

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 NHR 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>

The screenshot shows the 'Assign Primary Contact' window in PROTECT. The search filter is set to 'Last' and the search term is 'distribution'. The search results show a table with columns for 'Last', 'First', 'Organization', and 'Preferred Email'. Three distribution lists are listed: 'Distribution_List CC OPS', 'Distribution_List CC PHARM DL', and 'Distribution_List CC PRIA'. The first row is selected.

Last	First	Organization	Preferred Email
Distribution_List	CC OPS	Clinical Center	CC_Protocol_Services@...
Distribution_List	CC PHARM DL	Clinical Center	CC-PHARIRISprotocoldis
Distribution_List	CC PRIA	Clinical Center	PRIASubmission@mail.ni

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.

3 * Brief description:

A Randomized Phase II Study of Tecemotide in Combination with Standard Androgen Deprivation Therapy and Radiation Therapy for Untreated, Intermediate and High Risk Prostate Cancer Patients

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.

4. * What kind of study is this?
If all research activities are taking place at NIH site(s), then select Single-Site. If non-NIH sites are engaged, select Multi-Site

Multi-site or Collaborative study
 Single-site study
[Clear](#)

5. * Will an external IRB act as the IRB of record for this study?

Yes No

6. * Will the NIH IRB act as the single IRB of record for other participating sites?
IRB Office approval is required prior to the NIH IRB serving as the IRB of record. [NIH-Reliance-sIRB@nih.gov]

Yes No [Clear](#)

7. Is the NIH the coordinating center for this multi-site study?

Yes No [Clear](#)

8. Since NIH is the coordinating center, provide additional details for sites for which the NIH is not the IRB of record (sites for which the NIH is the IRB of record should be added via the 'Add Participating Sites' activity)

[+ Add](#)

Site Name	Site PI	Enrolling Subjects
There are no items to display		

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:

1. * Does this study include any of the following: (select all that apply)

Take place on American Indian / Alaska Native (AI / AN) land or territory
 Take place at an Indian Health Service (IHS) or other tribal AI / AN facility
 Use IHS resources (staff, funding, space, or other support)
 Access non-research data collected at an IHS facility
 Target enrollment of any AI / AN population
 Involve specimens or data from American Indian / Alaska Native populations tha
 None of the above

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:



8. * Does this study involve Human Fetal tissue?

Yes
 No
[Clear](#)

9. * Does this study involve Human Embryonic Stem Cells?

Yes
 No
[Clear](#)

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:

Add Tech Transfer Agreement

1. Type of agreement:

CRADA

CTA

[Clear](#)

2. Name of partner:

3. Are you receiving funding from this partner?

Yes No [Clear](#)

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.

RESEARCH SUITE

You Are Here: personnel field NDG

Editing: IRB000526

Local Study Team Members

1. Identify all NIH study team members who are engaged in your study

[+ Add](#)

	Name	Degrees	Other
Update	Philip Arlen	MD	CI
Update	William Dahut	MD	VI
Update	Madeline Dahut		FE
Update	Ravi Madan	MD	ET

2. Information about external team member(s):
(Only add external people here who are not listed in NED who are covered under by NIH IRB)

Add Study Team Member

1. * Study team member:

2. * Role in research:

- Associate Investigator (AI)
- Lead Associate Investigator (LAI)
- Medical Advisory Investigator (MAI)
- Adjunct PI
- Protocol Navigator
- Other

3. * Is the team member involved in the consent process?

Yes No [Clear](#)

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.

2. Information about external team member(s):
(Only add external people here who are not listed in NED who are covered under by NIH IRB)


[+ Add](#)

First Name	Last Name	Degree	Roles on Study
There are no items to display			

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 drug to 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 subcutaneous medications.)

					
	Investigational Name	Generic Name	Brand Name	Manufacturer Name	Attachment Name
		cyclophosphamide		Generic	
		cytarabine		Generic	
		etoposide		Generic	
		filgrastim	Neupogen	Amgen, Inc.	
		methotrexate	Rheumatrex	DAVA Pharmaceuticals, Inc	
		prednisone		Generic	
		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.

1. Consent forms: ?

+ Add		Document	Category	Date Modified	Document History	
	Update	 Minor Twin Sibling Assent_CRU.docx(0.01)	Consent Form	12/8/2022	History	
	Update	 Adult Proband or Twin-Sibling of Proband or Parent Consent for Minor Proband or Minor Twin Sibling- CRU.docx(0.01)	Consent Form	12/8/2022	History	
	Update	 03E0099 Parent of Proband or TS_CC_Clean_19MAR2021.docx(0.01)	Consent Form	12/8/2022	History	
	Update	 03E0099 Minor HV Assent__CRU_Clean_24FEB2021.docx(0.01)	Consent Form	12/8/2022	History	
	Update	 Minor Healthy Volunteer Assent- CC.docx(0.01)	Consent Form	12/8/2022	History	
	Update	 03E0099 Genetic Consent New Tracked 2020-CC_Clean_24FEB2021.docx(0.01)	Consent Form	12/8/2022	History	
	Update	 Genetics Consent for Adult Probands, Siblings, or Parents of Probands; Parent Consent for Minor Probands or Siblings_CC.docx(0.01)	Consent Form	12/8/2022	History	

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).