PROTOCOL DEVIATIONS & EXCEPTIONS

A protocol deviation that applies to an individual subject (not the study as a whole), and does not **increase the risk of harm to the subject does not need to be** reported to the Upstate IRB. Documentation in the study record (e.g., protocol deviation log) and sponsor notification (as applicable) should be done. Protocol deviation logs can be included during continuing review (as applicable).

- Example: If a subject cancels a visit because of concerns related to COVID-19, would not need to be reported to the Upstate IRB unless it impacts the risk to the participant.

- Example: In person visit is changed to a virtual visit (phone, telemedicine, etc.) would not need to be reported to the Upstate IRB unless it impacts the risk to the participant.

Protocol exceptions are circumstances in which the investigator wishes to deviate from eligibility criteria or one or more of the specific procedures called for in a research plan. Unlike modifications that apply to all subsequent subjects in the research, a protocol/research plan exception only applies to a specific subject or group of subjects.

- Example: All currently enrolled subjects will have in person visits changed to virtual visit (phone, telemedicine, etc.)

Exceptions are planned, and the investigator gets approval from the IRB ahead of time. Approval from the sponsor may be required. Procedures for exceptions are the same as for a Protocol Amendments (Change in Research).

A Protocol exception and/or protocol amendment would not require prior IRB approval, when the exception or change is necessary to avoid an apparent immediate hazard to the subject(s). In such cases, the exception/change must be submitted to the IRB as soon as possible.

IRB Notification of Study Hold/Suspension or Termination

Please submit all notifications of a study hold/suspension or termination imposed by the sponsor/CRO, investigator, other reviewing IRB, other government agency, or other party as soon as reasonably possible (except where the suspension or termination relates to noncompliance by an investigator or identification of safety issues impacting study participants- this must be reported immediately).

Measures should be in place to ensure that research participants are properly informed of any suspensions/termination and that any procedures needed for participant follow-up are in place.