# Notes to Researcher for PROTECT Migration

## Studies that will be migrated

In the first wave, the only protocols that will be migrated are approved studies that do not have an amendment or progress report in process. Studies that do not migrate in the "first wave" will migrate in the "second wave" if the action is completed or if not completed by the time of the second migration, then it will migrate without that action being processed (the investigator will need to start over with the mod or CR in PROTECT).

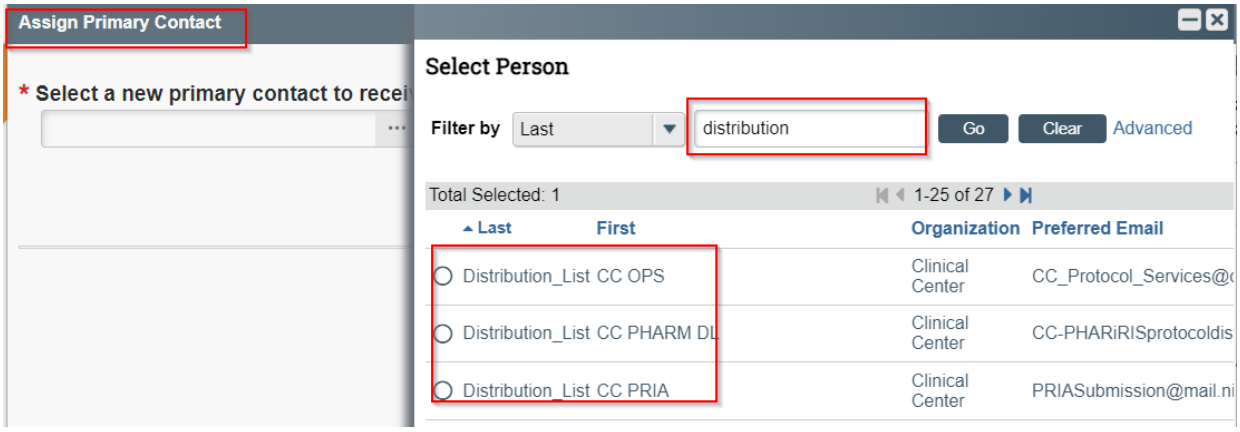
- Exempt protocols and NHSR projects will not migrate

## When you first go into PROTECT, review your list of protocols

Open each protocol under the IRB "active" tab and assign the primary contact for the protocol (it will default to the PI) and any proxies as you wish.

- Primary contact: can be chosen from any user in the system
- Proxy: must be listed as a study team member in PROTECT on the "Local Study Team Members" page. Only the PI can assign a study team member to be a proxy.
- Add any people to the guest list that you want to have read-only access to your protocol.

To add a primary contact to receive notifications and read only access for the project, select the "assign primary contact" activity. Then from the list, select the person. You can select a distribution list to be added as the primary contact if that list has been added as a "user" in PROTECT. To select a distribution list, start by typing in "distribution" as the last name and then choosing the correct DL from the list of choices. If you would like to have a distribution list added, enter a ticket to request this at our helpdesk: https://ohsrp.helpdesk.nih.gov



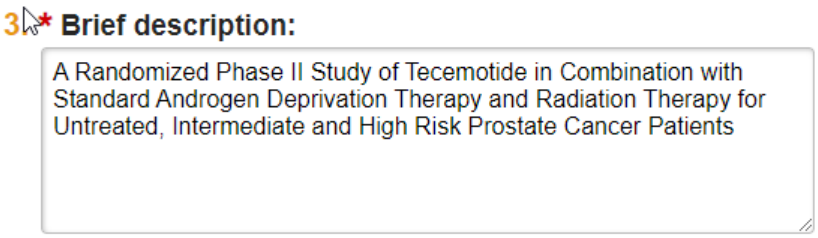
**Second, click on "view study" to review what information has migrated**

**Third, click on "create a modification/CR" to update your study information**


## Fields to review and update:

**Section "Basic Study Information", Question #3: Brief description**

This field needs to be updated with the full study summary. Only partial information was able to be migrated due to the inclusion of special characters in the text. You can cut and paste the study summary from your protocol document into this field, or alternatively write a short description of the study.




