PROTECT Tip Sheet for *Research Teams:*

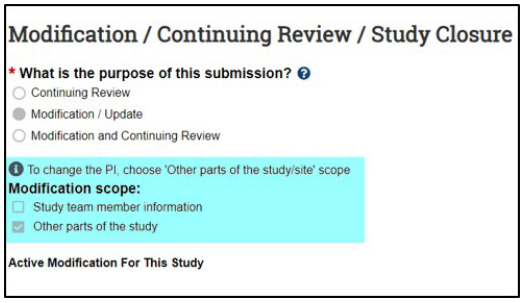
"Tips & Tricks: Preparing Modifications."

Access to read/write/submit:

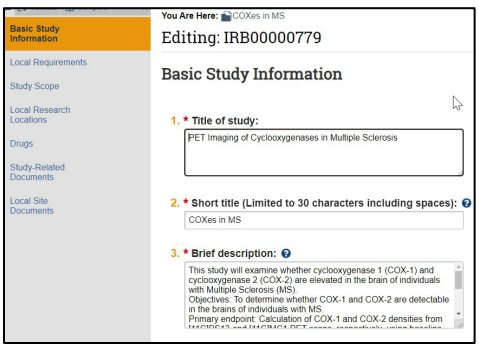
- For Modifications, only those listed on the study team for that protocol will have the ability to create a modification and only the PI/PI proxy can submit modifications.
- If someone is only listed as a Guest or as a Primary Contact on the study, they will only be able to view items related to that study. They will not be able to create, edit or submit any form for that protocol (except for RNIs, any user of the system can submit an RNI).
- If an ancillary review is added to a MOD, once the ancillary review is managed those on the committee will have read only access to the MOD workspace.

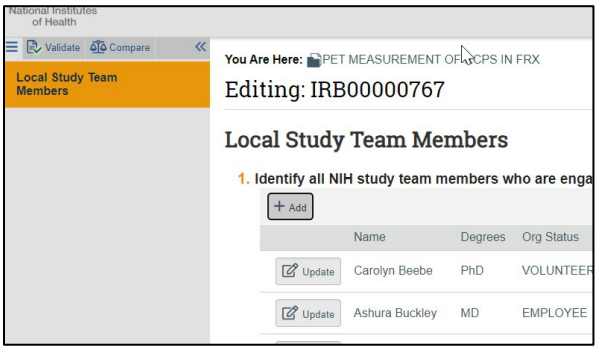
Types of MODS (NIH is the reviewing IRB):

- There are two types of modifications that can be created in PROTECT: "Study Team Member Information" or "Other Parts of the Study." For ONLY changes to study personnel choose the option for study team member information only.



- Two MODs can be submitted at the same time but ONLY if they are of different types. For example, if you submit a MOD for "other parts of the study", your only option is to submit a "study team member information" MOD until the initial MOD you submitted is approved.
- When you choose the "study team member information" MOD you are only able to edit the study personnel section of the whole form. When "other parts of the study" is chosen you can edit the entire form, study documents AND the Principal Investigator (PI).



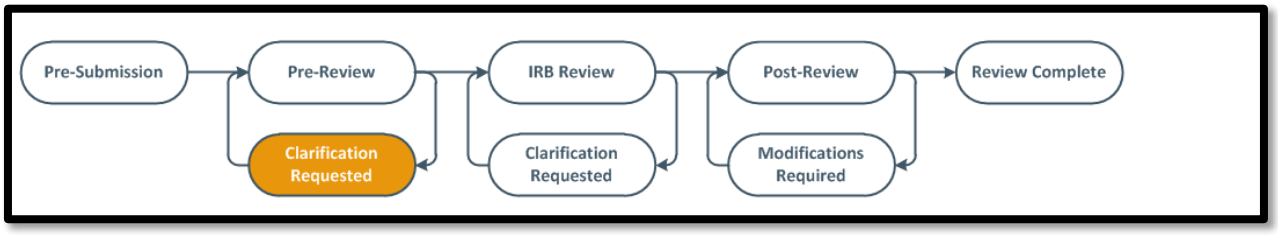


- To change the PI, you must choose the "other parts of the study" option so you have access to the study form and can update the study form, protocol, consents, etc. with the new PI's name & contact information.
    - We no longer have various "signoffs" for a PI change. Instead, please either have the new PI add a comment in the submission history or attach some form of documentation (e-mail or memo) from the new PI stating that they are willing and aware that they will be taking over the study as the new PI. This can be attached in the "supporting documents" section of your MOD form.

