

Ascension Wisconsin IRB Guidance & Submission Guide

IRB Reliance on the National Cancer Institute IRB

Ascension Wisconsin sites participate in the National Cancer Institute (NCI) Independent Model (IM) of review for Cooperative Group adult clinical trials.

This document provides background and guidance to PIs and study teams who work on studies delegated to the NCI CIRB including the following topics:

- [Overview of the NCI CIRB Initiative](#)
- [Criteria for Use of NCI CIRB](#)
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For NCI CIRB site instructions, including submission instructions, see the Handbook for Local Institutions on the NCI CIRB website (<https://ncicirb.org>).

For directions on submission new studies or updates through the Mentor eIRB system, see the [Mentor Researcher User Manual](#).

Contact the IRB office at IRB@ascension.org or 414-465-3134 if you have questions or problems.

Overview of the NCI CIRB Initiative

The Central Institutional Review Board (CIRB) Initiative is sponsored by the National Cancer Institute (NCI). The Adult NCI CIRB reviews Cooperative Group trials as well as any other studies opened in the Cancer Trials Support Unit (CTSU). CIRB is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). CIRB provides expert IRB review at the national level prior to Cooperative Group distribution of the protocol to local investigators. The CIRB is composed of individuals who represent a broad range of oncology disciplines and may include oncology physicians, nurses, patient representatives, pharmacists, ethicists and attorneys. Ascension Wisconsin sites have a formal agreement with the Adult NCI CIRB, so investigators are able to participate in Cooperative Group trials and can take advantage of this single IRB review model.

In this Single IRB review model, the NCI CIRB serves as the IRB of record for eligible NCI cooperative group trials. The Ascension Wisconsin IRB remains responsible for monitoring the conduct of the research at Ascension Wisconsin. All submissions for NCI CIRB review will be screened by Ascension Wisconsin IRB Office staff to determine that the research is appropriate for submission to CIRB, is consistent with local policies and guidance, and to confirm that the necessary NCI and institutional requirements (e.g., approved NCI *Annual Principal Investigator Worksheet about Local Context* form, CITI training, COI disclosure, HIPAA review) have been completed.

Criteria for Use of NCI CIRB

To take part in the CIRB initiative, principal investigators must be approved by the Ascension Wisconsin IRB and the NCI CIRB.

In general, a NCI Cooperative Group clinical trial may be eligible for submission to CIRB if it meets the following criteria:

- Protocol is eligible for review by CIRB (eligible studies are listed on the [NCI CIRB website](#))
- Protocol is being submitted by an authorized PI
- Protocol does not involve prisoners

Opening a New Study with the NCI CIRB

Requests to open a new study using the NCI CIRB must be reviewed and acknowledged by the Ascension Wisconsin IRB Office before beginning submitted to the NCI CIRB.

The purpose of this local IRB review is to confirm that the study meets local requirements for eligibility for deferral to the NCI CIRB and to assist in tracking research occurring throughout Ascension Wisconsin.

Steps to request to open a study with NCI CIRB are outlined below.

NOTE: All study staff must have a Mentor account and a personal CTEP ID prior to working with CIRB studies. Investigators, sub investigators and research staff must complete annual registration through the Registration and Credential Repository at <https://ctepcore.nci.nih.gov/rcr/IsUsersrc.action>. See [below](#) for instructions.

STEP 1: Obtain a username and password to access the secured NCI CIRB sites

The Oncology Research Coordinators will be set up to have access to add, remove and update the CIRB and CTSU rosters, through the CTSU website.

For instructions on using IRBManager refer to the NCI CIRB [Instruction Manual](#) for Worksheet Completion in IRBManager.

STEP 2: Opening a New NCI CIRB Study

- 1. Verify that the study to be opened is on the CIRB menu by checking the [CIRB Website](#).**
- 2. Confirm that the Annual Principal Investigator Worksheet about Local Context is approved by the CIRB.**

To participate in an NCI CIRB study, the PI must have an approved "Annual Principal Investigator Worksheet about Local Context" on file with NCI CIRB.

A study team member may enter information in the Worksheet on the PI's behalf, but only the PI can submit the completed form.

Instructions for completing the PI worksheets are available in the NCI CIRB Instruction Manual for Worksheet Completion in IRB Manager (available at www.ncicirb.org)

- 3. Complete the Study-Specific Worksheet About Local Context.**

This should be completed by the lead researcher (or designee) via [IRBManager](#).

Instructions for completing the worksheets about local context can be found on the [CIRB website](#), click on [Independent Model Information](#).

Complete the form but DO NOT click submit. Save a copy as a pdf file type.

- 4. Submit a new study request to the Ascension Wisconsin IRB using the [Mentor](#) online system.**

To submit the NCI CIRB study in Mentor:

- Log into Mentor
- Go to, "My Protocols", and click the submit new protocol button
- Complete the general information and select the approval status of "Delegate to External IRB".