**Section "Basic Study Information", Question #4: What kind of study is this?**

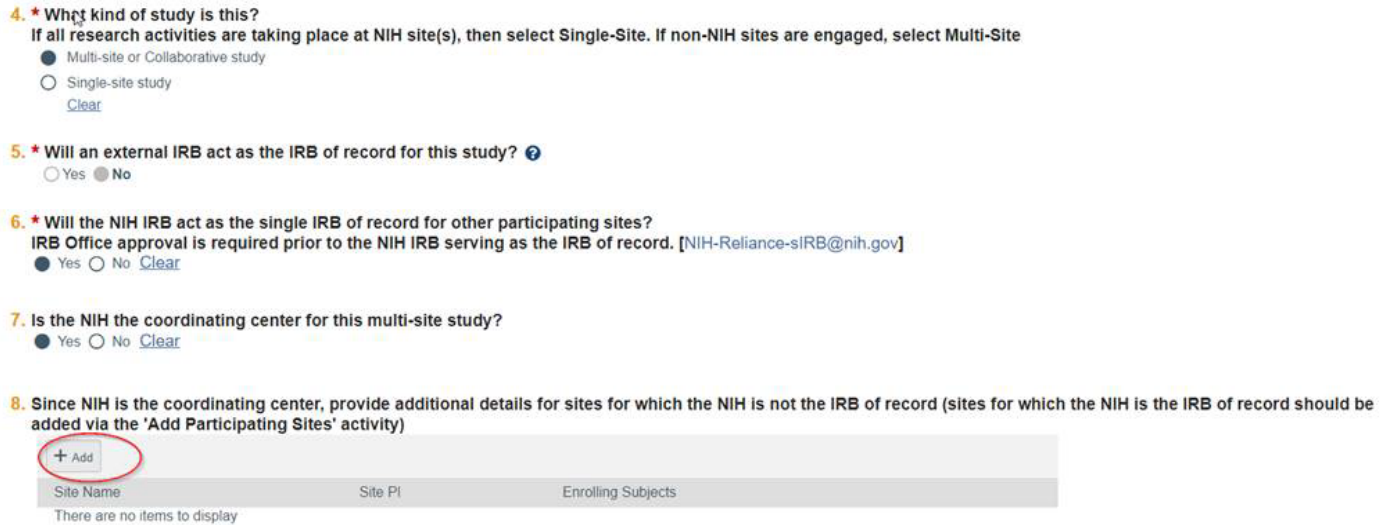
Confirm that multi-site/single site is appropriately selected for this question. If you are the coordinating center and the protocol has sites under local IRB review (those sites that are not being reviewed by the NIH IRB), these need to be entered into PROTECT for informational/tracking purposes if they are still active studies (meaning still under IRB review; recruitment status does not matter).

The non-NIH sites that are under their own local IRB review are **not** migrating into PROTECT. You will need to enter each site into the application with your first modification (MOD) (see screenshot just below). You only need to enter sites in this field if they are still under IRB review at that site (not closed/completed sites).

For situations where NIH is the coordinating center for a study and there are pSites that are reviewed by their local IRB, it is possible that you may have some sites which are under local IRB review and other sites that are being reviewed by the NIH IRB. In this case, you will list the pSites being reviewed by their local

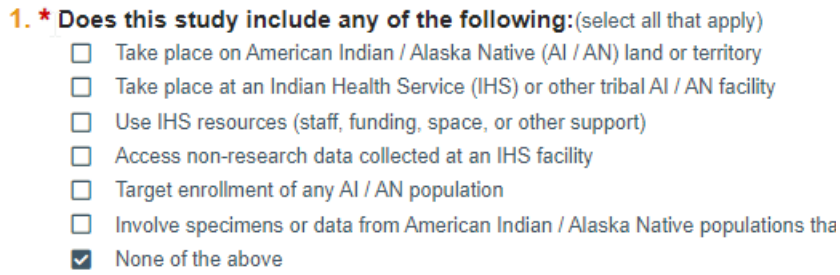
IRB here (in question #8), and the other pSites that are being reviewed by the NIH IRB will be listed under a different tab in the project as a participating site where we are the reviewing IRB.

The active pSites under NIH IRB review will be entered as a participating site by OHSRP staff in the Production server environment site when we go live.



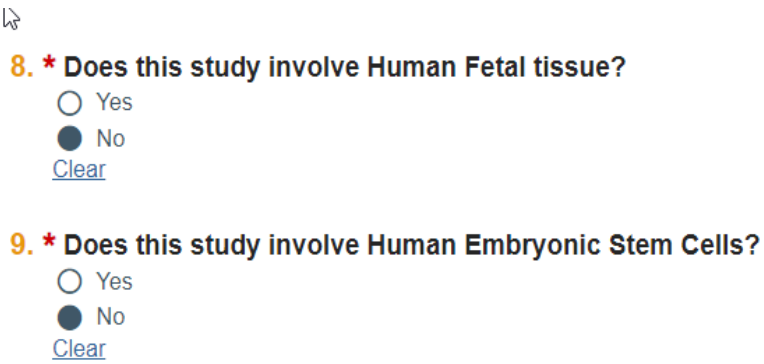

**Section "Local Requirements", Question #1: Does this study include any of the following?**

The following question was **not** able to be migrated and you will need to complete it as per the protocol:



