

# ***Completing the NCI CIRB Annual Principal Investigator Worksheet About Local Context and the Study-Specific Worksheet About Local Context at the University of Iowa***

All investigators conducting research with the National Cancer Institute's Central IRB (NCI CIRB) as the IRB of record are required to complete an "Annual Principal Investigator Worksheet About Local Context" and the "Study-Specific Worksheet About Local Context" and submit these documents to the NCI CIRB for approval. The NCI CIRB will use the information in these worksheets to document how local investigators will comply with site-specific elements of study conduct.

## ***Annual Principal Investigator Worksheet About Local Context***

To ensure that the information provided to the NCI CIRB is consistent with University of Iowa policies and guidance, the investigator must submit a draft of the Worksheet for review by the UI's Human Subjects Office prior to submitting the Worksheet to the NCI CIRB. The Worksheet may be submitted to the NCI CIRB only after the Human Subjects Office has confirmed that it is acceptable.

### **Step I: Obtain CTEP (Cancer Therapy Evaluation Program) Identity and Access**

Human Subject Protection training is required before you can receive a CTEP identity and access. If you have not yet completed your Human Subject Protection training, [review this page](#) on the UI's Human Subjects Office website for instructions to complete the training.

You must obtain and maintain this CTEP IAM account and ID number in order to be a member of a cooperative group/network group.

To obtain a CTEP IAM account and ID number, please follow the instructions below:

- Go to <https://eapps-ctep.nci.nih.gov/iam/privacyActDisclaimer.do?method=showDisclaimerText>
- When the Warning Notice box appears, click "I Agree".
- If the screen says "The user session has timed out." Click the word "Here" on the screen to continue.
- Under "User Account Maintenance", select "Request New Account".
- Follow the 4 Steps they give you to create your account.
- CTEP will then send you an email with your CTEP ID number.

- Once you receive your CTEP ID number, forward the CTEP ID number to [Clarine Halvorsen](#). Ms. Halvorsen will add your number to the ALLIANCE Membership Roster Form and submit it to the ALLIANCE.
- The ALLIANCE will send you an email once they have completed your membership.
- Your log in username and password will be the same ones you use to log into the CTSU (created when you obtained your CTEP IAM account and ID number above).
- When the ALLIANCE contacts you by email, please notify Ms. Halvorsen as she will need to go into the CTSU website to assign a role for you in the roster.

## **Step II: Obtain a username and password to access the NCI CIRB's IRBManager**

The UI's Human Subjects Office has provided the NCI CIRB with a list of principal investigators (PIs) and research staff who may be involved on NCI CIRB studies and need access to secure CIRB resources. Personnel on that list should receive a username and password from the NCI CIRB Operations Office. The username and password allow UI personnel to log in to the NCI CIRB's IRBManager system (an online submission tool akin to the UI's HawkIRB system). PIs or research staff who have not received a username and password from the NCI CIRB should contact [Anna Mertes](#) in the UI Human Subjects Office.

## **Step III: Access the Annual Principal Investigator Worksheet about Local Context**

Follow the directions in the NCI CIRB Instruction Manual for Worksheet Completion in IRB Manager (available at [www.ncicirb.org](http://www.ncicirb.org)) to log in to IRBManager and open a new Annual Principal Investigator Worksheet about Local Context. 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.

## **Step IV: Incorporate recommended language**

Answers for many of the questions in the Annual PI Worksheet will be specific to each PI. However, because recruitment practices, informed consent process, use of legally authorized representatives, and inclusion of vulnerable subject populations must be consistent with University of Iowa policies and guidance, study teams should be aware of the information provided below. In applicable instances, the information should be incorporated into these sections of the Worksheet.

- Question 4 (Research nurses): If these nurses and clinical research assistants are for the most part not hired by the Department of Nursing (DON) but rather hired specifically for research studies by PIs. Unless the PI is a nurse or the project is focusing on nursing staff or nursing practice, the Nursing Research Committee would not review NCI CIRB studies.