Upload the following with your submission:

- The draft Study-Specific Worksheet About Local Context completed in IRBManager
- The current approved NCI CIRB study protocol
- Initial CIRB Approval Letter
- Most recent CIRB Approved transaction (e.g., continuing approval or amendment approval that list the expiration date)
- Local AW consent form. Modify the model NCI CIRB-Approved Consent Form to include approved boilerplate language.
 - o The Ascension Wisconsin IRB has a list of “boiler plate” language for NCI CIRB consent forms. This is local required language that is approved for use by the NCI CIRB. This is the only information that can be changed in the NCI CIRB approved consent form. The template language is located in Mentor.
- HIPAA Research Authorization Form(s)- the standard stand-alone authorization should be used, NCI does not allow HIPAA incorporated in the consent form.
- Any other approvals required (Radiation safety, IBC, etc.)

5. The IRB office/reviewer confirms the Study Meets the Criteria for NCI CIRB Review by verifying the following:

- Applicable state laws and institutional requirements are met (e.g., radiation safety, biosafety, etc.)
- The study conforms to the Catholic Ethical and Religious Directives
- Confirms the draft local consent form is accurate
- Human subject protection training and financial disclosures are on file, and there are no financial conflicts of interest related to the study

If there is an issue with any of the above the study may not be eligible for deferral to NCI CIRB. The Ascension Wisconsin IRB will inform the PI and lead coordinator through Mentor whether or not study meets criteria for NCI CIRB review.

6. Submit the Study-Specific Worksheet About Local Context in IRBManager. After receiving IRB acknowledgment, the coordinator can then submit the study to NCI CIRB. IRBManager will send an email prompting the PI to concur with submission. Approval notification will be sent from the NCI CIRB indicating study approval and that the CIRB is the IRB of Record for this study.

7. Upload the NCI CIRB approval letter in Mentor using the NCI CIRB Update form. The coordinator or PI must submit the final NCI CIRB approval letter to the Ascension Wisconsin IRB by uploading the letter with the NCI CIRB Update form, located on the IRB info page in Mentor. IRB staff will acknowledge the completion of the NCI CIRB approval.

Post Approval Responsibilities

The lead researcher remains responsible for the conduct of the study; post approval responsibilities include:

- Oversee the conduct of the research
- Monitor protocol compliance
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects
- Investigate, manage, and provide notification to the CIRB of any study-specific incident, experience, or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance.
- Subject complaints
- Breaches of confidentiality
- Annual progress reports
- When closing a study, submit closing report to the Ascension WI IRB, include a copy of CIRB Study Closure report

Submissions After Approval

The NCI CIRB is the IRB of record and conducts all IRB reviews.

However, the AW IRB must be informed of Study Staff and PI updates, Unanticipated Problems and Noncompliance, and Study Closure using the NCI CIRB Update form.

See additional details on the following chart outlining the oversight responsibilities of the Ascension Wisconsin (AW) IRB and CIRB.

Submission type	NCI CIRB	AW IRB	Study site actions/details
Continuing Review	Obtain renewal documents to the appropriate oncology study on the CTSU website, as you would normally.	These documents do not need to be submitted to the AW IRB.	When the CIRB posts the renewal documents, update the Approval and Expiration dates on the CIRB-AW consent form to match the CIRB dates.
Cooperative Group Protocol Revisions posted on the CIRB website	These revisions have been approved by the CIRB.	These documents do not need to be submitted to the AW IRB.	Update all local documents, make the changes in your regulatory binder (including changes to practice and protocol) and proceed under the revised protocol.
Cooperative Group Consent Form Revisions	These revisions have been approved by the CIRB.	These documents do not need to be submitted to the AW IRB.	Consent forms are considered approved for use once the study team has updated appropriately per the amendment. The approval date should be updated to match the CIRB approved consent. It is not necessary to update the local consent if the study is closed to enrollment and NCI CIRB does not require that consent be re-obtained from subjects.
Other Documents posted on the CIRB website (memos about drug shortages, letters to families, etc.)	All documents posted on the CIRB website have been reviewed and approved by the CIRB.	These documents do not need to be submitted to the AW IRB.	Include in your local regulatory binder as appropriate.
Local document modifications (e.g., flyers)	These revisions are approved by the CIRB.	These documents do not need to be submitted to the AW IRB.	Submit to CIRB for review and approval. Include in your local regulatory binder as appropriate.
Annual Principal Investigator Worksheet	Principal Investigators with an approved Annual Principal Investigator Worksheet are also contacted on an annual basis	The Annual worksheets do not typically need to be submitted to the AW IRB, unless specifically requested on an IRB submission form	Follow the directions in the NCI CIRB Instruction Manual for Worksheet Completion in IRB Manager (available at www.ncicirb.org). Note that a study team member may enter information in the Worksheet on the PI's behalf, but only the PI can submit the completed form.
Changes to the HIPAA authorization or HIPAA noncompliance	These do not need to be reported to the CIRB.	<u>Notify the AW IRB</u> of HIPAA changes or non-compliance through Mentor using the AW IRB Update form.	The study team should use the current local approved HIPAA authorization form and ensure HIPAA compliance.
Revision that requires change of PI	These revisions are approved by the CIRB.	<u>Notify the AW IRB</u> of changes to research staff through Mentor using the AW NCI CIRB Update form.	The PI must log into IRBManager, select Start xForm, and then select <i>Study-Specific Worksheet About Local Context</i> . Choose "Change of PI" as the reason for submission.
Revision that requires change to the research personnel	Changes in staff are not submitted to NCI CIRB (other than the PI, outlined above).	<u>Notify the AW IRB</u> of changes to research staff through Mentor using the AW NCI CIRB Update form.	AW IRB staff will submit the change to the NCI CIRB Help Desk and notify the study team when the change is complete.
Change in local sites	Notify CTSU of the addition or removal of the site.	Submit the addition or removal of sites to the AW IRB after CIRB approval.	Include in your local regulatory binder as appropriate.
Unanticipated Problem or Noncompliance Events	Report to the NCI CIRB using the <i>Potential Unanticipated Problem or Serious or Continuing Noncompliance Form</i> found in IRBManager. The CIRB reviews, makes a determination, and reports to federal agencies as applicable.	<u>Notify the AW IRB</u> following the determination of the CIRB, by submitting a copy of the reports through Mentor using the AW NCI CIRB Update form.	The PI is responsible for reviewing local adverse events and noncompliance and reporting to CIRB if the event is determined to be a potential unanticipated problem or potential serious or continuing noncompliance.
Closing a NCI CIRB study	The NCI CIRB will acknowledge the closure.	<u>Notify the AW IRB</u> by submitting a copy of this report through Mentor using the AW NCI CIRB Update form.	Submit the NCI Study Closure form on the NCI website.