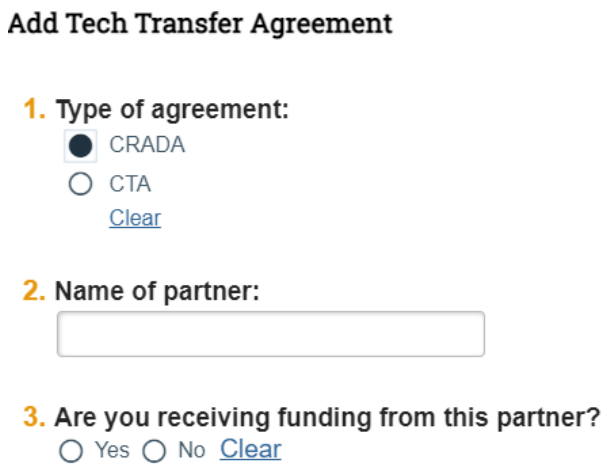

**Section "Local Requirements", New questions in PROTECT**

These are new fields that did not exist in iRIS and therefore during the migration, were auto set to "no". Please update if your answer is "yes" to accurately reflect your study:



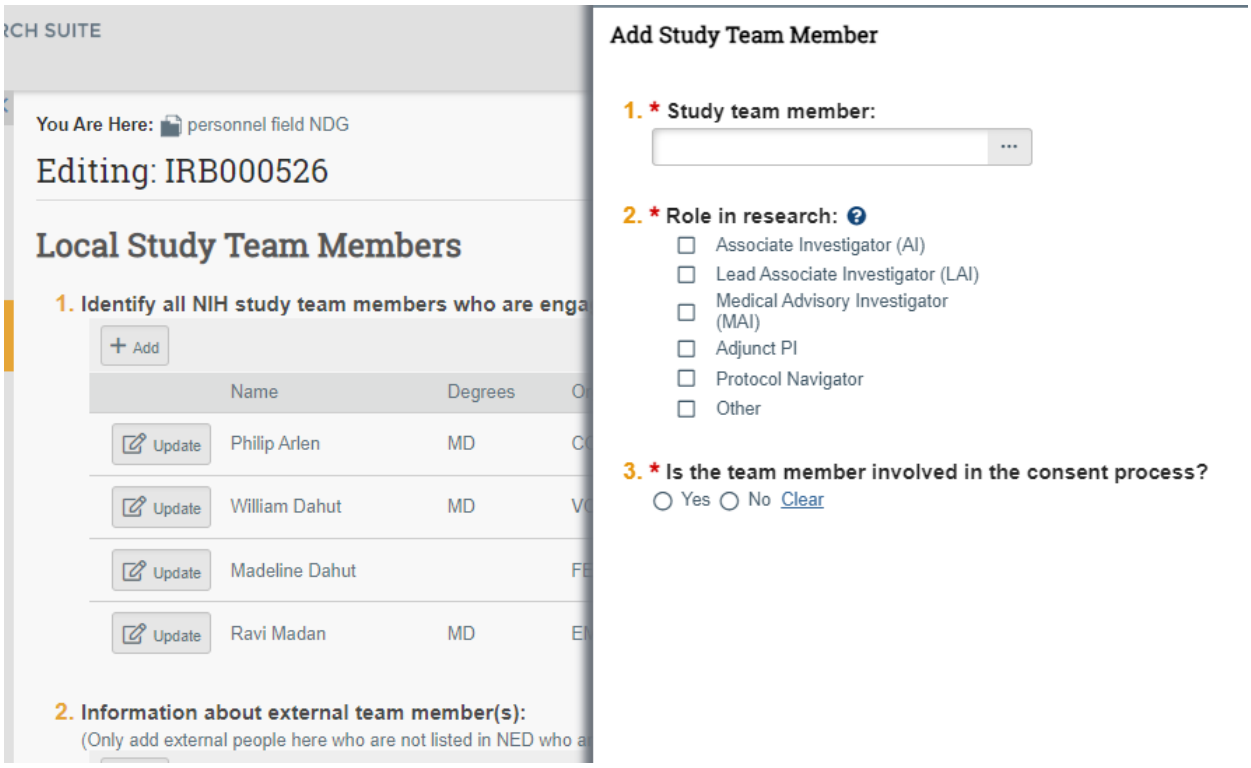
**Section "Local Requirements", Tech Transfer Agreements**

