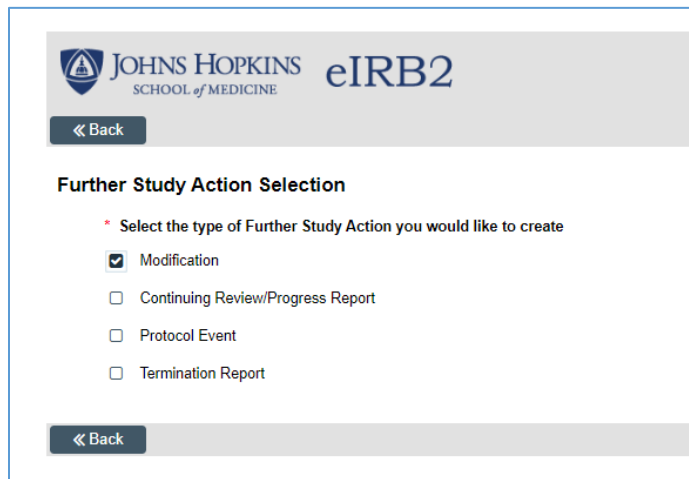
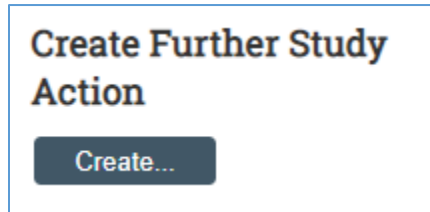
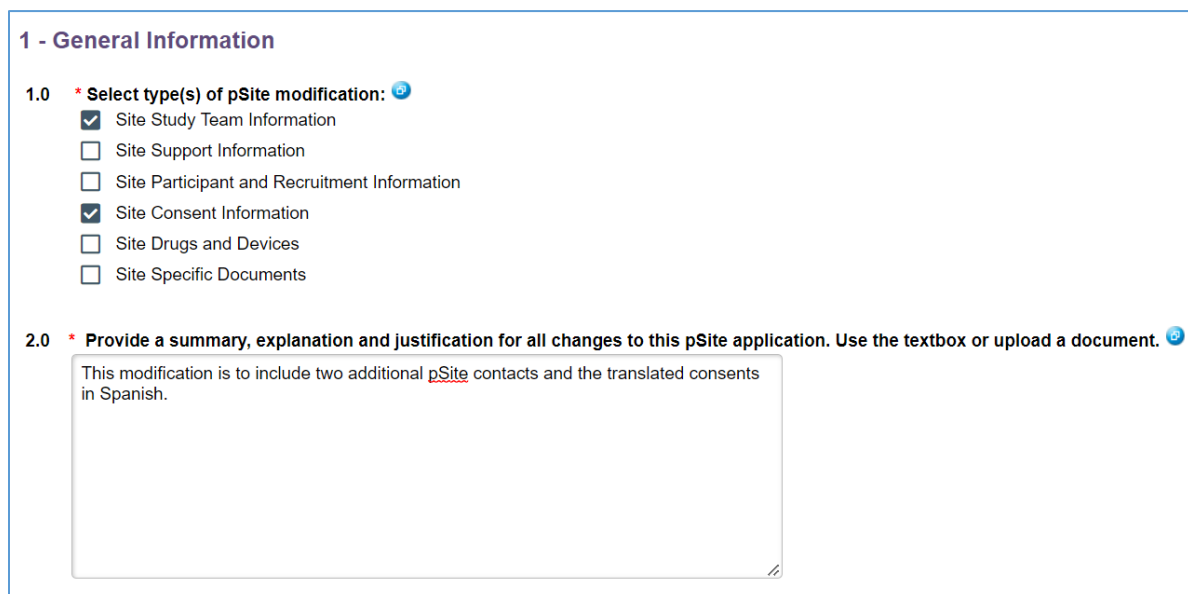




Submitting a Participating Site Modification Process and Workflow [JHM SIRB]

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



- 3) In Section 1 – General Information, select the sections of the pSite application you wish to modify, and provide a detailed summary of the changes requested.

A screenshot of the "1 - General Information" section of the pSite application. It contains two numbered items:
1.0 * Select type(s) of pSite modification: 
 Site Study Team Information
 Site Support Information
 Site Participant and Recruitment Information
 Site Consent Information
 Site Drugs and Devices
 Site Specific Documents
2.0 * Provide a summary, explanation and justification for all changes to this pSite application. Use the textbox or upload a document. 
A large text area contains the text: "This modification is to include two additional pSite contacts and the translated consents in Spanish."

Submitting a Participating Site Modification Process and Workflow [JHM SIRB]

If the pSite modification includes a change to the pSite PI or other study contacts, you will make these changes in Section 1 - Site Study Team Information, questions 3.0 – 5.0.

- If your study utilizes the direct access feature, allowing the pSite PI and other study contacts to access and submit pSite actions independently from the lead study team, please contact JHMIRBReliance@jhmi.edu to assist with account creation instructions before proceeding. Once accounts are established, individuals will be listed in the drop-down menu to add to the pSite application.
- If your study does not utilize the direct access feature, in “Section 1 - Site Study Team Information”, question 5.0, use the “**Click to create new contact**” link to create profiles for these individuals. Individuals will automatically be listed in the drop-down menu to add to the pSite application. They will receive email notifications but will not have direct access to eIRB.

3.0 * Site Principal Investigator:
Janelle Maddox-Regis ...

4.0 * Site Lead Study Team Member:
Scott Hines ...

5.0 Additional Contacts (select up to three):
[Empty dropdown menu] ...

Person
There are no items to display

If you are unable to find the person click link below:
[Click to create new contact](#)

- 4) The Lead PI/coordinating center PI or the pSite PI/pSite lead study team contact will complete the application. The Lead PI/coordinating center PI or the pSite PI will submit the pSite modification for review.
- 5) Once the pSite modification is submitted, it will undergo IRB review. Upon review, the pSite modification may be returned with issues that need to be addressed or it may be approved. If returned, the pSite study team will be required to address all review concerns.
- 6) *If the pSite modification includes changes to the consent form*, the consent form specialist (CFS) will build the appropriate documents for each pSite once the outcome for the pSite modification has been recorded as Approved.
- 7) IRB staff will process the pSite modification approval letter and the approved site-specific consent form (and any additional documents) for each pSite, *if applicable*.
 - The modification approval letter will include:
 - i. A list of documents approved with this pSite modification [e.g., site-specific consent form]
 - ii. A list of currently-approved documents (e.g., protocol version date) that are relevant to the pSite modification approval

Submitting a Participating Site Modification Process and Workflow [JHM SIRB]

- 8) Stamped documents can be retrieved from the pSite application workspace, under “Stamped Documents”. These documents will only be available on the pSite application workspace – not the parent application workspace.

History Log	Reviewer Notes	Further Study Actions	Additional Documents	Stamped Documents
Written consent form(s):				
Title				
View Ball State University Site-Specific ICF_11.27.pdf(0.01)				
Oral consent script(s):				
Title Date Modified Versio				
There are no items to display				
Written assent form(s):				
Title Date Modified Versio				
There are no items to display				
Oral assent script(s):				
Title Date Modified Versio				
There are no items to display				