**Today’s Date:**

**Date of Occurrence:**

**Date PI Notified**

**of Occurrence:**

**This report is (check only one):**

An Initial Report

A Follow-Up Report

**Principal**

**Investigator:**

**Phone:**

**Email:**

**HREB Protocol #:**

**Title of Project:**

Federal regulations and the SUNY New Paltz HREB policy require the prompt reporting of research problems, incidents, or new information that involves risk or harm to subjects or others. These are termed:

**Unanticipated Problem involving Risk/Harm to Subjects or Others (UP) - includes all 3 of the following conditions:** (a) not anticipated or foreseen (e.g., not described in the consent form); *AND* (b) involves risk or harm to a research participant or others; *AND* (c) probably, or definitely related to, or caused by, the research.

* UP is an umbrella term which includes *unanticipated* ‘Adverse Events’ and also includes other unanticipated events, such as ‘breaches in confidentiality’. An unanticipated event may be the availability of new information about risk from the sponsor or safety monitoring board.
* Risks of the research or side effects that are addressed in the protocol and informed consent document are generally not unanticipated problems **unless** they occur with greater frequency or severity than anticipated.
* Incidents which do not meet the UP definition above may be reported to the HREB using the Non-Prompt Reporting Form.

# How to Use This Form:

1. Review the definition of an unanticipated problem.
2. Specify urgency and identify the type of unanticipated problem.
3. Complete the Investigator’s Assessment Section.
4. *Email a copy of this form to the Human Research Protections Administrator (HPA@newpaltz.edu), the HREB Chair (*[*HREBchair@newpaltz.edu)*](mailto:HREBchair@newpaltz.edu)) *and the HREB Coordinator (HREBcoordinator@newpaltz.edu)* within ***5 business days*** of occurrence or notification of a problem.
5. **Specify Urgency**: In the PI’s opinion, does this UP warrant *immediate or urgent* attention by the HREB and perhaps others?  YES  NO
6. **Identify the Type of Unanticipated Problem** *(one or more may apply)*:
   1. **Adverse Even**t – that is unexpected, involves risk or harm, and related, or probably related, to research activities regardless of site location.
   2. **Unexpected increase in frequency or severity of an otherwise expected event.**
   3. **New information that increases the risk** (information can be from the literature, sponsor, lead site, and/or safety & monitoring board).
   4. **Sponsor-imposed protocol suspension** (due to harm or increased risk or other sponsor actions).
   5. **Changes in labeling or withdrawal from marketing** (drugs, devices, or biologics used in the research).
   6. **Breach of confidentiality** (such as lost or missing data which may increase risk to participants).
   7. **Protocol Deviation** (any change to the protocol without HREB-approval, in order to eliminate or lessen an unanticipated hazard or risk to the participant).
   8. **Protocol Violation** (accidental or unintentional change to the HREB-approved protocol that harmed participants or others or potentially increased risk of harm).
   9. **Complaint by a research participant or Legally Authorized Representative (LAR) that indicates unexpected risk or cannot be resolved by the research team.**

# Investigator’s Assessment

**Provide a full explanation to allow the HREB to assess the UP.**

1. **Summary**: *Briefly* describe the unanticipated problem. Indicate the current status of the situation and anticipated outcome. Give an assessment of the increased risk of, or the harm caused by, the unanticipated problem. (Fill in here or provide a separate page).
2. **ACTIONS**: Describe any immediate actions taken and/or planned in order to specifically address the unanticipated problem, including protocol violation or deviation. Include a corrective action plan for a protocol violation.
   1. Will this unanticipated problem result in modifications (changes) to the protocol or informed consent form?

No (*go to section III*)  Yes: Attached\*  Yes, the form has been previously submitted.

* 1. **\*REMINDER:** In order for a modification (to the protocol, informed consent, etc) to be approved by the SUNY New Paltz HREB, the change must be submitted using the SUNY New Paltz HREB Application for Modification Form. If applicable, this form can be attached to this UP Reporting Form.

1. **REPORTING TIMELINE**: If the timeline for required reporting to the SUNY New Paltz HREB has passed, the PI must (1) explain why the reporting requirement was not met and (2) explain what steps have been, or will be, taken to ensure prompt reporting (in accordance with SUNY New Paltz HREB policy) in the future.
   1. **Has the** **reporting timeline of 5 business days been met?  YES**  **NO.**
   2. **If NO, please explain:**
2. **Follow-Up Report**: Do you plan to submit a follow-up report?
   1. YES: A follow-up report is anticipated.
   2. NO: A follow-up report is not anticipated.
   3. **Note**: Regardless of the plan for follow-up, additional reports should be submitted as needed.
3. **PI SIGNATURE**:

I have personally reviewed each of the reported items, ensured correct classification in accordance with the SUNY New Paltz HREB reporting requirements, and understand my responsibilities to provide follow-up information (as it becomes available).

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Print Name of PI | Signature of PI | Date |