If your protocol includes a CRADA or CTA, you need to check that this information migrated correctly and add in the name of the partner and if there is funding received from the CRADA:




**Section "Local Study Team Members", Question 1: Identify all NIH study team members who are engaged in this research project who are also listed in NED**

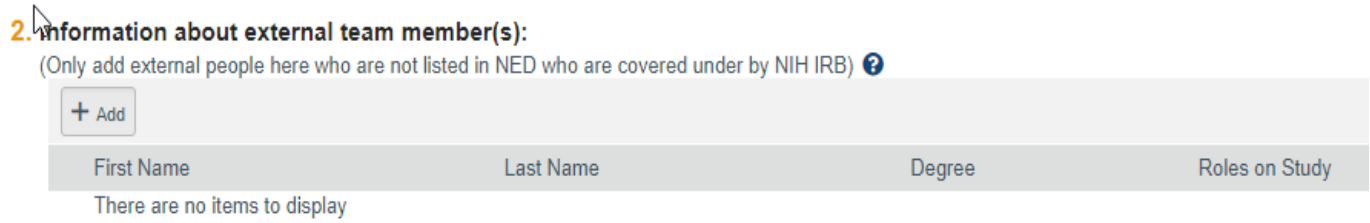
You will need to carefully check your study personnel to make sure this list is accurate. You will need to add any additional people (in particular, protocol navigators that you want to have access as that is a new role in PROTECT that did not exist in iRIS), and update for each person whether or not they are involved in obtaining consent. This field was automatically set to "no" in the migration for each person and will need to be updated with your first MOD.




**Section "Local Study Team Members", Question #2: Information about external team member(s)**

If you have study team members who are not listed in NED but are involved in your study at the NIH site(s) and covered by the NIH IRB, you will need to add these people here. For example, non-NIH individuals covered by an NIH IIA, FWA coverage agreement, or reliance agreement. Do not add collaborators who are not engaged in human subjects research in this section. This does not include non-NIH researchers working at non-NIH sites.

These people were **not** migrated over from iRIS so you will need to manually add all these people in this section.




**Section "Study Scope", Questions #1 & #2:**

For drugs and devices, pay particular attention to these fields if your protocol includes these. First, these fields must be correctly selected:

## Study Scope

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or di mitigate a disease or condition?

● Yes ○ No Clear

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?

○ Yes ● No Clear

**Section "Drugs" & "Devices"**

Next, review the drugs/devices that have migrated over. In PROTECT, we have a drop-down selection list for all drugs and devices. If you do not see your product on the list, please enter a ticket at: https://ohsrp.helpdesk.nih.gov with the information about your product and we can add it to the list so you can add it to your protocol. Check to be sure that the list is correct, and the right drug/manufacturer is selected. If not, remove the product that is incorrect and add the correct one.

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study: (Include all that being investigated as part of this study; do not include su medications.)

+ Add

| | Investigational Name | Generic Name | Brand Name | Manufacturer Name | Attachment Name | |
|---|---|---|---|---|---|---|
| Update | | cyclophosphamide | | Generic | | ⊗ |
| Update | | cytarabine | | Generic | | ⊗ |
| Update | | etoposide | | Generic | | ⊗ |
| Update | | filgrastim | Neupogen | Amgen, Inc. | | ⊗ |
| Update | | methotrexate | Rheumatrex | DAVA Pharmaceuticals, Inc | | ⊗ |
| Update | | prednisone | | Generic | | ⊗ |
| Update | | rituximab | Rituxan | Genentech, Inc | | ⊗ |

Pharmacy must be selected as an Ancillary Review if any drugs have been added to the IRB submission.

2. * Will the study be conducted under any IND numbers?

