**NIH PROBLEM REPORT FORM**

Use this form to report problems to the IRB that may be:

1. Unanticipated Problems (UPs) including Unanticipated Adverse Device Effects (UADEs)
2. Protocol Deviations (PDs) or
3. Non-compliance

For more information on UPs and PDs, see SOP 16**,** “Principal Investigator (PI) and IRB Reporting Requirements for Unanticipated Problems and Protocol Deviations”. For more information on Non-compliance, see SOP 16A**,** “Allegations and Incidents of Non-compliance with the Requirements of the NIH Human Research Protection Program (HRPP).”

**DEFINITIONS**

**Protocol Deviation (PD)**: Any change, divergence, or departure from the IRB-approved research protocol.

The impact of a PD is characterized by designation as serious or not serious (see SOP 16- Appendix E.) PDs include three types of protocol deviations:

1. Those that occur because a member of the research team deviates from the protocol;
2. Those that are identified before they occur, but cannot be prevented (e.g., when a subject alerts the research team that inclement weather will prevent the subject from attending a scheduled protocol visit); and
3. Those that are discovered after they occur.

**Unanticipated Problem (UP)**: Is any incident, experience, or outcome that meets **all** of 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 being studied;
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.

**Non-compliance**: The failure to comply with applicable NIH HRPP policies, IRB requirements, or regulatory requirements for the protection of human research subjects; (See SOP 16A, “Allegations and Incidents of Non-compliance with the Requirements of the NIH Human Research Protection Program (HRPP).”)

**Minor non-compliance:** Non-compliance that, is neither serious nor continuing.

**Serious:** A UP or PD is serious if it meets the definition of a Serious Adverse Event**\*** or if it compromises the safety, welfare or rights of subjects or others**.**

\* **Serious Adverse Event (SAE):** is any Adverse Event that: 1. Results in death; 2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred); 3. Results in inpatient hospitalization or prolongation of existing hospitalization; 4. Results in a persistent or significant disability/incapacity; 5. Results in a congenital anomaly/birth defect; or 6. Based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

**INSTRUCTIONS TO PRINCIPAL INVESTIGATORS**

1. Use this form to report all problems to the IRB including UPs, PDs, or Non-compliance
2. Use the appropriate electronic IRB system to complete this form (iRIS or PTMS.) If the PI is unable to access the appropriate IRB reporting system, PI may use this NIH Problem Report Form. The PI may elect also to report events (especially if Serious) to the IRB Chair/designee and/or the CD, in person or by phone or e-mail. However, such reporting is in addition to the required reporting using the NIH Problem Report Form.
3. Any modifications to the protocol and/or consent(s) resulting from a UP, PD or Non-compliance must be submitted via a separate amendment in the appropriate IRB system (iRIS or PTMS), except when necessary to eliminate apparent immediate hazard to the subjects as explained in SOP 10 – “Amendments to IRB-approved Research”.
4. Additional reporting requirements may apply, e.g., to the FDA, the NIH Office of Biotechnology Activities (OBA).

**IMPORTANT:** Notify the IRB and Clinical Director using the following timeframes:

* 1. **Serious UPs, UADEs, Serious PDs, and Serious Non-compliance:** as soon as possible, but not more than seven (7) days after the PI first learns of the event.
	2. **Not Serious UP, Not Serious PD or Minor Non-compliance:** not morethan fourteen (14) days after the PI first learns of the event.

