**Criteria for use of an external IRB**

One or more must apply:

* The external IRB is at an AAHRPP accredited organization and/or
* The funding has been secured or is pending and the funding agency requires that a central IRB be used for the project

When UCD determines it is appropriate to rely on an external IRB for review and oversight of a study involving UCD faculty, staff, the UCD requires a record to be maintained of this reliance.

The UCD PI is responsible for providing ongoing documentation of the study’s status with the IRB of record and for providing copies of these documents to the External IRB team for inclusion in the University’s shadow file.
The UCD Research Administration provides this service for all UCD faculty, for UCH employees, for DH employees, CHCO and UCHealth employees.

**Submission Process and Additional Requirements**

1. PI or designee creates a shell of a record in InfoEd as follows:
* Login to InfoEd (<https://era.cu.edu/>)
	+ - Within the menu on the left-hand side, selects “Human Protocol”
		- Select “Create New”
		- Enter the title of the study in the title box
		- Enter the PI’s name in the “Member” box
		- Click continue
		- Add additional personnel as needed using the personnel e-form
		- Click Save and Done
		- The record number (aka the COMIRB number) will be used to track the study and for submission through the HSR Portal.

2. The Human Subject Research (HSR) Portal will be utilized to route the study for appropriate reviews and approvals. This includes obtaining the signed reliance agreement. PI or designee submits the following documents through the HSR Portal.

* + Protocol
	+ Contract, including budget (draft acceptable) – only industry sponsored and industry funded
	+ Consent form (draft acceptable)
	+ Draft IRB Reliance Agreement when applicable
	+ Any additional information from the external site, such as IRB approval, etc., as available
1. UCD study staff will be required to complete and maintain UCD required Conflict of Interest (COI) disclosures and CITI training, in addition to requirements of the external IRB. This is reviewed and confirmed for each new study submission.
2. The External IRB Coordinators will confirm that documentation is complete, education requirements met, no conflict of issues are outstanding for the PI, sub-investigators, co-investigators or Primary Contact.
3. The External IRB Coordinators will assure that the required reliance agreement is sent for signatures and upload a fully signed copy into the InfoEd record when available.
4. Upon confirmation of final approval of all outstanding committees and reviews, and receipt of the signed IRB reliance agreement (when applicable), the External IRB coordinator will send the PI and designee documentation that the study is cleared to proceed by issuing an “Outside IRB approval memo” and, when appropriate, a “HIPAA Certificate” to confirm UCD sign off on the protocol and by the Privacy Board.
5. Prior to opening to accrual, any study in Oncore is required to be reviewed and comparison of the fully executed contract and IRB approved consent form are reviewed. Language regarding research related injury is reviewed to assure both are in alignment. If the documents are not in sync, regarding injury language, the study does not open to accrual until the consent form has been corrected.

**For Subsequent Changes and Continuing Review**

1. PI or designee should forward approvals for Amendments, Continuing Reviews, Serious Adverse Events (SAEs) and other miscellaneous changes to the External IRB Coordinators for inclusion in the study’s InfoEd record.
2. PI or designee will also email any of the following changes to the External IRB Coordinators at externalirb@ucdenver.edu:
	* PI, Primary Contact, sub-investigators/co-investigators
	* Study title
	* Site location
	* Study closure