'Request for Clarifications' vs 'Modifications Required to Secure Approval.'

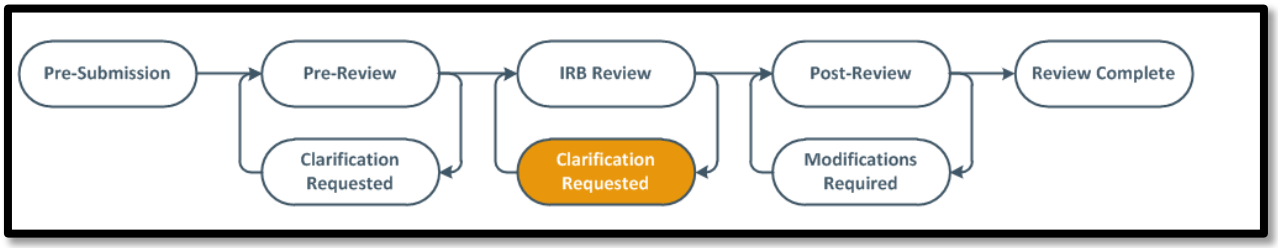
Request for Clarifications:

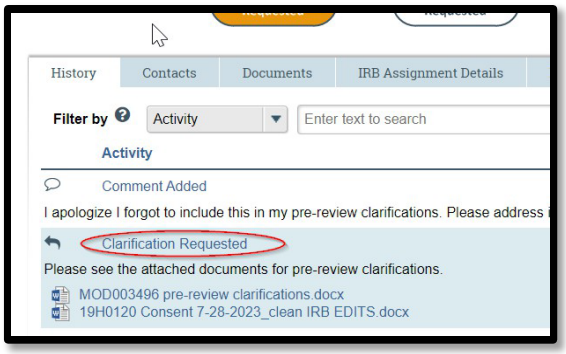
Pre-Review Loop: you CAN edit the MOD form.



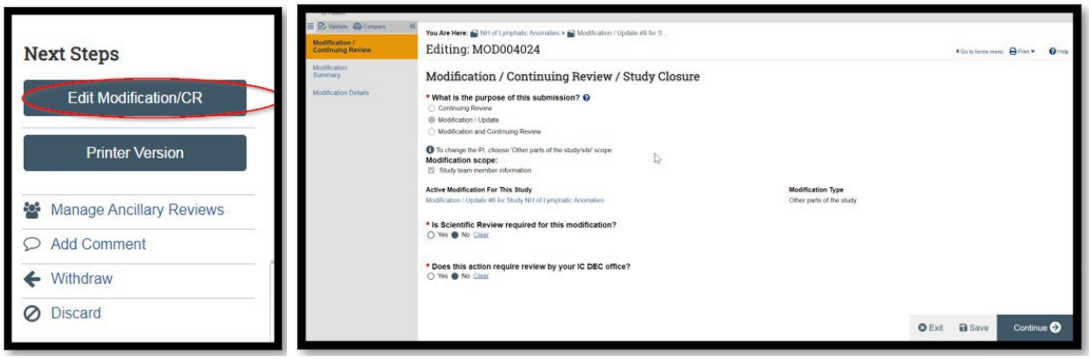
- When a modification is submitted to the IRB, the IRB coordinator will be assigned to perform a Pre-Review of the submission. During this part of the workflow if they require you to make changes to your form, documents, or they want to clarify something, it will be returned to the study team side and the "Clarification Requested" bubble will be highlighted. You will see the details of what is requested in the history tab of that action. This can also happen during an expedited or full board IRB review.

IRB review Loop: Designated IRB reviewer sends a clarification: you CAN edit the MOD form

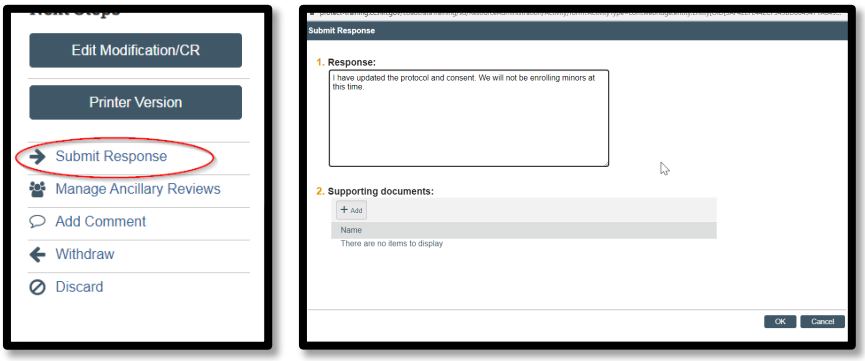




- Based on the clarifications needed this may require you to only submit a response back, or it may also require you to update your documents in your study form.
- If updating your documents is required, do this FIRST by editing your MOD form and BEFORE submitting your response back to the IRB staff or designated reviewer:

