

## **Review of Modifications Required to Secure "Approved"**

When non-committee or committee review is completed, a determination of Modifications Required to Secure "Approved" may be issued. The following are steps to complete review of the submission following this determination.

## 1. Complete the appropriate review form, and mark 'Modifications Required to Secure "Approved"



2. Complete appropriate post review tasks

- o Prepare letter
- o Send Letter
- 3. When the letter is sent, the submission transitions to Modifications Required, the study team receives a notification and the submission will be open for edits.



- 4. Once edits are completed, the study team completes the "Submit Changes" activity.
- 5. The submission transitions to Modifications Submitted, in Post Review.



## 6. Review the changes and choose the appropriate next step:



OR

Assign To Committee

OR

Assign Designated Reviewer

The changes made are directly in response to the requirements and do not alter a feature of the project or otherwise require member or board review.

Continue to step 7 to complete review that meet regulatory criteria for review of required modifications. The changes made in response to the requirements alter a feature of the project or otherwise require member or board review.

The review process following completion of one of these activities is standardized. Please view committee and non-committee review training materials for further details on next steps.

## 7. Complete the Review Required Modifications Form

Review Required Modifications		
This verification can update the determination from "Modifications Required determination.	d" to the final	
Notes:	Notes enter in the subm will be visib members.	ed here will appear ission history and le to study team
	Ŧ	
Supporting documents:	Attachments entered here will	
There are no items to display	history and	will be visible to
* Were the modifications completed as required? 2 🔘 Yes 🔘 No Clea	study team	members.
	OK Cancel	

- Marking 'yes' will transition the submission to Post Review.
  - $\circ$   $\,$  Completion of standard post review steps will transition the study to Approved.
- Marking 'no' will indicate that not all requirements were met.
  - The submission will immediately transition back to Modifications Required without the creation of a new determination letter (back to step 3 of this process).
  - $\circ~$  A notification is triggered indicating modifications are required.
  - The study team can determine what additional items are needed based on what is written in the notes of this activity form, which are visible in the history of the submission workspace.