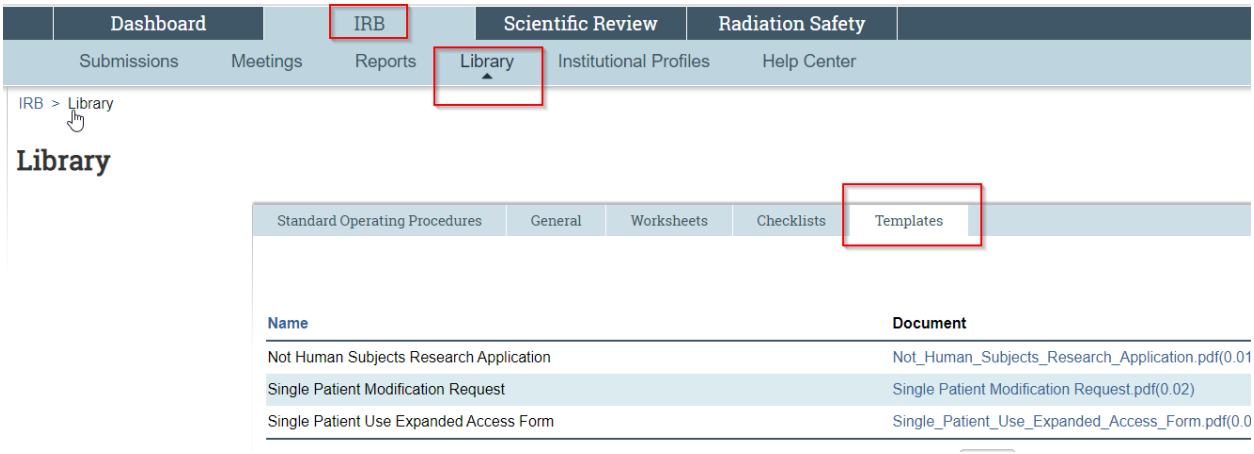
PROTECT UPDATE 01.26.2023

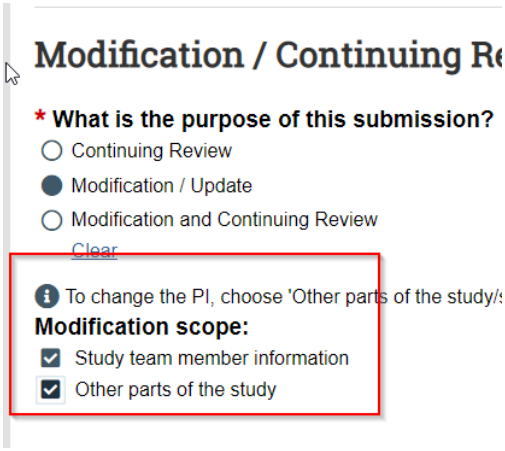
As a result of moving from iRIS to PROTECT there are several important process changes that may impact your research.

- Progress reports will no longer be required for minimal risk research that was approved under the revised Common Rule (approved by the IRB after January 20, 2019), unless at the time of initial review the IRB had determined that continuing review is required. Modifications and study closures will still need to be submitted as usual. Those studies approved under the pre-2018 Common Rule will still require annual continuing reviews. If a continuing review is required, the system will continue to send reminders.
- Reminder: Existing exempt projects did not migrate from iRIS into PROTECT.
- If you need to submit a new project that is a request for a NHSR determination, single patient expanded access, or request for an exemption, you must click on "create a new study", complete all the fields in the form, and attach the relevant documents.
    - If you have a request for an exemption, please include the word "Exempt" in the title of the protocol document. The protocol should be attached to the IRB application in the protocol section. If it is a modification to a previously approved exempt project in iRIS, please refer to the protocol number and title in iRIS in "brief description" section of your application.
    - For both the Not Human Subjects Research and Single Patient Use Expanded Access (emergency and non-emergency) you must download and complete a fillable pdf from the PROTECT library. The completed form should be attached to the IRB application in the protocol section.
- If you have a Single Patient Modification Request you must download and complete a fillable pdf from the PROTECT library. This must be attached to the modification form in PROTECT for that protocol, in the "local site documents" under "other attachments".

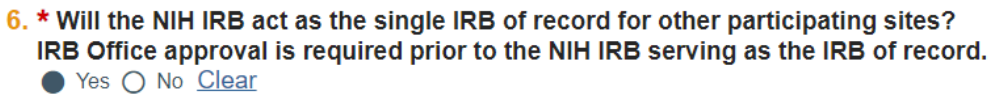


In addition, after reviewing multiple submissions, we have seen some common issues with the study forms we want to bring to your attention for migrated studies.

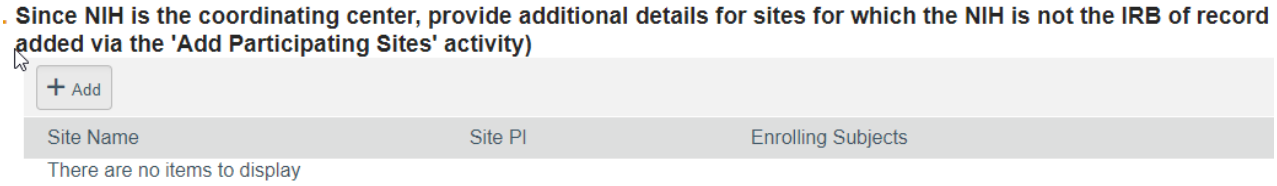
- **Please note we posted our migration notes for the researchers** and information about how to process your first SR action (either MOD, quad/AR). Please review this information when you are creating the first modifications or SR action for your migrated ticket: https://irbo.nih.gov/confluence/display/ohsrp/Timeline+and+Migration
- If you need to make changes to both the study team members and other parts of the study application, you **need to select both options for your MOD** (or MOD/CR) in order for these sections to open up and be editable. Once submitted to the IRB, this field cannot be changed for that submission.



- **Please be mindful about selecting "multi-site" vs. "single-site" in PROTECT**. This system handles this question differently than iRIS did.
    - If all research activities are taking place under the oversight of the NIH PI, even if there is an investigator who is covered under an IIA, FWA agreement etc., then select single site. Those investigators would then be included in the "local study team members" section.
    - If there are/were engaged research activities taking place at other sites, under the oversight of a different site PI, then it is multi-site. Once a study is multi-site, it is always multi-site, even if research activities are no longer taking place at other sites.
    - If NIH is the reviewing IRB for those sites, then say "yes" to #6 and the sites would then be entered via the "add participating sites" activity and each site will have its own workspace in the system. This information did not migrate from iRIS.



    - If NIH is the coordinating center for the study and there are sites that have local IRB review, then enter information about those sites in question #8. This information did not migrate from iRIS.



- **DOCUMENTS**: The currently approved protocol, consent(s), questionnaires, and recruitment materials were able to be migrated. No other categories of documents were migrated. It is possible that not all your currently approved documents migrated. Old consents still marked as approved in iRIS also migrated over. Please review your documents carefully so that when you delete old documents from PROTECT, that you do not delete currently approved documents. Please also take the time to upload any approved documents you see that did not migrate.

- **STUDY SCOPE:** Please be sure you review the study scope questions and answer "yes" if you have drugs/devices on your protocol that did not migrate over. Select the appropriate drug/device from the list and answer the remaining questions that will appear. We have a report under the "custom reports" in the IRB module that show you all the drugs that are currently in the system for you to choose from. We are developing a similar report for devices. If you don't see the drug/device on the list that you need to enter, please enter a ticket to have the product entered into the choice list.