- Question 5 (Conflicts of interest): If the answer to this question is “yes,” University of Iowa IRB’s review will be required. If the PI or any member of the research team has a conflict of interest related to studies on the CIRB menu that result in an actual or perceived financial conflict of interest, the UI will not defer IRB oversight to another IRB. Contact [Anna Mertes](#) in the UI Human Subjects Office.
- Question 8 (Recruitment): A description similar to what would be included in a HawkIRB application should be adequate here. Be sure to specify whether medical records will be reviewed prior to consent to check potential eligibility. The NCI CIRB will not serve as a UIHC Privacy Board. The UI IRB will be required to review, approve, and issue all partial and full waivers of authorization under HIPAA.
- Question 9 (Recruitment materials): If any recruitment materials require a local IRB Stamp, upload as attachments in the Recruitment Materials section of the HawkIRB application. The HSO will stamp the documents upon approval of the NCI CIRB.
- Question 10 (Compensation to participants): If compensation is available all [institutional policies](#) that apply must be followed.
- Question 16 (Consent process for non-English speaking subjects): Explain in the response
  - Consent Documents and other printed and/or electronic study materials must be provided in a language that is understandable to the subject. This will require translation into each language spoken by subjects the Principal Investigator wishes to enroll in the study.
  - The HRPP will review the English version of all documents prior to submission to the NCI CIRB.
  - The NCI CIRB will review and approve all non-English translations of the consent documents.
- Question 17 (Who provides consent): Note that, just as for studies under the UI IRB’s purview, subjects who lack consent capacity should not be enrolled unless there is justification for including these vulnerable subjects, and an appropriate plan for surrogate consent is provided. Do **not** select “LAR” for Q17 unless your research includes patient populations expected to have impaired decision-making capacity.
- Question 19 (institution’s policy on impaired adults):
 

For Impaired Adults: For studies conducted in the state of Iowa, the first person on the list below who is reasonably available and competent must sign as the legally authorized representative even if

another person on the list is more conveniently available. Guardians (Iowa Code 600A.2 (8 and 9))

1. The designated proxy (such as a Durable Power of Attorney for Health Care)
  2. Court-appointed guardian
  3. Spouse (does not include “Common-law” spouse)
  4. Adult child
  5. Parent
  6. Adult sibling
- Question 20 (institution’s process for receiving and addressing concerns from study participants and others about the conduct of the research): Include the following information:
    - UI template consent language directs subjects to discuss questions and concerns about the research with their study doctor; contact information is provided for investigators at the UI. It also states the following:
      - If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail [irb@uiowa.edu](mailto:irb@uiowa.edu). General information about being a research subject can be found by clicking “Info for Public” on the Human Subjects Office web site, <http://hso.research.uiowa.edu/>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.
    - The UI Human Subjects Office’s website also provides information where anyone can [report a concern about human subjects research](#).
  - Question 21 (pharmacy information): A “yes” response to this question will trigger a required review by the Pharmacy and Therapeutics Committee.
  - Question 23 Appropriate institutional data security measures will be required depending on response selected in this question.
  - Question 26 (intention to use a legally authorized representative [LAR] to enroll subjects): In most, if not all, cases, the response to this question should be “no.” Just as for studies under the UI IRB’s purview, subjects who lack consent capacity should not be enrolled unless there is justification for including such subjects, and an appropriate plan for surrogate consent is provided. Do **not** select “yes” for Q26 unless your research includes patient populations expected to have impaired decision-making capacity.

- Question 27: In studies conducted in the state of Iowa, the first person on the list below who is reasonably available and competent must sign as the legally authorized representative even if another person on the list is more conveniently available.
  - The designated proxy (such as a Durable Power of Attorney for Health Care)
  - Court-appointed guardian
  - Spouse (does not include “Common-law” spouse)
  - Adult child
  - Parent
  - Adult sibling
  
