

Investigator Guidance Series

Suspension of Study (HRPP 8.6)

Description:

This policy describes the process for study suspensions.

Definitions:

<u>Suspension of IRB Approval</u>: directive of the IRB at a convened meeting, or a directive of the IRB Executive Chair or designee, that all or some research activities in one or more protocols must be temporarily suspended.

Suspensions:

- The PI is responsible for notifying all study personnel that the study has been suspended and that all, or some, research activities are suspended.
- The PI must report to the IRB any adverse events or outcomes associated with the suspension.
- The PI must notify the research subjects currently on the study of the suspension.
 Subjects should be advised of any follow-up necessary for safety reasons.
- The PI may file a written appeal of the suspension to the IRB. The convened IRB has the final authority on the matter.

