

REPORTABLE NEW INFORMATION

Please post this prominently in your research or office space.

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. For example:
 - a. 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.
 - b. 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.
 - c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
 - d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
 - e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
 - f. Any changes significantly affecting the conduct of the research.
- 2) Any harm experienced by a subject or other individual which in the opinion of the local investigator is **unexpected** and at least **probably related** to the Human Research procedures and suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.
 - a. 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.
 - b. A harm is “a least probably related to the Human Research procedures” if in the opinion of the local investigator, the research procedures more likely than not caused the harm (greater than 50% probability).
- 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) Breach of confidentiality.
- 6) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- 7) Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- 8) Complaint of a subject that cannot be resolved by the research team.
- 9) Suspension or termination of the research by the sponsor or the investigator.
- 10) 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).
- 11) Audit, inspection, or inquiry by a federal agency.
- 12) Written reports of study monitors.
- 13) For Veterans Administration (VA) research only: any local or internal serious adverse event or serious problem that is both unanticipated and related to the research.
- 14) External IRB determination of serious non-compliance, continuing non-compliance, serious and continuing non-compliance, an unanticipated problem involving risk to research subjects or others, suspension or termination of (external) IRB approval. (This RNI category is to be used only when another IRB (external IRB) has made these determinations for this protocol).