

Guidance Document:

IRB Authorization Agreement

Overview

Every institution that conducts non-exempt human subject research files an assurance with DHHS. An assurance documents the institution's commitment to comply with HHS regulations for the protection of human subjects. This assurance is called the Federal-wide Assurance (FWA). An institution's responsibilities under the FWA apply whenever the institution, its agents, or its employees are Engaged in human subjects research, regardless of the geographic location of the research. An IRB's purview to review and oversee research involving human subjects under an FWA is limited to the actions of the employees or agents of its institution.

There are situations that arise when CU Boulder researchers are involved in multi-site research or collaborative projects with investigators at other institutions. Because an IRB's purview to review and oversee research involving human subjects under an FWA is limited to the actions of the employees or agents of its institution, such research requires IRB review by each site Engaged in the research. Alternatively, and with the agreement of both IRBs, an IRB Authorization Agreement (IAA) may be put in place. **An IAA is a joint review arrangement where one IRB relies upon the review of another qualified IRB to avoid duplication of effort.**

The IRB that performs the review is called the IRB of Record, the reviewing IRB, the lead IRB, and/or the primary IRB.

The IRB that relies on the review and oversight of the another IRB is said to be "ceding" oversight to the lead IRB.

When is an IRB Authorization Agreement (IAA) useful?

An IAA helps to reduce the burdens of multi-site research, which typically include multiple IRB applications for the same project, multiple changes (sometimes conflicting) to secure approval, and multiple continuing review and amendment submissions.

The following examples are the most common situations where an IAA is used:

- A CU Boulder Investigator is [Engaged](#) in non-exempt research to be performed at another institution that either has or will have IRB approval.
- A non-CU Boulder investigator is Engaged in research activities involving human subjects for a study reviewed and approved by the CU Boulder IRB.
- The involvement of the CU Boulder investigators is limited to analysis of identifiable data collected through the other institution or other minimal risk, non-exempt activities.
- CU Boulder acts solely as the funding recipient of an award and no research activities will be taking place at CU Boulder.
- The other institution's reviewing IRB is more properly constituted to review a certain scope or topic of work, or may have knowledge of the local research context. (For example, an international research project where the interaction with subjects is performed at an external site and that site has an FWA.)

When is an IAA not needed?

When CU Boulder, its agents, or its employees are **not Engaged** in research, IRB review (and therefore an IAA) is not required. For example, if an investigator from another institution is conducting interviews with employees or students at CU Boulder without Engaging any employees or student affiliated with CU Boulder, or collaboration with anyone affiliated with CU Boulder, then an IAA is not required.

In addition, an IAA is not appropriate for studies seeking Exempt determinations. The IRB Authorization Agreement allows one IRB to exercise regulatory oversight over the actions of another institution's investigators. Studies that are determined to be Exempt per the provisions at 45CFR46.101(b) are exempted from the regulatory oversight requirements. An IAA cannot be used if there is no oversight to exercise or cede. Independent review and determinations are required for Exempt studies.

Which IRB should be the IRB of Record?

Usually the institution of primary employment of the lead PI or the institution where most of the research is taking place will be the IRB of Record. The protocol should describe the specific procedures to be conducted at each research site, and the research personnel at each institution who will conduct those procedures.

Each IRB may decide the appropriateness of ceding or accepting responsibility for the review of any research involving human subjects. The IAA must be approved and signed by the Institutional Officials at both institutions.

Protection of participants in research projects remains the responsibility of all institutions and investigators involved in the research. Designating a reviewing IRB does not absolve another institution involved in the research of such responsibility.

How do I request that CU Boulder cede review to another IRB?

1. For a new study, follow the [instructions](#) on the IRB website for completing an **Initial Application** submission.
2. When you create the New Protocol, an eForm will automatically generate in the submission. Complete the eForm. Under the **IRB Authorization Agreement** section, check the **"Yes"** checkbox for the displayed question. A new question ("Will UCB be the IRB of record?") will populate; check the **"No"** checkbox. Follow the newly displayed instructions.
3. The [IRB Authorization Agreement – Other IRB of Record](#) template is downloadable from IRB website and within the eForm. Download and complete the form and attach it to the submission. Note that the University of Colorado Boulder Principal Investigator must be designated on the IAA and should also be the listed Principle Investigator in eRA.
4. The other documents attached to the submission should include:
 - Approved version of the protocol – The protocol should describe the specific procedures to be conducted at each research site, and the research personnel at each institution who will conduct those procedures.
 - Approved version of the consent form(s).

- Approval letter from the IRB of Record indicating the period of approval.
- 5. IRB staff will obtain the signature from the CU Boulder signatory official. A copy of the IAA will be returned to you via eRA. Once the signatory official from the IRB of Record (Institution A) has signed the IAA and the research is approved, you should submit the completed IAA and documents approved by the IRB of Record to us as a **Response to Incomplete** submission in eRA.
- 6. When the Response submission has been submitted with all required documents, an IAA-Acknowledgement letter will be emailed to the PI. The expiration date listed on the letter and entered in eRA will be the date that is listed on the approval letter from the IRB of Record.
- 7. If the study will continue following the original expiration date, the PI is required to submit the continuing review (CR) approval letter from the IRB of Record indicating the new approval period. This must be submitted in eRA as a **Continuing Review** submission. CU Boulder IRB staff will update eRA and a new IAA-Acknowledgement letter will be emailed to the PI.

How do I request that CU Boulder act as the IRB of Record (i.e., CU Boulder accepts responsibility for the review)?

1. For a new study, follow the [instructions](#) on the IRB website for completing an **Initial Application** submission. For an existing study adding new non-CU investigators, complete an **Amendment** submission.
2. Include an IRB Authorization Agreement with your submission. Most institutions will have a IRB Authorization Agreement template to be used when relying on another IRB for review. If the institution you are working with does not have such a template, we suggest using the [IRB Authorization Agreement – Ceding to CU Boulder](#) template from the IRB website. Before you submit the IRB Authorization Agreement, be sure you have filled out all of the fields.
3. Attach copies of your study documents as usual. In the protocol document describe the specific procedures to be conducted at each research site, and the research personal at each institution who will conduct those procedures.
4. IRB staff will obtain the signature from the CU Boulder signatory official. A copy of the IAA will be returned to you via eRA. The IAA will be active once both signatory officials have signed the IAA and the research is approved by the CU Boulder IRB. Upon approval the executed IAA should be given to the collaborating intuition(s) along with the IRB Approval Letter.