Study Hold, Suspension, and Termination (HRPP 8.6)

Description:

This policy describes the process for study holds.

Definitions:

Study Hold: planned or unplanned temporary pause to subject accrual and/or research activities imposed by the PI, the sponsor, the DSMB, or the FDA or other funding agency. A study hold may be full or partial.

Suspension of IRB Approval: directive of the IRB at a convened meeting, or a directive of the IRB Executive Chair/designee, to **temporarily stop/suspend** some or all research activities in one or more protocols.

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

Study Holds:

- The PI is responsible for informing all study team members that there is a study hold and subject accrual and/or research activities must be restricted
- The IRB will be notified at the next convened meeting
- If the study team or agency wants to lift the hold, they must request it in writing *(email or letter)* to the ORA
    - If the hold was due to safety concerns for participants, only the full IRB can approve restarting the study
    - If the hold was for reasons other than safety *(such as funding or administrative issues),* the IRB's Executive Chair or their delegate can approve restarting the study

Suspensions:

- The PI is responsible for notifying the study team that the study was suspended and that all, or some, research activities must pause
- 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 appeal the suspension in writing to the IRB, however the IRB has the final say on the matter
- Only the IRB can officially end/lift a suspension of a study

Termination of IRB Approval by the IRB:

- The **IRB may terminate a study if:**
    - There are serious concerns about the safety, rights, or well-being of participants, the research team, or others, OR
    - The research team has seriously or repeatedly failed to follow rules and/or regulations
- The IRB will give the PI a written explanation of why the study is being terminated
- The PI is responsible for notifying the study team that the study was terminated and that all research activities must stop
- The PI must report to the IRB any adverse events or outcomes associated with the termination
- The PI must notify the research subjects currently on the study of the termination
    - Subjects should be advised of any follow-up necessary for safety reasons
- The PI has **30 days to appeal** the decision in writing
    - 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 IRB will make the final decision and it cannot be changed

Termination of IRB Approval by the Organization:

- In consultation with appropriate Organization officials, the Institutional Official (IO) may decide to terminate one or more of an investigator's approved studies
- The IO will provide the PI with a written explanation of the decision
- The PI is responsible for notifying the study team that the study was terminated and that all research activities must stop
- The PI must report to the IRB any adverse events or outcomes associated with the termination
- The PI must notify the research subjects currently on the study of the termination
    - Subjects should be advised of any follow-up necessary for safety reasons
- The PI has **30 days to appeal** the decision in writing
    - The IO 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 IO will make the final decision and it cannot be changed