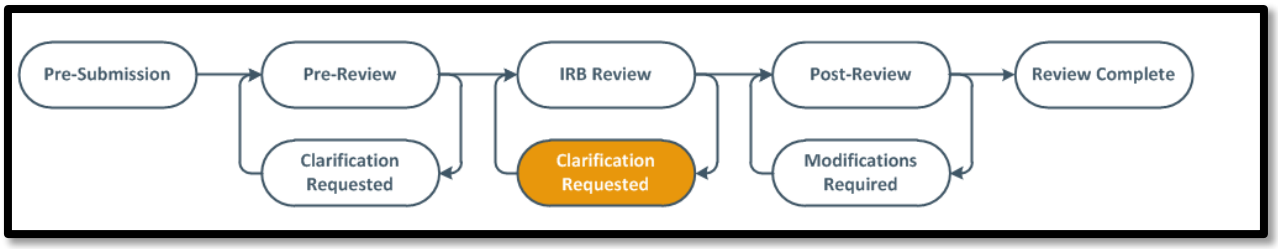


- Once you have made all the changes necessary to your form, click the "submit response" button and add any additional information in the text box or attach any additional supporting documents (if needed). Please do not upload your updated protocol/consent documents here. These need to be updated in the actual study form for them to be approved. Once this is done it will be back with the IRB staff.
  NOTE: only the PI or PI proxy can respond to clarifications.



- Do not use the *Add Comment* activity to respond to a clarification. Comments are ONLY a communication function and they do not send the action back to the IRB.

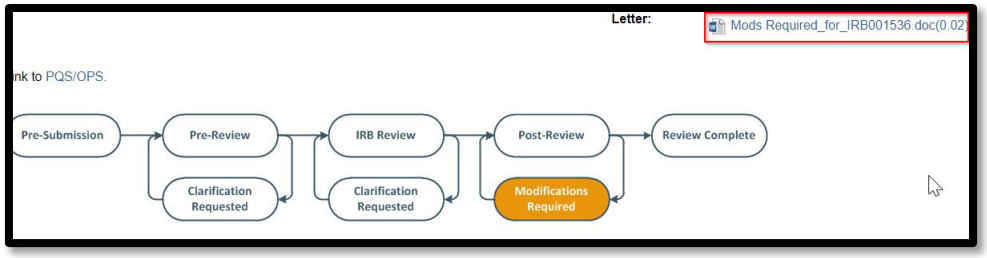
IRB review Loop: Full board IRB Reviewer sends a clarification: you CANNOT edit MOD form, must attach documents in Add Comment activity



- If the MOD is scheduled for Full Board review, and an IRB committee member has sent a clarification to the study team, you cannot edit the study form. Please just respond to the question from the IRB reviewer. In this case, you should not attach the revised protocol and/or consent. You must submit the response back and may attach any needed supporting documents to the response for the Board to review at the meeting. This is the one situation where you can attach the supporting documents in the submit response activity. NOTE: Please don't wait to respond to the IRB committee member's questions. This will ensure that the members have all the information they need prior to the IRB meeting to facilitate review of the submission.

Modifications Required to Secure Approval:

- If an action is assigned to a Full Board IRB meeting, the board may require the PI to make some changes before providing the final approval. The action would then be in the "Modifications Required" state of the workflow and a letter will be issued stating the requirements of the IRB.

