

Obtaining IRB Approval for a Collaborative Project

Request to have another organization cede to DU to serve as the IRB of Record

DU PI must **obtain confirmation** from the external organization or external PI that ceding can occur to have the DU IRB serve as the IRB of Record for the collaborative project.

DU PI must **submit a request** through IRBNet, as part of the initial submission or as an amendment for review and evaluation to allow ceding.

To evaluate the ceding request, submit the following documents:

- [Appendix P Form](#)
- Evidence of **human subjects protection training** for all external study personnel
- If PHS-funded project, provide a copy of the external investigator's "Financial Conflict of Interest" Policy
- **Data Transfer/Use Agreement (DUA)**, if applicable

If ceding is allowed, DU will forward DU's IRB Authorization Agreement (IAA) to the external IRB Administrator contact to obtain official signature.

DU IRB will obtain DU's official signature and forward the fully executed IAA to the DU PI and to the external IRB.

Request to have DU cede to another organization to serve as the IRB of Record

DU PI must **obtain confirmation** from the external IRB or external PI that their organization will allow ceding and agree to serve as the IRB of Record for the collaborative project.

DU PI must **submit a request** to IRBAdmin@du.edu for review and evaluation to allow ceding.

To evaluate the ceding request, **submit the following documents** to IRBAdmin@du.edu:

- [Appendix Q Form](#)
- Copy of **IRB Approval Letter**
- Copy of **Informed Consent**
- Evidence of **human subjects protection training** for all DU study personnel
- **Data Transfer/Use Agreement (DUA)**, if applicable

If ceding is allowed, DU will request the external organization's IRB Authorization Agreement (IAA).

DU IRB will obtain DU's official signature, will obtain the external organization's official signature, and will forward the fully executed IAA to the DU PI and to the external IRB.

If NIH-funded, Single IRB (sIRB) must occur for collaborative research

PIs and Institutions must identify one IRB to serve as the IRB of Record for the collaborative research.

If DU is identified as the institution to serve as the IRB of Record, refer to the steps in the blue section, to have another organization cede to DU.

If another institution is identified to serve as the IRB of Record, refer to the steps in the green section to have DU cede to another institution.

The DU IRB will maintain a copy of the full executed agreement and the accompanying documents to support this review and approval process.

Each investigator will obtain IRB approval from their own institution's IRB

PI must obtain IRB approval through the DU IRB. This must be completed through submitting an IRB application, following all of the requirements outlined in the submission checklist, through IRBNet.

The following documents must be submitted through IRBNet for review (additional documents may be required depending on the specific project):

- **Part I: Human Research Application** Copy of **Informed Consent or Exempt Information Letter** as applicable
- Evidence of **human subjects protection training** for all DU study personnel
- **Data Transfer/Use Agreement (DUA)**, if applicable

The DU IRB will issue a final approval letter to the PI when the proposed research proposal has satisfied all of the IRB requirements.

Add an unaffiliated independent individual to a DU research project who is NOT affiliated with an organization that has a Federalwide Assurance (FWA)

DU PI must submit a request through IRBNet as part of the initial submission or as an amendment to assess whether an unaffiliated independent individual may be added to a DU IRB protocol.

To evaluate this type of request, submit the following documents:

- [Appendix R Form](#)
- [Individual Investigator Agreement \(IIA\)](#)
- Evidence of **human subjects protection training** for all unaffiliated individuals who will be engaged in the research
- **Data Transfer/Use Agreement (DUA)**, if applicable

If the request for adding an unaffiliated independent individual is allowed, the individual would need to be added to the Part I: Human Research Application either initially in the New Project submission or as an amendment after the project receives full approval or exempt status.