

University of Iowa **(UI)** Procedures for Using the National Cancer Institute Central Institutional Review Board (NCI CIRB)

This describes the University of Iowa requirements and procedures for conducting research sponsored by the National Cancer Institute (NCI) and under the purview of the NCI Central Institutional Review Board (NCI CIRB). For general information about the NCI CIRB, see the [University of Iowa Human Subjects website](#) and www.ncicirb.org

REQUIRED USE OF NCI CIRB

University of Iowa investigators intending to conduct any clinical trial that has been reviewed and approved by the NCI CIRB are now required to use the CIRB as the IRB of record for the study. When planning to conduct any NCI-sponsored cooperative group trial, consult the [NCI CIRB website](#) to see if the trial is listed on the menu of CIRB-approved trials. The menu is available using the "Current List of Studies under CIRB Review" link on the NCI CIRB homepage. Search by Group, Study Number, CIRBs, and keywords within a Study Title or Study Number.

INSTITUTIONAL REVIEW REQUIRED PRIOR TO SUBMISSION TO NCI CIRB

University of Iowa investigators planning to conduct a study for which the NCI CIRB can serve as the IRB of record **must first undergo local human research protection program (HRPP) review** to ensure compliance with institutional requirements that are not assessed by the CIRB's Local Context Subcommittee. This local review will be conducted by the Human Subjects Office on behalf of the HRPP. Follow the steps below to prepare a submission for UI review. **NOTE:** Do **not** submit a Study-Specific Worksheet to the CIRB prior to confirmation from UI Human Subjects Office that a study can be deferred to the NCI CIRB.

A. Obtain access to secured NCI CIRB sites

The UI principal investigator for the study must have an NCI CIRB "Annual Principal Investigator Worksheet About Local Context" on file with the CIRB prior to submitting a new study. See Completing the Initial NCI CIRB Annual Principal Investigator Worksheet About Local Context at the University of Iowa.

Research personnel responsible for preparing submissions for the NCI CIRB must have access to the [CIRB website](#) Participant's Area and to the CIRB's [IRBManager](#). Only registered users of the NCI CIRB may access study documentation, receive communications from the CIRB, and maintain current study records. To obtain access for new research staff, contact the [External IRB Coordinator](#) in the Human Subjects Office.

B. Prepare an application in HawkIRB

Please follow the instructions below for specific sections:

1. Select [UI](#) NCI CIRB as the reviewing IRB in question I.1.
2. Enter Study Team members (Section II) of the application.
 - A current [eCOI](#) disclosure is required.
 - UI Human Subjects Research (CITI) training is required.
3. Enter the funding source (Section III), if any.
 - Answer the question about financial conflicts of interest.
4. Project Type (Section IV) Waiver of HIPAA Authorization
 - Indicate if you are requesting a full waiver of HIPAA Authorization and complete the related questions. The Institutional Review Board retains Privacy Board oversight of NCI CIRB applications.
 - Unless there is a special request from the federal funding source to use ICH-GCP standards for review, answer “No” to this question.
5. Other Committee Review (Section V). Please note: [Other UI Committee](#) review is required prior to NCI CIRB submission. Committees are:
 - Pharmacy and Therapeutics Committee (P&T)
 - Pharmacy and Therapeutics Committee Investigational Drug Service (IDS)
 - Medical Radiation Protection Committee (MRPC)
 - Institutional Biosafety Committee (IBC)
 - Clinical Research Unit (CRU)
 - Holden Comprehensive Cancer Center (PRMC)
 - UIHC Research Billing Compliance (JOC)
 - Nursing Research Committee (NRC)
 - Research Billing/CMS Device approval via the Joint Office for Compliance (JOC)
6. Subject Information, including the recruitment of prisoners (Section VI)
 - **NOTE:** NCI CIRB **will not** review research involving prisoners. If prisoners are enrolled in an NCI CIRB sponsored study, submit the project under IRB-01.
7. Project Description (Section VII), including:
 - Location of research activities
 - Use of registries, repositories, type of study, etc.

