HRP-214-FORM: Reportable New Information

ADA Compliant Form – April 21, 2014

**General Instructions:** Use this form to report information items listed below. These information items must be reported to the IRB within **5 business days** of the date the Principal Investigator became aware of the information. **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)

**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.**

# Study Information

1. Protocol Number (eRA):
2. Protocol Title:
3. Principal Investigator:

# Reportable New Information Details

**Instructions:** Attach any supporting documents to the submission in eRA.

1. Provide a description of the reportable information:
2. On what date did you become aware of this information?
3. Identify which specific category or categories characterize this new information (categories are listed at the beginning of this form):

**Answer “Yes” or No” for the following questions. If Yes to either question, explain below and submit a separate Amendment submission in eRA.**

1. In your opinion, does this information indicate a new or increased risk?
2. Does the consent document need revision?

# **IRB USE ONLY**

All information below this point will be completed by IRB staff; *IRB Coordinator* – complete and upload this form to the Reportable New Information submission in eRA.

**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