



Study Hold (HRPP 8.6)

Description:

This policy describes the process for study holds.

Definitions:

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

Study Holds:

- The PI is responsible for notifying all study personnel 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.