Updating Study Staff on Studies Delegated to NCI CIRB

Get a CTEP ID and Update Rosters

Before an Investigators and associates (non-Investigators) can be added to NCI CIRB or CTSU, they need to have a CTEP person ID and complete the registration process.

For information on how to do this, see the CTSU [Instructions for Getting Started](#) guide on the CTSU [website](#).

Each local site has a CTSU Site Administrator (Oncology Coordinators). These individuals can update the rosters for the local site. If the person will work at more than one site, they must be added to the roster of each site. Contact the coordinator(s) at each site to ensure this update occurs.

Please note, Individuals must be added to a cooperative group roster before they can be added to the CTSU roster.

Once this is complete, you can log into CTSU and see the studies you have access to.

Notify the IRB of the update

Notify the Ascension WI IRB of changes to research staff using the local *NCI CIRB Update form* (available in Mentor). Submission instructions are on the form.

- If the new staff has not already been listed on NCI CIRB studies at Ascension WI, be sure to include the persons CTEP number on the amendment form.
- As with any Ascension WI staff updates, the following must also be done before new team members can be added (if not already completed):
 - **Mentor Account** All study staff needs a Mentor account *before they can be added to a study*. You only need to request an account once.
The User Account must be complete before you send the submission for review.
 - **Human Subject Protection Training:** The IRB requires Human Research Protection Training for all study personnel before they can be involved in study activities.
 - **COI Research Conflict of Interest Questionnaire:** All study staff working on funded research must have a research

More information and instructions to complete the above are found online [here](#).

IRB staff will update Mentor notify the study team when the change is complete.

Changes in personnel are not submitted to NCI CIRB, with the exception of PI changes.

Revision that requires change of PI: The PI or designee must log into IRBManager, select Start xForm, and then select *Study-Specific Worksheet About Local Context*. Choose "Change of PI" as the reason for submission. The new PI will need to approve the worksheet.

After the *Study-Specific Worksheet About Local Context* is complete, notify the Ascension WI IRB using the *NCI CIRB Update form* (available in Mentor). Submission instructions are on the form.

Updates and Annual Requirements

All investigators and associates participating in CTEP clinical trials need to register and maintain registration records at least yearly or when there are other changes.

CTEP Instructions:

- [Person Registration \(IAM\)](#)
- [NCI Registration and Credential Repository \(RCR\)](#)
- [Registration Expiration Date](#)

Investigator Annual Registration

Food and Drug Administration (FDA) regulations require IND sponsors to select qualified investigators. NCI policy requires all persons participating in any NCI-sponsored clinical trial to register and renew their registration annually.

The investigator must now complete the yearly registration on line at the following web address:

<https://ctepcore.nci.nih.gov/rcr/lsUsersrc.action>

Updating Personal Registration Information with CTSU

Access to the CTSU web site is managed through the CTEP-IAM system. If you need to make a change in your personal registration information (address change, telephone number, etc.) you may do so through the CTEP-IAM Web Site.