HRP-814 | 1/1/2024

FORM: Site Reportable New Information

Use to report information items listed at the end of this form[[1]](#endnote-2)

basic information

|  |  |
| --- | --- |
| **Basic Study Information** | **Study Details** |
| Study IRB Number (if known): | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Site Investigator: | Click or tap here to enter text. |
| Person completing form: | Click or tap here to enter text. |

Description of problem:

|  |  |
| --- | --- |
| **Reportable New Information Description Questions** | **Reportable New Information Details** |
| Briefly describe the new information:  (Attach supporting documents to this form) | Click or tap here to enter text. |
| Date you became aware of this information: | Click or tap here to enter text. |
| Number of business days between the date of the event and the date you became aware of this information: | Click or tap here to enter text. |
| Identify which specific category from page 3 of this form that this new information falls under (i.e., 1, 6): | Click or tap here to enter text. |

in the Opinion of the SITE Investigator

|  |  |
| --- | --- |
| **Reportable New Information Questions for Site Investigator** | **Site Investigator Responses** |
| Does this information indicate a new or increased risk or safety issue? | Yes  No |
| Does the protocol need revision?  (If “Yes”, describe above and submit a modification) | Yes  No |
| Does the consent document need revisions?  (If “Yes”, describe above and submit a modification) | Yes  No |

SITE Investigator Acknowledgement

I have personally reviewed this information and agree with the above assessment

(Reports completed by research staff must be signed by the site investigator).

SITE Investigator Signature

Date of Signature: Click or tap here to enter text.



SIRB 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 no-compliance with no basis in fact

None of the above

*(Must be completed by IRB Chair or a Designated Reviewer within 5 business days of receipt of report)*

*For unanticipated problems involving risks to subjects or others, indicate whether any actions are warranted to eliminate any apparent immediate hazards to subjects.*

SIRB Signature

Date of Signature: Click or tap here to enter text.



Reportable New Information Categories

**Report the information items that fall into one or more of the following categories to the IRB within 5 business days of becoming aware of any of the following information items.**

*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 indicating events to be reported to the IRB.
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.)

1. This document satisfies AAHRPP elements I-9, III.2.D [↑](#endnote-ref-2)