**Harrisburg University of Science and Technology**

**Institutional Review Board**

**UNANTICIPATED PROBLEM REPORT FORM**

***Please forward this completed form, signed either physically or electronically, to*** [***IRB@HarrisburgU.edu***](mailto:IRB@HarrisburgU.edu) ***if an unanticipated problem occurs during the study.***

IRB File No. Click or tap here to enter text.

Project Title: Click or tap here to enter text.

Date of this report: Click or tap to enter a date.

Project Title: Click or tap here to enter text.

Primary Investigator: Click or tap here to enter text.

Email: Click or tap here to enter text.

Faculty Advisor (if applicable): Click or tap here to enter text.

Email: Click or tap here to enter text.

**PART I- BASIC INFORMATION**

1. Date the unanticipated problem occurred: Click or tap to enter a date.
2. Date the research team became aware of the problem: Click or tap to enter a date.
3. Where did the problem occur? Click or tap here to enter text.

Was this site inside  or outside  the university campus?

1. Does the study include a drug?  Yes  No

If yes, provide the name of the drug(s): Click or tap here to enter text.

Date of last study drug administration: Click or tap to enter a date.

1. Does the study include a medical intervention or device?  Yes  No

If yes, provide the name of the intervention or medical device(s):

Click or tap here to enter text.

1. Date of latest study-related intervention or interaction (relevant to this event): Click or tap to enter a date.
2. Description of latest study-related intervention or interaction (relevant to this event): Click or tap here to enter text.
3. Was there harm, complaint, or death of the participant?  Yes  No

If yes, describe the harm, complaint, or event of death of the participant.

Click or tap here to enter text.

**PART II: DESCRIPTION OF UNANTICIPATED PROBLEM**

(Adverse Event, Incident, Experience or Outcome)

1. List key words describing the problem (e.g., breach of confidentiality):

Click or tap here to enter text.

1. Briefly describe the problem: (identify/describe the medical nature of the unanticipated problem, including background, relevant history, major medical or physical problem, types of medication or treatments and dates.)

Click or tap here to enter text.

1. If it is a social/behavioral study, include information such as nature of the unanticipated problem, description of the situation that led to the problem, individuals present, referral for medical/psychological care, etc.)

Click or tap here to enter text.

**PART III. CHARACTER OF UNANTICIPATED PROBLEM**

Yes  No The problem is **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 being studied.

**If yes, explain the basis for determining that the problem is**

**unexpected:** Click or tap here to enter text.

Yes  No The problem is **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). **If yes, explain the basis for determining that the problem is related or possibly related:** Click or tap here to enter text.

Yes  No The problem **places participants or others at a greater risk of**

**harm** (including physical, psychological, economic, or social

harm) than was previously recognized. **If yes, explain the basis for determining that the problem placed participant or others at a greater risk of harm:** Click or tap here to enter text.

**IV. CORRECTIVE ACTIONS**

Yes  No **Should the protocol be revised?**

If yes, provide a description of the proposed protocol changes:

(Attach a protocol modification form with a revised protocol for any proposed change to the protocol.) Click or tap here to enter text.

Yes  No **Should the research be suspended?**

If yes, describe the procedures you will follow for the suspension or

termination of the research. Click or tap here to enter text.

Yes  No **Should enrolled participants be notified about the problem/event?**

If yes, attach a protocol modification form with a revised consent

form or draft letter of notification with this report.

Yes  No **Should other corrective action be taken in response to the unanticipated problem?**

If yes, provide a description of the proposed corrective action:

Click or tap here to enter text.

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Signature of Investigator Date

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Signature of Faculty Advisor or Dissertation Chair Date

***For IRB Use Only***

IRB Chair/Designee Review of Problem Report:

The Institution was notified via confidential reporting by participant or observer.

The Problem:

Does **not** represent an unanticipated problem involving risks to participants or

others (review by expedited procedures)

Does represent an unanticipated problem involving risks to participants or

others (refer to convened IRB for review)

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Signature of IRB Chair/Designee Date

**Office of Human Research Protection**

**OHRP Recommendations for unanticipated problems involving risks to subjects or others:**

A detailed description of the problem; and Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

**For serious or continuing noncompliance:**

Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

**For suspension or termination:**

A detailed description of the reason for the suspension or termination; and actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

**Time frame for reporting incidents:**

The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting, except to say this must be done "promptly." For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report and indicate that a follow-up or final report will follow by the earlier of a specific date; or when an investigation has been completed or a corrective action plan has been implemented.

**OHRP focus on corrective actions when reviewing incident reports:**

When reviewing a report of an unanticipated problem, OHRP assesses most closely the adequacy of the actions taken by the institution to address the problem. Likewise, when reviewing reports of non-compliance or suspension or termination of IRB approval, OHRP assesses most closely the adequacy of the corrective actions taken by the institution. OHRP assesses whether the corrective actions will help ensure that the incident will not happen again, with the investigator or protocol in question, with any other investigator or protocol, or with the IRB. Therefore, OHRP recommends that, when appropriate, corrective actions be applied institution wide.

**OHRP response to incident reports:**

After receiving and evaluating an incident report from an institution, OHRP will respond in writing and will either state that the report was adequate or request additional information. For questions on reporting, please contact the Director of the Division of Compliance Oversight, 240-453-6900 or 866- 447-4777.

**Where to send incident reports:**

Send reports (PDF or Word documents preferred) to the following email address: [IRPT.OS@hhs.gov](mailto:IRPT.OS@hhs.gov) **if applicable**