

## Submitting a Participating Site Progress Report Process and Workflow [JHM SIRB]

- 1) The Lead PI/coordinating center will initiate a **Continuing Review [CR]** application which will also trigger the creation of pSite Progress Reports [PR] for all approved pSites.
- 2) The pSite PI/lead site contact can access the PR form from a link on their pSite application workspace, under the “Further Study Actions” tab:

The screenshot displays a web application interface with a navigation bar at the top containing tabs: History Log, Reviewer Notes, Further Study Actions (highlighted in yellow), Additional Documents, and a menu icon. Below the navigation bar, there are two sections: 'Modification' and 'Continuing Review/Progress Report'. The 'Modification' section shows a search filter set to 'Name' with a search box containing 'Enter text to search for' and a search button. Below it, it states 'No data to display.' and shows pagination for 'page 1' with 'no results' and a '10 / page' selector. The 'Continuing Review/Progress Report' section also has a search filter set to 'Name' with a search box containing 'Enter text to search for' and a search button. Below it, there is a table with the following columns: Name, Date Created, State, and Last State Change. The table contains one row: 'Progress Report: PR00001119 For: CR00036869/IRB00260051', '6/15/2021 11:13 AM', 'pSite Prep', and '6/15/2021 11:13 AM'. Below the table, it shows '1 items' and pagination for 'page 1 of 1' with a '10 / page' selector. Two green arrows are present: one pointing to the 'Further Study Actions' tab and another pointing to the first column of the table.

Name	Date Created	State	Last State Change
Progress Report: PR00001119 For: CR00036869/IRB00260051	6/15/2021 11:13 AM	pSite Prep	6/15/2021 11:13 AM

- 3) The Lead PI/coordinating center PI or the pSite PI will complete the pSite PR and submit the pSite PR for review.
- 4) Once all pSite PRs are submitted, the parent study CR can be submitted and it will undergo IRB review. Upon review, pSite PRs MAY be returned with issues that need to be addressed. If returned, the pSite study team will be required to address any review concerns.
- 5) IRB staff will process the CR approval letter which will include the new study expiration date and a list of all currently-approved pSites.