- Question 29 (Vulnerable populations): If the study involves children AND pregnancy testing, select “Other” under “Safeguards” and include the following UIHC Policy language from the Informed Consent Document:
  - Pregnancy Testing for Females Under the Age of 18
    - All females who are physically able to become pregnant will be required to have a pregnancy test before [describe each time the testing will occur in relation to study procedures]. If the test shows that you are pregnant, you will not be able to [have this test/continue in the study.] This testing will occur in a private area without any of your family members with you.
    - If you are 12 years of age or older we will only tell you the results of the test.
    - You can decide whether or not to tell your parents or guardian the results of the pregnancy test, however, if you are pregnant we will need to tell your parents you cannot [have – fill in the study procedure/continue in the study.]
    - If the pregnancy test shows that you are pregnant we will ask you whether or not you want us to talk with your parents or guardian about your pregnancy.
    - If you are under 12 years of age and the pregnancy test shows that you are pregnant, we are required to report the pregnancy to the proper authorities.
    - **IMPORTANT:** No matter how old you are - if we think that your pregnancy may have happened because of abuse, we will tell the proper authorities and your parents or guardian will be told about your pregnancy.

## **Step V: Prior to submitting the Worksheet to the NCI CIRB, submit to the HSO for local review**

If you are completing your Annual Principal Investigator Worksheet About Local Context, review by the Human Subjects Office is required before the Worksheet is submitted to the NCI CIRB. This is a courtesy to study teams, intended to ensure that information related to recruitment and consent process are consistent with institutional policies and procedures. To submit for review:

- When you reach the end of the Worksheet, select “Print” and save the Worksheet as a PDF. Then select “Save for Later.” Do **not** submit to the NCI CIRB at this point.
- Attach a copy of the Worksheet to your Profile in HawkIRB. Instructions to complete this can be found at the end of this document in Appendix A.
- The form will be reviewed within two business days of receipt. Any questions or recommended revisions will be sent to the study team via email.
- The Human Subjects Office will send an email to the study team confirming that the Worksheet may now be submitted to the NCI CIRB once the review is complete.
- Follow the *NCI CIRB Instruction Manual for Worksheet Completion in IRB Manager* to submit the Worksheet to the NCI CIRB.

## **Step VI: Receive NCI CIRB confirmation of approval for the Annual Principal Investigator Worksheet**

When the UI PI submits the Annual Principal Investigator Worksheet About Local Context to the CIRB, it is reviewed in detail by the NCI CIRB’s Local Context Subcommittee. This subcommittee determines if the Worksheet is acceptable and the PI is eligible to conduct studies under the NCI CIRB’s oversight.

### ***Study-Specific Worksheet About Local Context***

The Study-Specific Worksheet About Local Context is required by the NCI CIRB to be completed for each study which a principal investigator wishes to conduct. The completed Worksheet should be uploaded to the corresponding HawkIRB application. You can upload this document within the “Personalize” tab in HawkIRB. Steps to take: Personalize→Update My Profile→Upload NCI CIRB Worksheet

The Worksheet will ask for specific changes to any questions that were answered on the Annual Principal Investigator Worksheet. Each Study-Specific Worksheet will be reviewed by the Human Subjects Office. Any changes (such as conflict of interest) may prevent submission to the NCI CIRB.

**BOTH AN ANNUAL PRINCIPAL INVESTIGATOR WORKSHEET AND A STUDY-SPECIFIC PRINCIPAL INVESTIGATOR WORKSHEET MUST BE APPROVED BY THE NCI CIRB BEFORE A NEW STUDY MAY BE CONDUCTED.**

See [National Cancer Institute Central Institutional Review Board \(NCI CIRB\)](#) for University of Iowa requirements for opening new CIRB studies, as well as the *NCI CIRB Instruction Manual for Worksheet Completion in IRB Manager* ([www.ncicirb.org](http://www.ncicirb.org)).

