|  |
| --- |
| **Use to report information items listed on page 2 of this form** |
| **IRB Number:** |       |
| **Protocol Name:** |       |
| **Investigator:** |       |
| **Primary Contact:** |       |
| **Person completing form:** |       |
| **Description of problem: (Attach supporting documents to this form)** |
|       |
| Date you became aware of this information : |       |
| Identify which specific category from page 2 of this form that this new information falls under (i.e. 1, 6): |       |
| **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 describe above and submit a request for modifications using form HRP-213.  |
| Does the consent document need revision? | [ ]  Yes [ ]  No |
| **I have personally reviewed this information and agree with the above assessment:**(Reports of research staff must be signed by the investigator) |
| Signature  | Date |
|       |  |
| IRB Use Only |
| Problem involves: (Check all that apply)[ ]  An unanticipated problem involving risks to subjects or others[ ]  Suspension or termination of IRB approval[ ]  Serious non-compliance[ ]  Continuing non-compliance[ ]  Non-compliance that is neither serious nor continuing[ ]  None of the above |  |
| IRB signature | Date |
|       |       |

**Report the information items that fall into one or more of the following categories to the IRB within 5 business days using this form:**

1. [ ]  Information that indicates a new or increased risk, or a safety issue. For example:

New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk

Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol

Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm

Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm

Any changes significantly affecting the conduct of the research

1. [ ]  Any harm experienced by a subject or other individual, which in the opinion of the

investigator are **unexpected** and **probably related** to the research pro**c**edures.

A harm is “**unexpected**” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

A harm is “**probably related**” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.

1. [ ]  Non-compliance with the federal regulations governing human research or with the

 requirements or determinations of the IRB, or an allegation of such non-compliance.

1. [ ]  Audit, inspection, or inquiry by a federal agency.
2. [ ]  Written reports of study monitors.
3. [ ]  Failure to follow the protocol due to the action or inaction of the investigator or

research staff.

1. [ ]  Breach of confidentiality.
2. [ ]  Change to the protocol taken without prior IRB review to eliminate an apparent

immediate hazard to a subject.

1. [ ]  Incarceration of a subject in a study not approved by the IRB to involve prisoners.
2. [ ]  Complaint of a subject that cannot be resolved by the research team.
3. [ ]  Premature suspension or termination of the research by the sponsor, investigator, or

institution.

1. [ ]  Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-

threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)