Collaborating with Researchers outside of CSU

When a CSU human subjects research project will involve one or more institutions or individuals/businesses not associated with CSU, the regulations provide for a few mechanisms to facilitate that collaboration.

From the Office of Human Research Protections (OHRP):

[***§46.114 Cooperative research:***](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.114) ***Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may:***

* ***Enter into a joint review arrangement,***
* ***Rely upon the review of another qualified IRB, or***
* ***Make similar arrangements for avoiding duplication of effort.***

Below is some information to help guide you through the process.

1. **IAA (IRB Authorization Agreement)**: If you are working with an investigator at a collaborating institution(s) that has its own FWA; CSU may be able to enter into an IAA with this institution. An IAA is an agreement in which one institution’s IRB agrees to accept the review of another institution’s IRB (this is referred to as “ceding” to the other IRB). This is signed off by the Institutional Official (IO) of each institution. Essentially, this agreement allows one IRB to be the IRB of record. The second IRB relies on the other IRB’s review, approval, and monitoring of the research.

Example:
	* CSU as Institution A: IRB of record. CSU is generally the IRB of record if funding for the project goes through CSU and if the CSU PI is the one collecting the data. The CSU IRB Coordinator provides the collaborating institution’s IRB with the approval letter, consent document, instrument(s), and protocol along with a copy of the IAA and asks if their IRB will cede to CSU’s IRB. If agreeable, Institution B will obtain their IO’s signature and return the signed document for CSU IO’s signature.
	* CSU as Institution B: CSU’s IRB relies on another institution’s IRB to be the IRB of record. CSU will be Institution B if, for example, the data will be collected at the other institution and CSU will only receive the data for analysis or a PI has recently transferred to CSU and the human subjects data collection will remain at the other institution. The IRB does not approve the proposed research at the other institution, but rather, reviews the approved material and can request changes if needed. Materials to be reviewed are the approval letter, consent document, instrument(s) and protocol. Since Institution B is agreeing to cede to another IRB, Institution B usually initiates the IAA. This process first involves approval from the IRB Chair to allow CSU to cede. The IRB Coordinator will process the documents, and obtain the IO’s approval and signature on the agreement. The IRB Coordinator will then work with the collaborating PIs and IRB and finalize the agreement.
2. **IIA (Individual Investigator Agreement)**: Working with a collaborating institution(s) or individual investigator who is not affiliated with an institution that has an FWA; CSU may be able to engage in an IIA.

An IIA isn’t used very often at CSU, but an example of when an IIA may be needed is where research will be conducted at a primary/secondary school system where they do not have an FWA, and it is not possible for them to have their own IRB. Generally the schools will be collecting the data for the researcher. One person who the CSU PI will be working with will be the responsible party to sign the IIA. Training materials are provided to the contact person for review and they must agree to the information in the IIA. The IRB Collaborator works with the CSU PI and the individual who will be the IIA contact.

[OHRP Guidance on Engagement of Institutions in Human Subjects Research](http://www.hhs.gov/ohrp/policy/engage08.html)

[OHRP Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement (IIA)](http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html)

To find out if an IAA or IIA will work for your research, please contact the IRB.