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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Use to report information items listed on the back 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: | | | | | | |  |
| Number of business days between the date of the event and the 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 the protocol need revision? | | | Yes  No | | If “Yes” for either, describe above and submit a modification request | | |
| Does the consent document need revision? | | | Yes  No | |
| **I have personally reviewed this information and agree with the above assessment:**  (Reports complete by research staff must be signed by the investigator) | | | | | | |
| Signature | | | Date | | | |
|  | | |  | | | |
| IRB Use Only | | | | | | |
| 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 | | |  | | | |
|  | |  | |
| 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:**

*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. 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
   3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
   4. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
   5. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
   6. Any changes significantly affecting the conduct of the research
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. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
5. Written reports of study monitors.
6. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. Breach of confidentiality.
8. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
9. Incarceration of a subject in a study not approved by the IRB to involve prisoners.
10. Complaint of a subject that cannot be resolved by the research team.
11. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
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.)