- Protocol details
- Compensation
- Request for full or partial HIPAA Waiver
- Recruitment

8. The final section is for Attachments. Attachments should include:

- Consent Document (created from the NCI CIRB approved template generated in HawkIRB in the Attachments section)
 - Select all appropriate template language as it pertains to the study
 - Note – NCI CIRB does not allow for deletion of any approved material. Information may be added, but only if it falls under one of the following categories:
 - Local contact information-
 - State and local laws pertaining to informed consent-
 - Institutional policies related to research on NCI-funded studies
 - All other non-permissible institutional language (as outlined below under “Institutional Information Sheet”) will be submitted on a study-by-study basis via the Study-Specific Worksheet, or included in the Institutional Information Sheet
- Consent Summary Document
 - Choose the appropriate form
 - General, Phase 2 or Phase 3
 - General could be used for any NCI CIRB study, while Phase 2 and 3 forms should be used for the respective type of Phase 2 or 3 trial
 - Note: University of Iowa Template Consent Summaries are ONLY required if a summary is *not already present* within the NCI approved template Consent Document
 - Complete each section per the bolded instructions
 - Remove the bolded instructions before uploading the Consent Summary Document
 - Upload the Consent Summary Document to the Record of Consent/Consent Summary category of Consent & Assent Documents attachment page
- University of Iowa Institutional Information Sheet
 - This new document (generated in HawkIRB under Consent documents in the Attachments section) includes HIPAA Authorization and ~~boilerplate~~ institutional language, as appropriate, that is no longer permitted in the body of the consent form.
 - This document must be signed **in addition to** the full Consent form (i.e. you will obtain a signature on the Consent document, as well as the Info. Sheet)
 - This language is already present in the template document, and includes:
 - University of Iowa HIPAA Authorization

- [Pregnancy Testing for Females Under the Age of 18](#)
 - [SSN Usage for purposes other than compensation](#)
 - [SSN Usage for Compensation](#)
 - [MRPC Language \(Pregnancy Issues; Radiation Exposure in Women Capable of Becoming Pregnant; Radiation Exposure \(fetal radiation dose <1mrem; Addition “As required” Radiation Risk Language\)](#)
 - [State of Iowa Required Legally Authorized Rep. Language](#)
 - [Be sure to remove any language not applicable to the study](#)
- ~~Record of Consent Document (created from the template generated in HawkIRB in the Application section)~~
- [Consent Short Forms for non-English speaking individuals:](#)
 - [The University of Iowa will not issue its own Short Forms for NCI CIRB approved reviews studies. Consent Short Forms may be supplied by NCI CIRB. Approval of these forms and any translations are deferred to the NCI CIRB.](#)
- A copy of the protocol
- A copy of the draft NCI CIRB research application, if available
- A copy of the Study-Specific Worksheet
 - ~~The Additional Information section, “if changed or new information” question, of the Study Specific Worksheet (Question 33 on the Annual PI Worksheet About Local Context) section is where you should document the changes requested by the HRPP Committees for the Informed Consent Document. Per the NCI CIRB Boilerplate Informed Consent Template policies, sites are no longer permitted to include specific boilerplate institutionally required language in the body of the NCI CIRB Template consent form.~~
 - [Only that language which is included in the updated UI NCI CIRB Informed Consent Language document may be added to the NCI Template consent form.](#)
 - [Requests for additional boilerplate institutional language must now be submitted on a study-by-study basis via the Study Specific Worksheet. Other language no longer permitted in the primary NCI CIRB Informed Consent Document may be included in the University of Iowa Institutional Information Sheet.](#)
 - ~~NCI CIRB You should attach a track changes version and a clean version of the Informed Consent Document to this question on your Study Specific Worksheet.~~
- [For Children's Oncology Group \(COG\) studies only: If the CIRB has determined that assent is required for a COG study, upload COG Youth Information Sheets or assent documents. The University of Iowa will no longer utilize U Iowa Assent](#)

[templates, and will instead utilize the Youth Information Sheets or Assent documents as provided by NCI CIRB.](#)

Once a HawkIRB application has been submitted to the HSO for review, all required Other UI Committees will receive a notification that its review is required. After the HSO has reviewed the HawkIRB Application in its entirety and determined all UI requirements are being met, the Institutional Approval Memo will be attached to the application. The application will then be routed back to the PI in HawkIRB Workflow.

C. What Happens After Submission in HawkIRB?

After the application is submitted in HawkIRB, it is reviewed by the HSO to ensure that:

- Institutional requirements for reliance are met, such as training and absence of conflict of interest issues.
- Consent documents use the current CIRB-approved template and include all required UI language.
- [Institutional Information Sheet](#) ~~HIPAA authorization forms~~ meets UI requirements.
- If revisions are needed, these will be communicated to the study team via workflow notes in HawkIRB. The application will be routed back to the PI for the required revisions.

