|  |
| --- |
| **Reportable Events Form**Investigators must use this form to report to HRPP any Reportable Event as defined in the Brown University [Reportable Events Policy](https://www.brown.edu/research/sites/research/files/Reportable%20Events%20Policy%20%28Final_12Nov18%29.pdf). All qualifying events must be reported consistent with reporting time frames, also noted in the policy. |
| **Protocol Title:** **Protocol #:** | **PI Name:** | **Date of Report submission:** |

|  |  |
| --- | --- |
| **Date of Event:** | Click here to enter a date. |
| **Date PI became aware** | Click here to enter a date. |

**SECTION I: I am reporting (please check all that apply):**

1. \_\_\_\_\_\_\_\_ An adverse event (AE) that is unexpected and related or possibly related to participation in the research

1. \_\_\_\_\_\_\_\_ Any Unanticipated Problem (UP)
2. \_\_\_\_\_\_\_\_ Any breach of privacy or confidentiality, including lost or stolen confidential information.
3. \_\_\_\_\_\_\_\_ Any medical, procedural, or laboratory error (e.g., errors in drug administration or dosing, surgical or other procedures, testing of samples or test results)

1. \_\_\_\_\_\_\_\_ Any interim analysis, safety monitoring report, publication in a peer reviewed journal, or other finding indicating that there are new or increased risks to subjects or others, or that subjects are less likely to receive any direct benefits from the research study than as initially presented to the IRB.
2. \_\_\_\_\_\_\_\_\_ Any complaint by or on behalf of a subject indicating that the rights, welfare, or safety of the subject have been adversely affected.
3. \_\_\_\_\_\_\_\_\_ Any change in the Food and Drug Administration (“FDA”) labeling; any change in the status of an Investigational New Drug or Investigational Device Exemption; any withdrawal from market; any manufacturer alert from the sponsor of the research study; or any recall of an FDA-approved drug, device, or biologic under investigation in the research study.
4. \_\_\_\_\_\_\_\_\_ Any event that requires prompt reporting to the sponsor of the research study, if applicable.
5. \_\_\_\_\_\_\_\_\_ A suspension or termination of a research study or of a study’s enrollment by the FDA, the sponsor of the research study, or others, based on information indicating that the research study places subjects at an increased risk of harm than was previously known or recognized
6. \_\_\_\_\_\_\_\_\_ Any other event that is unanticipated and indicates that the research study places subjects or others (e.g. other investigators, research assistants, students, the public, family members or partners of subjects, etc.) at an increased risk of harm or otherwise adversely affects the rights, welfare or safety of subjects or others.

**Section II:**

Please provide a detailed description of the event including relevant dates and times.

**Section III:**

Please provide a detailed description of any corrective action or change to the protocol, planned or already taken, to ensure that the Reportable Event is corrected and will not occur again.

**Section IV:**

Please provide (i) an assessment of whether any subjects or others were placed at risk as a result of the Reportable Event, or suffered any physical, social, or psychological harm and (ii) any plan to address these consequences, and any other relevant information.