When UCD determines it is appropriate to rely on an external IRB for review and oversight of a study involving UCD faculty, staff or students, we are required to create a record with appropriate details of this reliance.

**Submission Process and Additional Requirements**

1. PI or designee creates a shell of a record in InfoEd
2. and obtains a COMIRB number, as follows:
* Login to InfoEd (<https://era.cu.edu/>)
	+ - Within the menu on the left-hand side, select “My Human Subjects”
		- Select “Create New”
		- Enter the title of the study and click “Continue”
		- Select the PI, enter the Primary Contact and sub-investigators/co-investigators and click “Continue”
		- The COMIRB number has now been generated for your study

2. The Human Subject Research (HSR) Portal <http://www.ucdenver.edu/research/ResearchAreas/Pages/HumanSubjectResearchProtocolSubmission.aspx>, will be utilized to route the study for appropriate local reviews and approvals including to UCD’s External IRB Coordinators. PI or designee submits the following documents through the HSR Portal:

* + Protocol Assessment Form
	+
	+ 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. The PI is responsible for ensuring this is done.
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 acknowledgement that the IRB reliance agreement (when applicable) is in place, the External IRB coordinator will send the PI and designee documentation that the study is cleared to proceed by issuing an “Outside IRB Approval”. For instances when the external IRB and institution do not provide privacy board review, UCD will do so and issue a “Certificate of HIPAA Compliance” to the PI and designee.

**For Changes and Continuing Review**

1. PI or designee should forward approvals for Amendments, Continuing Reviews, UAPs 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:
	* PI, Primary Contact, sub-investigators/co-investigators
	* Study title
	* Site location
	* Study closure

Contact External IRB Coordinators at: externalirb@ucdenver.edu