After any needed revisions have been resolved and all Other Committee approvals are in place, the study team will receive institutional approval memo in HawkIRB:

- If all institutional requirements are met, the institutional approval memo will state that the study is eligible for reliance on the NCI CIRB.
- The University of Iowa may determine that a study cannot be ~~conducted, or~~ conducted ~~or~~ submitted to the NCI CIRB. In these instances, a disapproval notice will be issued.
- Please note: Waivers of HIPAA authorization will not be released until the CIRB approval has been received by the HSO.

D. Obtaining NCI CIRB Approval to Conduct a Study

Once the study team has received the institutional approval memo in HawkIRB confirming that the study can be submitted to the NCI CIRB, the UI principal investigator must submit a Study-Specific Worksheet to the NCI CIRB to obtain approval to conduct the study at the University of Iowa. **NOTE: Do not submit a Study-Specific Worksheet prior to receiving confirmation in HawkIRB that a study can be submitted to the NCI CIRB.**

The Study-Specific Worksheet is submitted online in the NCI CIRB's IRBManager system following the *NCI CIRB Instruction Manual for Worksheet Completion in IRBManager* (on the [CIRB website](#)). Questions about this process should be directed to the NCI CIRB Helpdesk.

The Study-Specific Worksheet and subject information sheets will be reviewed by the NCI CIRB per their standard operating procedures.

Once the CIRB has approved the study for conduct at UI, the NCI CIRB is the IRB of record for the study and is responsible for local site issues as well as study-wide oversight. This means:

- Study teams must monitor the NCI CIRB website and web-posting summary emails for NCI CIRB approval of modifications and other IRB actions for the study.
- Any locally-occurring reportable events must be reported to the NCI CIRB via IRBManager, following the *NCI CIRB Instruction Manual for Worksheet Completion in IRBManager* (on the [CIRB website](#)).
- Study teams must comply with all other NCI CIRB requirements, as described in the NCI CIRB's Standard Operating Procedures manual (on the [CIRB website](#)) and any other CIRB directives.

E. Ongoing Local Compliance Review

The University of Iowa remains responsible for monitoring institutional compliance as described in the NCI CIRB's Division of Responsibilities document and the Annual Signatory Institution Worksheet. Compliance monitoring will be the shared responsibility of study teams and the IRB Compliance Program.

It is the responsibility of the Principal Investigator to be aware of all University of Iowa policies and procedures that may affect the conduct of their research. Regardless of the IRB of record, it is the Principal Investigator's responsibility to adhere to these policies. This also includes any Human Research Protection Program Committee policies, reviews and approvals. The Human Subjects Office provides HawkIRB as a venue for the HRPP committees to complete these reviews when NCI CIRB serves as the IRB of record. All items listed in the following sections should be submitted to both HSO, via HawkIRB AND directly to NCI CIRB. In HawkIRB, users should initiate a Modification Form. Questions regarding the HawkIRB Modification form should be directed to uirb-external@uiowa.edu. Any questions regarding the submission process to the NCI CIRB can be directed to ncicirbcontact@emmes.com.

F. Modifications to Approved Protocols

Submit all project modifications to HawkIRB (study team member changes, protocol changes, etc.) using the Modification option in HawkIRB. Please refer to the NCI CIRB Handbook for Local Institutions regarding allowable modifications. Any local context reviews (Other Committees, etc.) will be re-reviewed when the Modification form is submitted in HawkIRB.

- **Consent Documents**

A standard Modification to the application should be submitted in HawkIRB concurrently with the modification submission to NCI CIRB. The required UI language cannot be altered in any way.

- **Record of Consent**

~~It is the PI's responsibility to update the Record of Consent, as appropriate, if study procedures, contact personnel, or other information changes during the course of a study. Modified versions of the Record of Consent do not need to be submitted to the HSO or to NCI CIRB. The Record of Consent can be generated from the HawkIRB application in the Attachments section. It should be reviewed for accuracy and then submitted to the EPIC medical record.~~

- **Research Team Changes**

[UI policy](#) requires any team members being added to the research team have training in human subjects protections. Research team members include the Principal Investigator and all other individuals (faculty, staff, or student) who have contact or interactions with research subjects or with their private, identifiable information must be certified. Technicians performing standard clinical procedures that are part of the research protocol, such as a blood draw, do not need to be named as a member of the research team and do not need to be certified.

