# **APPENDIX C:**Multi-site Sample Unanticipated Problem Form

Version\_November 2020

## SAMPLE UNANTICIPATED PROBLEM (UP) FORM

|  |
| --- |
| **Protocol Number:**  |
| **Protocol Title:**  |
| 1. **Principal Investigator Name:**
2. **Site Investigator Name:**
3. **Site ID #:**
4. **Site Phone #:**
5. **Site Fax:**
6. **Site E-mail:**
 |
| 1. **Participant ID:**
 |
| 1. **Participant Age:**
 |
| 1. **Participant sex:**
2. ☐ Male
3. ☐ Female
4. ☐ Unknown
5. ☐ Undifferentiated
 |
| 1. **Type of report:**
2. ☐ Initial
3. ☐ Follow-up #
 |
| 1. **Brief identification of UP:** *(categorize the incident, experience, or outcome that occurred in one or two words, full description is provided in Question 12)*
 |
| 1. **The event was unexpected in terms of nature, severity, or frequency:**
2. ☐ Yes
3. ☐ No
 |
| 1. **The event is related or possibly related to participation in the research:**
2. ☐ Yes
3. ☐ No
 |
| 1. **The event suggests that the research places participants or others at a greater risk of harm than was previously known or recognized:**
2. ☐ Yes
3. ☐ No

***\*If the answers to items 7-9 above are ALL Yes, report the event as an Unanticipated Problem to NIAMS, OHRP, and IRB. All UPs should be reported to OHRP within one month of the IRB’s receipt of the report of the problem from the investigator.******If any answer is No to items 7-9 above, do not use this form to report the event.*** |
| 1. **Was IRB notified?**
2. ☐ Yes; If yes, date notified: (dd/mmm/yyyy)**:**
3. ☐ No; Please explain: (*indicate plans to notify IRB*)
 |
| 1. **Was OHRP notified?**
2. ☐ Yes; If yes, date notified: (dd/mmm/yyyy)**:**
3. ☐ No; Please explain: (*indicate plans to notify OHRP*)
 |
| 1. **Is the UP a serious adverse event (SAE)?**
2. ☐ Yes
3. ☐ No

\****If the UP is a SAE, complete and submit the SAE form in addition to this form.*** |
| 1. **Full description of the UP:** *(Attach additional pages or supplementary information as necessary.)*
 |
| 1. **Date of report** (dd/mmm/yyyy)**:**
 |
| 1. **Date discovered** (dd/mmm/yyyy)**:**
 |
| 1. **UP onset date** (dd/mmm/yyyy):
 |
| 1. **UP stop date** (dd/mmm/yyyy): or check if Ongoing ☐
 |
| 1. **Did the participant receive the study intervention prior to this UP?**
2. ☐ Yes; If yes, last date study intervention given (dd/mmm/yyyy):
3. ☐ No
4. ☐ N/A
 |
| 1. **Action(s) taken with the study as a result of the UP:** *(Check all that apply.)*
2. ☐ Revision of protocol to eliminate apparent immediate hazards to participants
3. ☐ Modification of inclusion or exclusion criteria to mitigate newly identified risks
4. ☐ Implementation of additional procedures for monitoring participants
5. ☐ Modification of consent documents to include a description of newly recognized risks (site and/or study wide)
6. ☐ Suspension of enrollment to new participants
7. ☐ Suspension of research procedures in currently enrolled participants
8. ☐ Study terminated by IRB or any other regulatory bodies
9. ☐ Other, specify:
10. ☐ No action taken; rationale:
 |
| 1. **Based on the analysis of this event,** (*record explanation for either response*)
2. **Should currently enrolled participants be notified?** ☐ Yes ☐ No
* If yes, please clarify the plan to notify the participants:

Explain: 1. **Should participants who have completed the study be notified?** ☐ Yes ☐ No
* If yes, please clarify the plan to notify the participants:

Explain:  |

**PI Signature**:

**Date** (dd/mmm/yyyy):