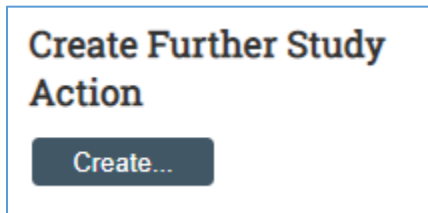


Submitting a pSite Termination Report Process and Workflow [JHM sIRB]

pSite Termination Reports should be submitted to the JHM IRB only when site activity is completed and access to study identifiers (if applicable) is no longer required for data analysis or manuscript writing.

- 1) The Lead PI/coordinating center **or** the pSite PI/pSite lead study team contact will initiate a pSite Termination Report in eIRB2.
- 2) On the pSite application workspace, under “Create Further Study Action”, the investigator will select “**Create...**”, selecting the type of FSA type [**Termination Report**]:



Creating New: Submission

Further Study Action Selection

* Select the type of Further Study Action you would like to create

Modification

Protocol Event

Termination Report

- 3) In Section 1 – Site Enrollment Information, complete the enrollment charts and summarize the conclusions of the study [**relevant to your pSite**].
- 4) In Section 2 – Problems, Events and Deviations, summarize any events and/or complaints that have occurred during the last approval period [e.g., from the last continuing review approval to present].
- 5) The Lead PI/coordinating center PI **or** the pSite PI/pSite lead study team contact will complete and submit the pSite termination report for review.
- 6) Once the pSite termination report is submitted, it will undergo an expedited IRB review. Upon review, the pSite termination report may be returned with issues that need to be addressed or it may be acknowledged. If returned, the lead PI/coordinating center PI **or** the pSite PI/pSite lead study team will be required to address all review concerns.
- 7) IRB staff will process the pSite termination report acknowledgment letter. The letter will be made available on the pSite termination report application workspace. The pSite should receive a copy of the termination acknowledgment letter.