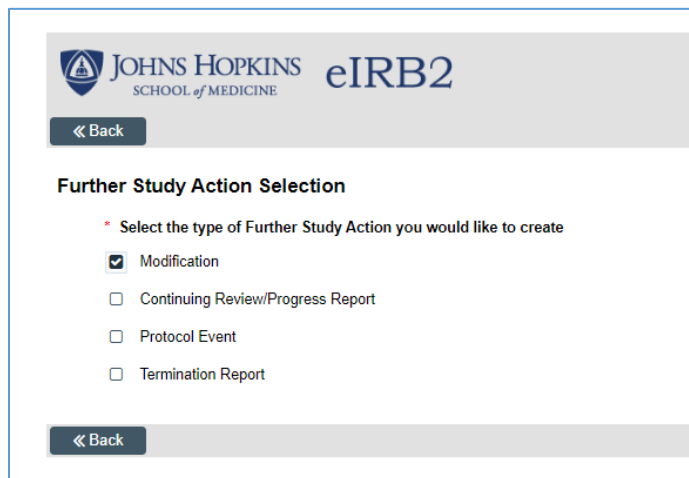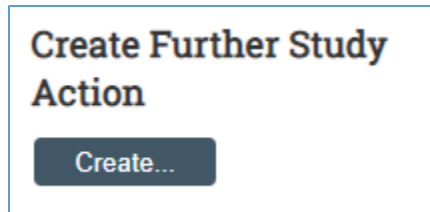## Submitting a Participating Site Problem Event Report

Process and Workflow [JHM SIRB]

1) Both the Lead PI/coordinating center and the pSite PI/lead site contact can initiate a Protocol Event report in eIRB2.

2) On the approved pSite application workspace, under "Create Further Study Action", the investigator will select "**Create…**", selecting the type of FSA type:

3) The Lead PI/coordinating center **OR** the pSite PI/lead site contact can complete the report. A PI must submit the pSite problem event report for review.

4) Once the pSite problem event report is submitted, it will undergo IRB review. Upon review, the pSite problem event report may be returned with issues that need to be addressed or it may be acknowledged. If returned, the Lead PI/coordinating center **OR** the pSite PI/lead site contact can will be required to address all review concerns.

5) IRB staff will process the pSite problem event report acknowledgment letter. The pSite problem event report acknowledgment letter will include:

- Site Name
- Participant ID(s)
- Date(s) of discovery of reportable event