**Use this report to submit information to the Drexel IRB which falls into one or more of the following categories. Submission must be made within 5 business days from the date of awareness. When the Drexel IRB relies on an external IRB, reporting requirements for the Drexel IRB are described in the terms of the Reliance Agreement. For urgent issues contact the IRB/HRPP directly prior to submitting this report. This form must be completed and signed by the Principal Investigator for the research.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IRB Number:** | |  | | |
| **Protocol Name:** | |  | | |
| **Investigator:** | |  | | |
| **Primary Contact:** | |  | | |
| **Person completing form:** | |  | | |
| **Date of Awareness for This Information:** | |  | | |
| **In the opinion of the investigator does the information section fit into one or more of the following categories (check all that apply):**  **1.** **New or increased risk**  **2. Protocol deviation that harmed a subject or place subject at risk of harm, made without prior IRB approval to eliminate an immediate hazard to a subject, or due to the action or inaction of the investigator or research staff.**  **3. Audit, inspection, or investigation by a federal agency or other entity including Drexel.**  **4. Written report or action of a government agency, regarding the research, the PI, or the research staff, or if research staff were added a past history of such report or action including: conviction of a crime, FDA Warning Letter, NIDPOE (Notice of Initial of Disqualification Proceedings and Opportunity to Explain), suspension or termination by an IRB, suspension by a federal or government agency (such as the FDA, HHS, or Health Canada), OHRP Determination letter, Health Canada Inspection Letter with observations) or similar, or Form FDA 483 in the past 5 years**  **5. Allegation of Noncompliance or Finding of Noncompliance**  **6. Unauthorized disclosure of confidential information or an event that involves potential inappropriate sharing or disclosure of participant personal identifiers or protected health information or other breach of security, privacy, or confidentiality.**  **7. Unresolved subject complaint**  **8. Suspension or premature termination by the sponsor, investigator, or institution**  **9. Incarceration of a subject in a research study not approved to involve prisoners**  **10. Adverse or IND safety report that requires a protocol or consent change**  **11. State medical board or hospital medical staff actions (denial, revocation, suspension, reduction, limitation, probation, non-renewal, relinquishment, sanction, fine or discipline) regarding any of the following for the PI or research personnel, or if the research personnel are added, a history of each action : clinical privileges at any site, DEA licensure, fellowship/board certification, medical licensure in any state, nation or province, prescribing privileges, professional sanctions including fines or public reprimands, professional society membership or research privileges at any site**  **12. Unanticipated adverse device effect**  **13. Written report of a study monitor**  **14, Any event, incident, or situation that has generated adverse media attention or congressional interest**  **NOTE:**  **Changes in a financial interest disclosure or any other information previously submitted to the IRB must be submitted to the IRB as a modification.**  **Information not listed above or described in the HRP-071 POLICY: Prompt Reporting Requirements does not need to be submitted as Reportable New Information. If there are questions regarding submission, contact hrpp@drexel.edu.** | | | | |
| **Describe the circumstances in detail and attach any supporting documents with the submission. If applicable, also include a Corrective and Preventative Action (CAPA) plan which must include:**   1. **The root cause of the problem(s) and details such as timeline, people, and sites involved.** 2. **The corrective actions taken to mitigate or reduce any actual or potential risk or harm.** 3. **The steps, measures, and timelines for how you will prevent the problem from occurring again.** 4. **If no changes are proposed, justify this decision.** | | | | |
| **In the opinion of the investigator:** | | | | |
| Does this information indicate a new or increased risk, or a safety issue? | | | | Yes  No |
| Does the protocol need revision? | | | Yes  No | If “Yes” for either, then submit a Modification. |
| Does the consent document need revision? | | | Yes  No |
| **I have personally reviewed this information and agree with the above assessment:** | | | |
| Signature of Principal Investigator | | | Date |
|  | | |  |