Human Subjects Research Reporting Form

Reporting Overview

This form is designed to report deviations, adverse events, exceptions, unanticipated problems involving risk to subjects or others (UPIRSOs), or potential non-compliance to the WSU IRB/HRPP office.

**Definitions:**

**Deviation**: Any change, divergence, or departure from the study design or procedures of an approved research protocol prior to approval by the IRB/HRPP and/or sponsor. Most deviations are considered non-compliance (e.g., failure to follow the IRB approved protocol), however the nature of the deviation impacts the required remediation.

**Exception**: A deviation from the standard research protocol, when implemented for the protection of a research participant. Some exceptions may be anticipated and either described in the research protocol or implemented with prior approval from the sponsor, IRB or HRPP.

**Adverse Event**: Any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article.

**Anticipated Adverse Event**: Events that are described in the research protocol, and that do not exceed the anticipated incidence rate, do not have to be reported until the continuing review, annual update, or protocol closure.

**Reportable Events**: Any event defined above that is not described in an approved research protocol is reportable to the IRB, however additional reporting requirements may apply (e.g., sponsor, data safety committee).

**Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO**): Any incident, experience, outcome, or new information that meets **all** the following criteria:

**1. Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population.

**2.** **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

**3.** Suggests that 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.

 **Instructions**

***When completing this form:***

* *Do not delete or re-format any portion of this form.*
* *Do not utilize tracked changes or comments features.*
* *Do not leave any white response field blank. If a response field is not applicable to your research, please respond as “N/A.”*

*If you have questions regarding this form, please contact our office at* *irb@wsu.edu* *with a subject line of “IRB # (#####) Reporting Guidance Request”* ***prior*** *to submission.*

 If you are reporting an Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO), the report should be submitted to the IRB within 5 days of the discovery of this event, or as soon as practicable, and reasonable steps must be taken to prevent additional harm to subjects or others.

**Section 1. Protocol Information**

**1. Study Title**

*Provide the approved study title.*

**2. IRB #**

Provide the assigned IRB number of the approved study.

**Section 2. Key Personnel**

**1. WSU Principal Investigator (PI)**

*Include the WSU PI’s information in the table below.*

| **Name** **(First Last)** | **WSU ID #** | **WSU Email** | **WSU Phone #****(###)###-####** | **WSU College/Department Affiliation** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**2. Details of Individual Reporting the Event**

*Include information about the individual reporting the event in the table below (if different from PI).*

| **Name** **(First Last)** | **WSU ID #** | **WSU Email** | **WSU Phone #****(###)###-####** | **WSU College/Department Affiliation** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

**Section 3. Report Details**

1. Type of Event

Select all that apply.

[ ]  Deviation

[ ]  Exception

[ ]  Adverse Event

[ ]  Anticipated Adverse Event

[ ]  Reportable Event

[ ]  Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO)

[ ]  Non-Compliance

[ ]  Unsure

**2. Date Event Occurred**

Provide estimated or approximate date.

**3. Date Event Was Discovered**

Provide estimated or approximate date.

4. Event Overview

Provide a comprehensive description of the event.

5. Adverse Effects

Explain whether the participant(s) were adversely affected by the event.

6. New/Increased Risks

Explain whether the event increased risk to participants or revealed a new risk to future participants.

7. Retention of Effected Participant(s)

Explain whether the participant(s) will stay in the study or whether you will continue to use their identifiable data.

8. Status of Study/Data Integrity

Explain whether the event influences the integrity of the study data.

Section 4. Previous Event Occurrences

1. Has this event, or a similar event, previously occurred for this study?

Select one

[ ]  Yes

[ ]  No

[ ]  Unsure

**Section 5. Reporting/Corrective Actions/Remediation Plans**

1. Reporting Actions

Explain whether the event has been or will be reported to the study sponsor.

2. Corrective Actions

Describe any corrective action that was or will be taken by the researchers.

3. Remediation Actions

Explain how you will prevent future occurrences of this event/problem.

**Section 6. Study Modification**

Modifications to Approved Materials Required

Explain whether the research procedures or consent form need to be modified as a result of this reporting event.

**ATTACHMENT REQUIRED:** If the research procedures need to be modified, please submit an amendment request form for review.

**Submission Instructions**

Completed reporting forms and required supporting attachments must be submitted as unprotected PDF file attachments by email to irb@wsu.edu with an email subject line of “IRB #(#####) Reporting Submission” by the WSU PI from their WSU email account. Do not submit required supporting attachments as zip files, links, or via cloud sharing platforms.

If WSU key personnel listed on the application are submitting materials or corresponding on behalf of the WSU PI, the WSU PI **must** be Cc’d at their WSU email for all project related matters.

**Include all the applicable following attachments in your submission:**

* Reporting form.
* A copy of an amendment request form and the relevant updated materials if applicable

File names and document headers must clearly identify the supporting materials.