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**Effective January 1, 2018:** There will be a one-time fee of $5000 for use of a commercial Institutional Review Board. The one-time fee goes to UCD.

Please feel free to negotiate with sponsors to have them pay your commercial IRB review fees directly. Many sponsors will allow this, though some may not.

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**Get your new study in the queue for UCD review**

**Pre-IRB Approval - Initial Submission**

1. PI or designee creates a shell of a record in InfoEd
2. and obtains a COMIRB number, as follows:

* Login to eRA 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
  + – select appropriate IRB of record, include the name of billing contact (from your department) and speedtype
  + Protocol
  + Contract, including budget (draft acceptable) – only industry sponsored and industry funded
  + Consent form – draft is acceptable

1. UCD study staff will be required to complete and maintain UCD required Conflict of Interest (COI) disclosures and CITI training. The PI is responsible for ensuring this is done.
2. The UCD requires standard language in three sections of the consent form: payment, injury and HIPAA. Please use standard language from the UCD consent template that is located on CRSC’s [website](http://www.ucdenver.edu/research/ORC/CRSC/Pages/Ceding.aspx). The External IRB Coordinators will review the consent form to verify that it contains UCD standard language, or to obtain UCD permission to use non-standard language. The External IRB Coordinators will confirm that documentation is complete, education requirements met, and no conflict of issues are outstanding for the PI, Primary Contact, or sub-investigators/co-investigators, only. The External IRB Coordinators will contact the study team if any changes or additional information is required.
3. The External IRB Coordinators will issue “Institutional Sign-off to submit to the IRB”, to the Primary Contact. This document provides clearance to the study staff to submit to the IRB of record.
   * Study teams utilizing WIRB will submit through WIRB’s submission portal, Connexus, using WIRB’s forms and instructions. A Connexus account can be created through <https://connexus.wcgclinical.com/>.
   * Other Commercial IRBs will likely have their own portal for submission.

**Post-IRB Approval**

2. Email the IRB approval certificate and IRB approved consent form(s) to the External IRB team, unless utilizing WIRB. WIRB automatically provides the External IRB team with these documents.
3. External IRB Coordinators will update the InfoEd record and contact the study team for the fully executed contract.
4. The External IRB team will assure that the language in the fully executed contract is in harmony with the IRB approved consent form to obtain UCD sign-off.
5. Upon receipt of UCD sign-off, the External IRB Coordinators will issue an “Outside IRB Approval” and a “Certificate of HIPAA Compliance” to the PI and designee.
6. The PI is responsible for providing the External IRB team with copies of all IRB approvals, continuing reviews, amendment approvals, and other approvals for miscellaneous changes, throughout the life of the study, unless using WIRB. WIRB automatically provides the External IRB team with these documents.
7. The PI is responsible for submitting UAPs to the IRB of record, per their policy, and for providing this information to the External IRB team as well.

**For Changes and Continuing Review**

1. PI or designee will email any of the following changes to the External IRB Coordinators:
   1. Any requests to change the standard language to the consent form must be reviewed by the External IRB team prior to submission to the IRB of record
   2. PI, Primary Contact, sub-investigators/co-investigators
   3. Study title
   4. Site location
   5. Study closure
2. PI or designee will send Amendments, Consent Form changes, Continuing Reviews, UAPs and other miscellaneous changes directly to the IRB of record, following their instructions.

Contact External IRB Coordinators at: [externalirb@ucdenver.edu](mailto:externalirb@ucdenver.edu)