRHSOs may include:

- (un)intentional changes to the IRB-approved protocol (protocol deviation);
- breach of privacy or confidentiality;
- complaint from a participant or family member;
- disqualification or suspension of a study investigator;
- change in the status of a participant that might affect their eligibility to remain in a study; or

- new information that suggests an unexpected change to the risk-benefit assessment or results in sponsor-imposed suspension of study or enrollment due to newly recognized risk

Serious Adverse Event (SAE). An adverse event is defined by § 314.80. The IRB will deny all studies with potential SAEs per SOP 1.

SOP 1. Reference to SOP 1: Allowed and Banned Research.

POLICY

Primary investigators must immediately submit to the IRB any unanticipated problems involving risk to human participants or others.

Assessment

If an individual determines that the incident, experience, or outcome represents an unanticipated problem, the investigator must report it promptly to the IRB. AEs experienced by participants enrolled in research studies may meet the criteria for *unanticipated problems involving risks to participants or others* and so must be reported promptly to the IRB.

The investigator must determine that AE conditions are met before reporting the event to the IRB:

- assessment of whether an adverse event is unexpected; and
- assessment of whether an unanticipated problem is related to the research.

Events may be caused by one or more of the following: (a) the procedures involved in the research; (b) an underlying disease, disorder, or condition of the participant; or (c) other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the participant.

Unanticipated problems and adverse events that are determined *to be at least partially caused by one or more procedures involved in the research activity* are considered related to participation in the research, whereas *adverse events* determined to be solely caused by a participant's underlying disease or other circumstances unrelated to the research are considered unrelated to participation in the research.

Events requiring reporting. Events exposing participants or others to a risk of physical, social, or psychological harm, which is greater than the risk to participants that was previously known or recognized, should be promptly reported when they warrant a change in the research protocol, the informed consent process, the informed consent document or other protective action is required to protect the rights and welfare of research participants or others.

Examples of events requiring reporting to the IRB include:

- breach of privacy or confidentiality, including lost or stolen confidential information that might involve risk to that individual or others;
- publication in the literature, safety monitoring report, including a Data and Safety Monitoring Report, interim result, or another finding indicating an unexpected change to the risk-benefit assessment;
- accidental or unintentional change to the IRB-approved protocol that involves risks or has the potential to recur;
- complaint from a participant or family member that indicates an unanticipated problem;
- disqualification or suspension of an investigator;
- sponsor-imposed suspension of the study or study enrollment for risk;
- change in the status of a participant might affect their eligibility to remain in the study, require their withdrawal from the study, or require the IRB to re-review the research to determine that adequate protections are in place to protect vulnerable populations. Examples include:
    - incarceration within a penal institution or detention facility;
    - pregnancy at any time during participation in a research study;
    - transfer of a child from their parents/guardians to foster care (ward of the state);
    - other events that are unanticipated and indicate the potential for increased risk of harm to participants or others; and
- potential noncompliance with IRB policies, federal research regulations, or State laws controlling the conduct of research must be reported.

Reporting unanticipated problems involving risks to participants or others to the IRB. All unanticipated problems that are both serious and related (at least possibly related) to the research procedures must be reported promptly to the IRB:

- those events that are either life-threatening or which result in death must be reported to the IRB via telephone or email within one business day of discovery. The full report must be submitted to the IRB within 48 hours of initial notification; and
- events that are not life-threatening and do not result in death must be reported to the IRB within 48 hours of discovery;

Reports may be filed via the Adverse Event Reporting Form.

Evaluation. The IRB will process the completed Adverse Event Reporting Form and:

- The form will be screened by the IRB Chair or Institutional Official (IO) to determine:
    - Whether the events are possibly unanticipated problems, are related to the research, and increase risks to participants or others. If there are questions regarding the classification of the event, the IRB will be contacted.

    - Whether the currently enrolled or prospective participants in the trial may be subject to immediate increased harm to their health, safety, or welfare. If a concern arises, the Chair or IO will be promptly contacted, and if necessary, the protocol be suspended or terminated.
- Reports that do not meet these reporting criteria will be acknowledged and retained in the IRB's records.
- The primary investigator will receive notification, acknowledging receipt, and whether additional information, action, or reporting is required.

IRB Determinations and Reponses. Upon determining the event possibly constitutes an unanticipated problem involving risks to participants or others, all information will be shared with committee member(s) charged with verifying the determination. Those events that do not meet the criteria will be acknowledged and filed,

For events meeting the criteria, the Chair and the verifying committee member(s) should reach a consensus on whether:

- additional information is required to clarify the events or circumstances;
- no further IRB action is required;
- to recommend modification of the protocol—including inclusion and exclusion criteria, the consent process, the consent document(s), the monitoring frequency, or other aspects of the safety management and reporting plan;
- that the protocol should be suspended or terminated;
- to refer the report for additional investigation (audit) of the study;
- to notify participants;
- to require that enrolled participants be provided with additional information (e.g., verbal information, written addendum, revised consent document);
- the incident may involve serious or continuing noncompliance;
- to observe the informed consent process; and/or
- to refer concerns or findings to other parts of the organization that administer other policies, laws, and regulations.

The IRB Chair will determine whether the research still meets the criteria for approval, whether risks to participants have been minimized and are reasonable in relation to anticipated benefits, if any, to the participants and the importance of the knowledge that may reasonably be expected to result, and whether the IRB may require additional action(s) to protect current and potential participants.

Unanticipated problems involving risks to participants or others will be acknowledged and retained in the IRB's records.

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RESPONSIBILITIES

IRB Chair and Reviewers are charged with ensuring SOP 12.

IO will monitor compliance and revise the SOP, as needed.

Dissertation chair, committee, and primary investigator are responsible for documenting events reported by participants.

REGULATIONS AND GUIDANCE

§ 314.80

§ 46.109

§ 46.113

§ 56.109

§ 56.113

Adverse Event Reporting to IRBs — Improving Human Subject Protection

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Title/Role
	Institutional Official
Brett Gordon	IRB Chair

DISCLAIMER

The University reserves the right to modify or amend sections of this SOP at its sole discretion.