○ Yes ● No Clear

**Section "Local Site Documents", Consent forms:**

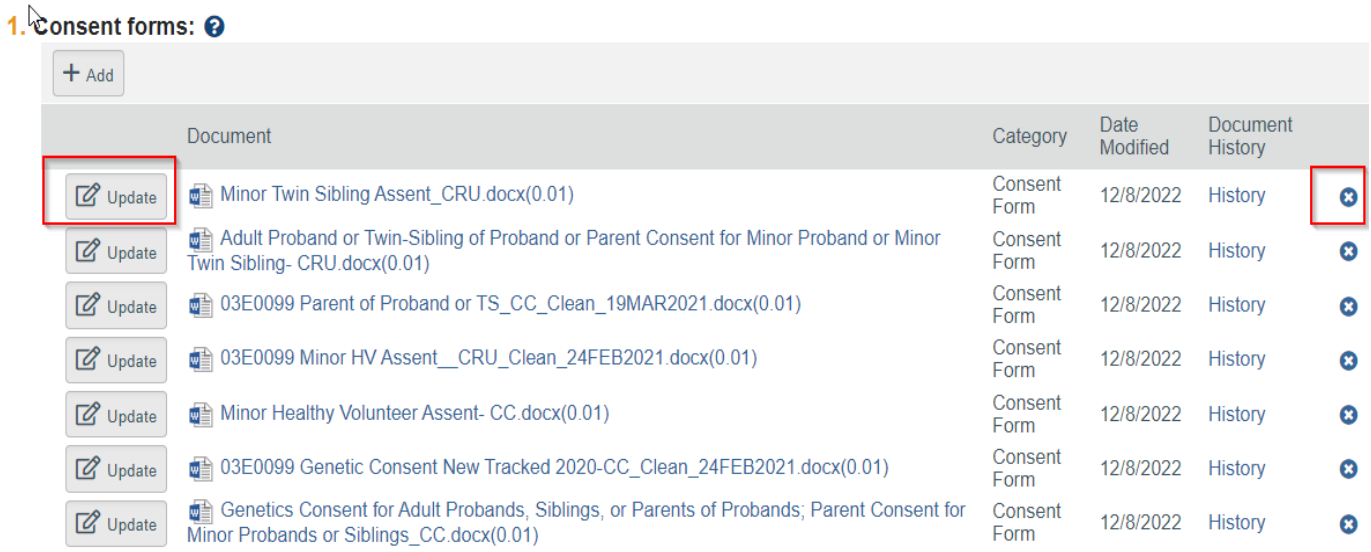
Carefully review consents and delete any versions that are old (not currently approved) or belong to a non-NIH site.

- All consents that are currently marked as approved will migrate into PROTECT in one place, the "local site documents" page. That means that if there are old consents still marked as approved in iRIS, they will be pulled into PROTECT at the time of the migration.

  **IMPORTANT** - Please review your list of consents and delete out the ones (if any) that are not currently approved.

- If your study is multi-site and you have a model consent, delete the model consent from the "local site documents" section and add it to the "study-related documents" section.

- If your study has pSites for which the NIH is the reviewing IRB, delete the pSite consents from the "local site documents" section and add them to the appropriate pSite if they are not already included there.
- You can also use this opportunity to "update" the currently approved consent with the correct file name as per the approved nomenclature so that it is easy to identify the document moving forward.




**Section "Local Site Documents", other documents:**

Carefully review any other local site documents that have migrated, including any study instruments, questionnaires, surveys, or recruitment materials. If all your currently approved documents of this nature did not migrate, upload the currently approved versions here in PROTECT so they are available for your future use/reference. Note in your modification summary that these are currently approved documents that you are attaching now (not new for IRB review).

## Radiation Safety

For studies that go to Radiation Safety for review, the first submission will have to be entered as if it is an initial submission to create the safety protocol in the system. No data from radiation safety will be migrated.

How will you know when your protocol is due for the next triennial review?

- Refer to the outcome letter that PIs received from iRIS, as that will state the triennial due date.

For your first triennial (de novo) review, if you have not done an amendment in the system (which pushes back the triennial review due date) then you need to create a safety submission and complete all the fields for that first review in PROTECT.

If you want to close a migrated protocol with the RSC before any other action has taken place (mod, de novo), then you should email RSCExecSec@nih.gov to let the committee know the protocol needs to be closed (in this case it will never be in PROTECT).

## Other reviews completed outside the system prior to PROTECT going live:

You may have studies that had DEC, IBC, SR, or RSC approval prior to the migration for the action that you now need to submit into PROTECT for IRB review.

**For protocols that have had scientific review or radiation safety review completed in iRIS but the protocol has not been submitted to the IRB yet:**

- Ensure your study application indicates that scientific and/or radiation safety review is required. Initiate the scientific/safety review in the system and complete all required fields. Attach the scientific review/RSC approval letter you have already received via iRIS. There is no need to obtain signatures in this case as these have already been reviewed/approved.
- SRC & RSC coordinators--process these through like an expedited review and record the committee decision. There is no need to send to the CD or Dr. Gallin as an ancillary review as this is now being administratively processed.
    - Send new approval letter in the system that reflects the original approval dates.

**For studies that had DEC or IBC approval prior to submitting the IR:**

- You will need to execute the "manage the ancillary review" activity in PROTECT and send it through for approval in PROTECT. The system will block the review unless these reviews are completed in the system if they are required reviews. Attach the approval you already received as a supporting document.
- DEC and IBC staff will need to accept the review in PROTECT (they do not need to conduct a new review).