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| **Instructions**  Use this form to report information items listed at the end of this document. These information items must be reported to the IRB **within 5 business days** of the date the Principal Investigator became aware of the information.  **If changes to the protocol or consent are required based on the information being reported, an Amendment must also be submitted as a separate submission in eRA.** | | | | | | | |
| **IRB Number:** | |  | | | | | |
| **Protocol Title:** | |  | | | | | |
| **Principal Investigator:** | |  | | | | | |
| 1. **Description of the reportable information (Attach supporting documents in eRA):** | | | | | | | |
|  | | | | | | | |
| Date you became aware of this information : | | | | | | |  |
| Identify which specific category or categories (listed on page 2) characterize this new information: | | | | | | |  |
| In your opinion, does this information indicate a new or increased risk? | | | | | | | YES  NO |
| Does the protocol need revision? | | | Yes  No | | If “Yes” for either, describe above and submit an Amendment submission in eRA | | |
| Does the consent document need revision? | | | Yes  No | |
| **IRB Use Only**  **Note to IRB Coordinator: Download this form, complete table below and upload completed form to the Reportable New Information submission** | | | | | | |
| This information involves: (Check all that apply)  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  Allegation of non-compliance with no basis in fact  None of the above | | |  | | | |
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**Report the information items that fall into one or more of the following categories to the IRB within 5 business days using this form:**

**Information that does not fall under any of the categories does not require reporting to the IRB.**

1. Information that indicates a new or increased risk, or a new safety issue, for example:
   1. *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.*
   2. *Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm*
   3. *Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm*
   4. *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*
   5. *Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol*
   6. *Changes significantly affecting the conduct of the clinical trial or increasing the risk to participants*
2. Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably** related to the research procedures.
   1. *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.*
   2. *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.*
3. 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
4. Failure to follow the protocol due to the action or inaction of the investigator or research staff
5. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
6. Breach of confidentiality
7. Complaint of a subject that cannot be resolved by the research team
8. Premature suspension or termination by the sponsor, investigator, or institution
9. Incarceration of a subject in a study not approved by the IRB to involve prisoners
10. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483)
11. Written reports of study monitors
12. 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)