FORM: Reportable New Information		
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Use to report information items listed on the back of this form

IRB Number:	
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):	

If reporting a harm (2) or a failure to follow the protocol due to action or inaction of the investigator (6), complete and submit the Reportable New Information Template (HRP-508) with this form. Please include any supporting documentation.

In the opinion of the investigator:

Does this information indicate a new or increased risk, or a safety issue?	☐ Yes ☐ No	If "Yes", describe above and submit a modification request
Does the protocol need revision?	☐ Yes ☐ No	
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:

☐ 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) Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.

☐ 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 "**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 by Research Quality Assurance and/or 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.)