

Termination of Study (HRPP 8.6)

Description:

This policy describes the process for study termination.

Definitions:

Termination of IRB Approval: directive by the IRB at a convened meeting that all research activities must permanently cease in one or more protocols.

Terminations:

- The PI is responsible for notifying all study personnel that the study has been terminated and that all research activities must cease.
- The PI must report to the IRB any adverse events or outcomes associated with the termination.
- The PI must notify research subjects currently on the study of the termination.
 - 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 within 30 days of the termination.
 - The IRB shall give the PI an opportunity to appear before the board.
 - The PI will be afforded due process and may bring legal counsel who will be restricted to observation only.
 - The convened IRB has final authority on the matter.