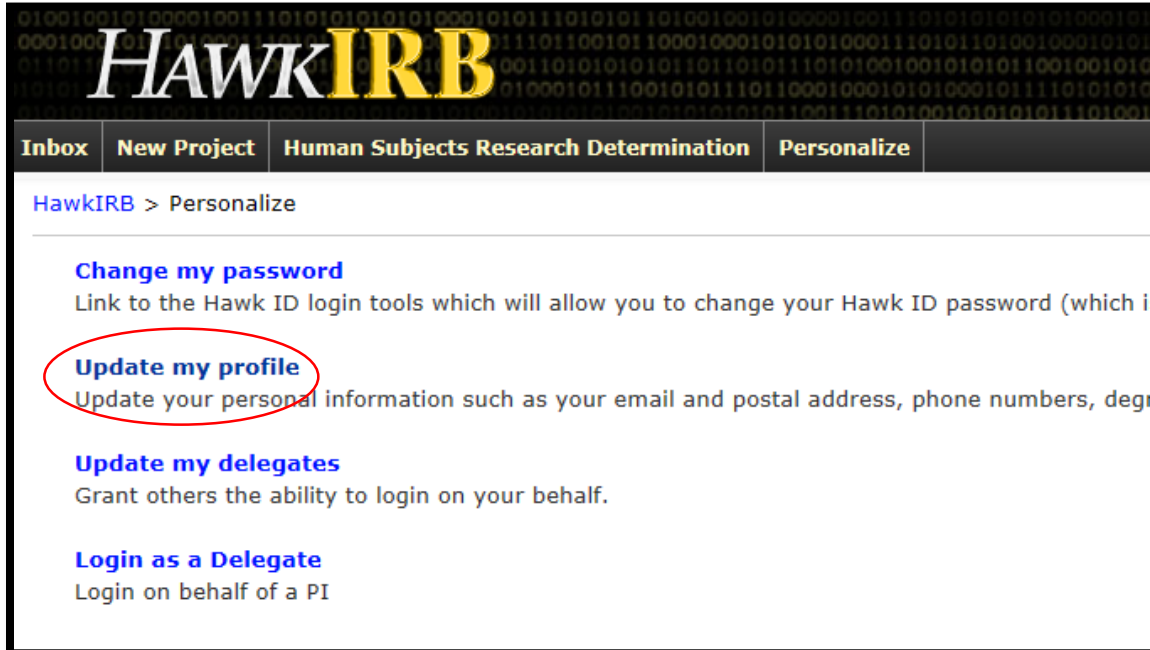
# Appendix A

## How to upload your completed Annual Principal Investigator Worksheet about Local Context to HawkIRB

Step 1: Log into HawkIRB and click on the “Personalize” tab at the top



Step 2: Click “Update my Profile”





**Step 3: At the bottom of your profile page you will see a new window “Upload NCI CIRB Worksheet”**

The screenshot displays the HawkIRB User Profile page. At the top, the HawkIRB logo is visible, followed by a navigation menu with items: Inbox, New Project, HSRD, Search, Reports, Scheduling, IRB Member, Admin Tools, and Personalize. Below the menu, the breadcrumb trail reads "HawkIRB > Personalize > User Profile".

The main content area is titled "User Profile" and contains the following fields and options:

- Hawk ID:** mertes (can't update)
- First Name:** [text input]
- Last Name:** [text input]
- College:** Admin - VP - Research
- Dept/Admin Unit:** Vrrsh-Human Subjects IRB Office
- Address:** [text input]
- Telephone:** [text input]
- Hospital Pager:** [text input]
- E-mail:** [text input] You will receive automatic e-mails from the HawkIRB system. The e-mail will be added to your 'accepted' e-mail list.
- Degree(s):** [dropdown menu with options AA, BA, BBA, BFA] You can select multiple degrees by holding down the "Ctrl" key and clicking on the desired degree(s).

Below the profile fields, there is a section titled "Turn on the Delegate Permission System (allows you as a PI to assign permissions to projects for your delegates).". It includes radio buttons for "Yes" and "No" (selected), and an "Update Fields" button.

At the bottom of the page, there is a section titled "Upload NCI CIRB Worksheet:". This section is highlighted with a red circle. It contains a table with the following structure:

Attachment Name	Category
No attachments found	
<a href="#">Click here to ADD or DELETE attachment(s)</a>	

An "Update Fields" button is located at the bottom left of this section.

**Step 4: After you have completed this form, save it as a PDF and upload it to your attachments**

Attachment Name	Category
No attachments found	

[Click here to ADD or DELETE attachment\(s\)](#)

**Remember, you will need to download the *Annual Principal Investigator Worksheet about Local Context* from the [NCI CIRB website](#). Only the PI will be able to access this form and only the PI can submit it into his/her profile in HawkIRB.**

**If you have questions, please contact Anna Mertes at [uirb-external@uiowa.edu](mailto:uirb-external@uiowa.edu) or 319-335-9915.**