HRP-204-Promptly Reportable Information

**Project Title:**

**IRB number:**

**Principal Investigator:**

# Reportable Information

**Category of Information:**

Which of the following category(ies) best describes the information? Check all that apply.

*Note: The following items require prompt reporting to the IRB within 10 days.*

[ ]  New or increased risk

[ ]  Protocol deviation due to the action or inaction of the investigator or research staff

[ ]  Protocol deviation that harmed a subject or placed subject at risk of harm

[ ]  Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject

[ ]  Audit, inspection, or inquiry by a federal agency\*

[ ]  Written reports of federal agencies (e.g., FDA from 483)\*

[ ]  Written reports as follows: industry or internal monitoring reports, data monitoring board reports, or IRB required internal or external audit reports\*

[ ]  [Allegation of Noncompliance] or [Finding on Noncompliance]\*\*

[ ]  Unauthorized disclosure of confidential information\*

[ ]  Unresolved subject complaint

[ ]  Suspension or premature termination by the sponsor, investigator, or institution

[ ]  Incarceration of a subject in a research study not approved to involve prisoners

[ ]  Adverse events or IND safety reports that require a change to the protocol or consent

[ ]  State medical board or hospital medical staff actions\*

[ ]  Unanticipated adverse device effect

\*This information must also be reported to AdventHealth Orlando IRB when relying upon an external IRB.

\*\*This information must also be reported to the AdventHealth Orlando IRB when relying upon an external IRB only when it relates to local requirements.

**Information Provided By:**

Enter the name of the person providing this information.

**Problem(s) Description:**

Describe the item in detail as follows and as appliable (e.g., date of occurrence and discovery, ID# of affected subject(s), timeline, cause, immediate actions taken, changes made).

**Actions Proposed or Taken:**

What actions are proposed to be taken to protect research subjects or others, prevent future occurrences, and/or resole any outstanding issues? (e.g., root cause analysis, training, re-training, revisions to protocol, consent and/or other documents). If corrective action is being development, provide the date it will be complete. If no actions or changes will be implemented, provide justification.

**Review by Principal Investigator:** [ ]  Yes [ ]  No

**Agreed by Principal Investigator:** [ ]  Yes ☐ No