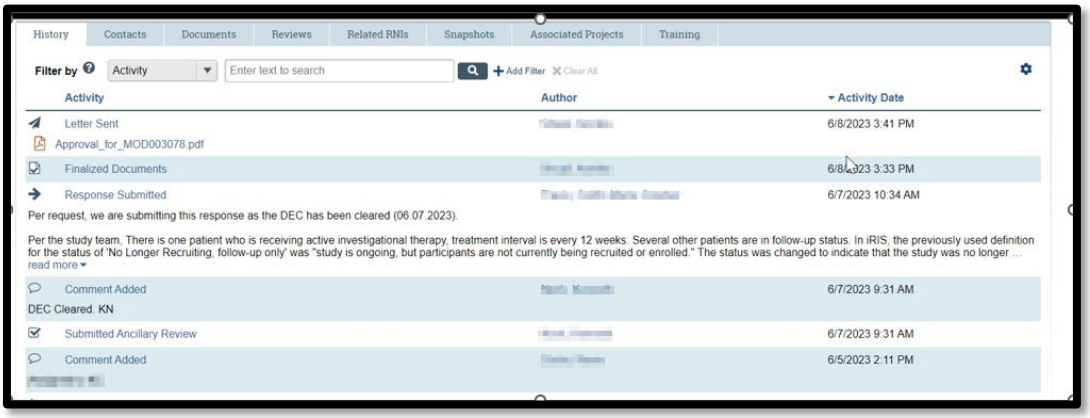


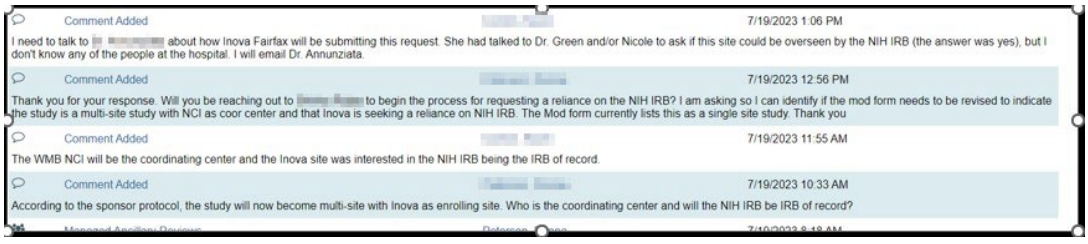
- The PI/PI Proxy will make edits to the study form and study documents as needed and "S*ubmit Response*" back to the IRB. Only the PI/ PI proxy can respond to modifications required to secure approval.
- Once the IRB has reviewed the changes and deemed them acceptable, the final approval letter will be drafted and sent to the study team.
- Your MOD will now be in an Approved state. Any documents revised on the MOD then get copied up to the parent study workspace so that the most currently approved documents can always be found there.

Comments vs. responses:

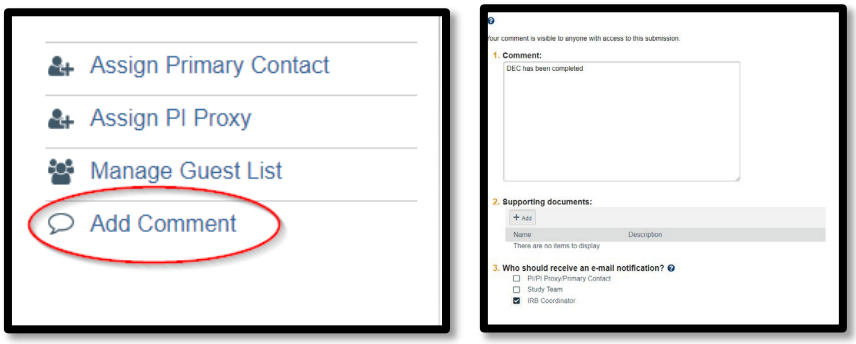
Comments:

- The comment function is only a communication piece and is used to document information in the history of that action or to provide quick communication on an issue.





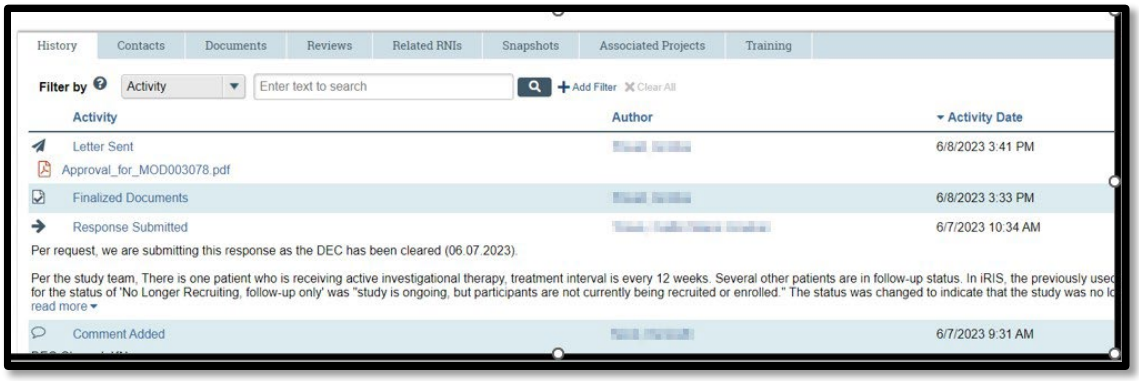
- If you are adding an important communication to an IRB coordinator as a comment, they will not be alerted of the comment unless you choose them to receive a notification:



ANY user with access to that specific study can add a comment to that study.