**NIH PROBLEM REPORT FORM**

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| **Protocol #:** Click here to enter text. | **Protocol Title:** Click here to enter text. |
| **System Ref#:** (*Enter the IRB System reference number for this submission*)Click here to enter text. | **Report version:** *(select one)*[ ] Initial Report [ ] Revised Report[ ] Follow-up **If revised report or follow-up, enter the original System Ref #:** Click here to enter text. |
| **Principal Investigator:**Click here to enter text. | **Institute:** Click here to enter text.**Office Phone:** Click here to enter text.**E-mail:** Click here to enter text. |
| **FDA Regulated Research** *(indicate if this research is FDA regulated)*[ ] YES [ ] NO  | Study Sponsor: Click here to enter text.IND/IDE# Click here to enter text.IND/IDE Name:Click here to enter text. |
| **Date of problem:** Click here to enter text. | **Location of problem:** *(e.g., NIH Clinical Center or Name of Site/Location)*[ ] NIH CC[ ] Other, specify: Click here to enter text. |
| **Who identified the problem?** *(provide role: nurse, investigator, monitor, etc…)*Click here to enter text. |
| **Brief Description of Subject** *(if applicable)* (*Do NOT include personal identifiers)* Click here to enter text. | Sex: [ ]  Male [ ] Female Age: Click here to enter text.  [ ] Not applicable (more than subject is involved) |
| **Diagnosis under study:** Click here to enter text. |
| **If the subject is enrolled on any other studies, list the protocol number(s) here:** *(If applicable, submit a separate report form for each protocol listed)* Click here to enter text. |
| **Is this problem?** (*select all that apply*)[ ] An Unanticipated Problem that is: [ ] Serious [ ] Not Serious [ ] A Protocol Deviation that is: [ ] Serious [ ] Not Serious[ ] Non-compliance |
| **Is the problem also** *(select all that apply)* [ ] AE [ ] Non-AE |
| **Name the problem:** *(select all that apply)* [ ] Adverse drug reaction [ ] Abnormal lab value [ ] Death [ ] Cardiac Arrest/ code [ ] Anaphylaxis [ ] Sepsis/Infection [ ] Blood product reaction[ ] Unanticipated surgery/procedure [ ] Change in status (e.g. increased level of care required) [ ] Allergy (non-medication) [ ] Fall [ ] Injury/Accident (not fall) [ ] Specimen collection issue [ ] Informed consent issue [ ] Ineligible for enrollment [ ] Breach of PII [ ] Tests/procedures not performed on schedule [ ] Other, brief 1-2 word description: Click here to enter text.**Detailed Description of the problem:** (*Include any relevant treatment, outcomes or pertinent history*): Click here to enter text. |
| **Is this problem unexpected?** *(i.e., event not described in protocol, consent, or Investigator Brochure)* [ ] YES [ ] NO **Please explain:** Click here to enter text. |
|  **Is this problem related or possibly related to participation in the research?**  [ ] YES [ ] NO **Please explain:** Click here to enter text. |
| **Does the problem suggest the research places subjects or others at a greater risk of harm?** [ ] YES [ ] NO **Please explain:** Click here to enter text. |
| **Have similar problems occurred on this protocol?**  [ ] YES [ ] NO **If “Yes”, how many?** Click here to enter text. ­­­ **Please describe:** Click here to enter text. |
| **Describe what steps have you already taken as a result of this problem?**Click here to enter text.**What steps do you plan to take as a result of the problem?** (*select all that apply*)[ ] No action required[ ] Amend consent **(*Separate amendment submission required*)**[ ] Amend protocol **(*Separate amendment submission required*)** [ ] Inform existing subjects **(*Include example of information to be provided to subjects*)**[ ] Close the protocol **(*Separate closure submission required*)**[ ] Temporarily halt the protocol **(*Provide plan for management of enrolled subjects*)**[ ] Increase frequency/type of safety or other monitoring **(Separate amendment submission**  **required)**[ ] Other corrective action, describe:Click here to enter text.  |
| **In addition to the IRB, this problem is also being reported to:** (*select all that apply*)[ ] IC Clinical Director[ ] Study Sponsor[ ] If Investigator-held IND/IDE, report to FDA [ ] Manufacturer: Click here to enter text. [ ] Institutional Biosafety Committee [ ] Office of Biotechnology Activities [ ] Data Safety Monitoring Board[ ] CC Occurrence Reporting System (ORS)[ ] Other: Click here to enter text. [ ] None of the above applicable |
| **INVESTIGATOR’S SIGNATURE:**  | **DATE:** Click here to enter text. |
| **MEDICAL ADVISORY INVESTIGATOR’S SIGNATURE:** *(if applicable)* | **DATE:** Click here to enter text. |
| **CLINICAL DIRECTOR:** *(If a UP, UADE, or a Serious PD)*Click here to enter text. | **DATE :** Click here to enter text. |

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**IRB Use Only**

**IRB Determination**

System Ref# : (*Enter the IRB System reference number for this submission*) Click here to enter text.

Date IRB received: Click here to enter text.

Date of IRB review: Click here to enter text.

Select the IRB’s determination below: (*select all that apply*)

Unanticipated Problem (UP), confirm that the following 3 criteria are met: (*Report to OHSRP*)

[ ] Unexpected

 [ ] Related or possibly related to research

 [ ] Suggests greater risk of harm to subjects or others

 If any of the above are not selected, explain: Click here to enter text.

UP: (*select one*)

[ ] Serious

[ ] Not Serious

Non-compliance: (select all that apply)

[ ] Serious (*Report to OHSRP*)

[ ] Continuing (*Report to OHSRP*)

[ ] Not serious or continuing

Protocol Deviation (*select one*)

[ ] Serious

[ ] Not Serious

IRB meeting minutes: Click here to enter text.

Indicate the IRB’s action in response to this event: *(specify time frames where applicable if not already addressed in the minutes)*

[ ] No action required

[ ] Follow-up report required: Click here to enter text.

[ ] Amend consent(s)/assent(s): Click here to enter text.

[ ] Amend protocol:Click here to enter text.

[ ] Inform existing subjects: Click here to enter text.

[ ] Increase frequency/type of safety or other monitoring

[ ] More frequent continuing review, specify review period:Click here to enter text.

[ ] Suspend the protocol: (*Report to OHSRP*) Click here to enter text.

[ ] Terminate the protocol: (*Report to OHSRP*) Click here to enter text.

[ ] Other corrective action, describe: Click here to enter text.

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**OHSRP Use Only**

Date OHSRP received the preliminary report: Date IRB determination report received:

Click here to enter text.

This event is presumed to be :

[ ] Possible UP

[ ] Possible Non-compliance

Date first reported to OHRP: Click here to enter text.

Date final report to OHRP, no stips: Click here to enter text.

Date of final report, IRB follow-up: Click here to enter text.

OHSRP Notes: Click here to enter text.

OHRP Response Date: Click here to enter text.

OHRP Comments: Click here to enter text.