A standard Modification to the application should be submitted in HawkIRB concurrently with the Modification submitted to the NCI CIRB. When adding new study team members, human subjects training certification and an eCOI disclosure must be completed prior to the addition of the new members to the Hawk IRB application.

- **Attachments**

Consents/Assents, protocols and the draft NCI CIRB application should be uploaded as a revised version, not as new documents. Any additional documents submitted to the NCI CIRB should be attached in zip folder labeled "Submitted_To_NCICIRB_Month.Date.Year." The date included in the label should be the date the modification was submitted to NCI CIRB. The zip folder should be uploaded to the Copy of External IRB Application Section on the Attachments page.

- **Other Attachments**

The new NCI CIRB Policies and Procedures (updated January 21, 2019) implemented changes to ~~boilerplate~~institutional language additions in the NCI template consent form. Per these new policies, HIPAA Privacy Language will no longer be permitted in the informed consent documents, and must be attached as a separate **University of Iowa Health Care Information Sheet and HIPAA Authorization document**. This document is available in the HawkIRB Consent Attachments category.

- **Other Committee Reviews and Institutional policies**

The Principal Investigator must notify any applicable committees of changes to the research protocol that may affect the HRPP committee approval. **This notification occurs via a modification to the HawkIRB application.**

Other Committee ~~consent~~boilerplate language is generally no longer permitted as Boilerplate language within the NCI CIRB Template Consent document. Any ~~boilerplate~~ language requested or required by a University of Iowa HRPP Review Committees must be submitted for approval to the NCI CIRB via a Study Specific Worksheet. Other non-permissible language (such as Social Security language for compensation, Pregnancy testing language, etc.) will be added to the Institutional Information Sheet as required.

- **Updateding actively enrolling studies to the new NCI CIRB policyAnnual Institutional Worksheet Transition Modifications**

All NCI CIRB studies that are currently active and recruiting (or will recruit) are required to adhere to the University of Iowa's newly approved 2019 Annual Institutional Worksheet. The changes, as outlined above, must be submitted to the NCI CIRB for each study that is actively enrolling (or will enroll) via a Study Specific Worksheet. This requirement does **not** apply to studies that are Closed to Accrual, or otherwise no longer enrolling subjects.

The following should also be submitted in HawkIRB, for compliance monitoring purposes:

G. Continuing Reviews

Documents pertaining to the continuing review by the NCI CIRB should be uploaded to the corresponding HawkIRB application by using the Continuing Review option in HawkIRB. The NCI CIRB retains all regulatory responsibilities for the continuing review as required by federal regulations. Any local context reviews (Other Committees, etc.) will be re-reviewed when the Continuing Review form is submitted in HawkIRB.

H. Reportable Event Forms

Reportable event forms (REFs) should be submitted in HawkIRB after they have been reported to the CIRB. To report to the CIRB, the PI or his/her designee completes the appropriate CIRB reporting worksheet.

Along with the CIRB worksheet, the Principal Investigator will develop and report the initial management plan for either the noncompliance or an adverse event to the CIRB for consideration. The following situations require submission of a management plan to mitigate this event or prevent future occurrences, as appropriate to the situation:

- Section C completed with a yes response for C-1, C-2, and C-3,
- Section D completed with a yes response for either D-1, or D-2,
- An incident which may not meet the above conditions, but has occurred several times in the past.

The management plan will be considered by the CIRB along with the review of the event. Any management plan approved by the CIRB including any additional corrective actions as mandated by the CIRB must be implemented at the University of Iowa. Should the CIRB request feedback or assistance in determining the appropriateness of the management plan for the institution, the HSO will obtain feedback from the IRB-01 Biomedical Chairs.

Any/all applicable responses from the CIRB must be filed by the PI or his/her designee in the University of Iowa eResearch (HawkIRB) application. The HCCC Protocol Review & Monitoring Committee will be notified of the management plan. Implementation of the plan may be monitored by the HSO Compliance Program. In the event external reporting is required, the HSO will work in conjunction with the CIRB to ensure reporting is completed appropriately to the FDA and OHRP on behalf of the University of Iowa.

I. Study closure:

When all study activities are completed at UI and the study has been closed with the CIRB, submit a Project Closure in HawkIRB.