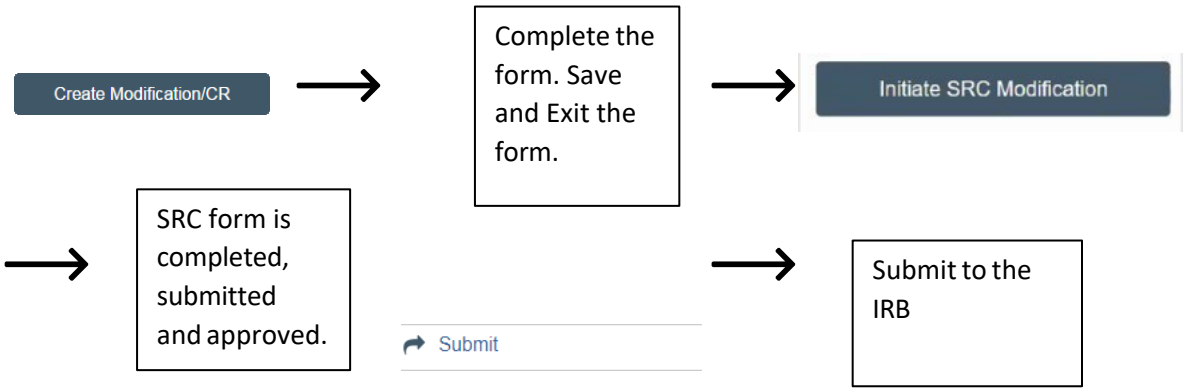
Responses:

- *Responses* can only be submitted by the PI or PI proxy. Submitting Responses will send actions back to the IRB staff.



Modifications that require Scientific Review:

- If within your MOD form, you answer YES to the question "Is Scientific Review Required for this modification?" you will need to submit a Scientific Review form for the MOD and wait for the approval until you can submit your MOD to the IRB office.
- Once you complete the MOD form, you will have to exit out of the MOD form and choose the Initiate Scientific Review for a MOD button (only the PI and PI proxy will see this button).
- Once your SRC submission for that MOD has been approved THEN you may submit your MOD to the IRB for review.

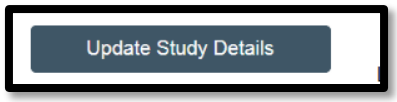


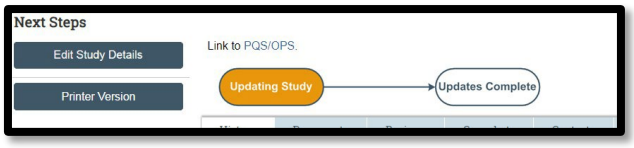
Ancillary Reviews:

- If you answered YES to any additional reviews being needed for your MOD (IBC, DEC, pharmacy if new drug) this should be added prior to submission to the IRB.

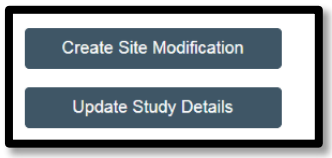
External IRB studies:

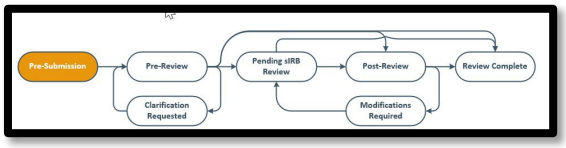
- For a single site study for which we are NOT the IRB of record, the study team uses the "study update" function to submit modifications to the NIH site.





- For a multi-site study for which we are NOT the IRB of record, study teams will need to submit a study update (used for study-wide changes) and a site modification (used to update specific NIH information/documents).





Sites Relying on the NIH IRB:

- For multi-site studies for which we are the IRB of record, our study teams submit modifications the same way as a single site study. Participating sites (pSITE) will have access to their site in PROTECT and can submit a site modification from within their site page. The NIH study team can also submit pSite materials to the NIH IRB on behalf of the pSIte.