

**PRINCIPAL INVESTIGATOR GUIDE**

**FOR RDRC APPLICATION**

The following processes are meant to aid the Principal Investigator (PI) in the application for RDRC authorization as identified in Federal Regulations 21CFR 361.1.

* The PI submits their protocol to COMIRB through InfoEd as per University of Colorado Denver | Anschutz Medical Campus policy.
* While completing the COMIRB application, the PI will be asked if their protocol uses radioactive materials.
* When the PI clicks “yes” to the question regarding the use of radioactivity, a prompt will notify the PI that s/he needs to contact the RDRC to determine if they need RDRC authorization.
* At this point in time, the PI may submit their protocol to the RDRC Coordinator at rdrc@ucdenver.edu for pre-review. Within three (3) business days, the RDRC Coordinator will respond to the PI via email to notify them of the pre-review determination.
	+ If the determination is that the protocol does not require RDRC purview, the Coordinator will provide the PI with the appropriate documentation for the PI to upload into InfoEd. At this time, the Coordinator will evaluate the PI’s and Co-PI’s huCIR authorization status and advise the PI as necessary.
	+ If the determination of the pre-review is that the protocol needs RDRC authorization, the Coordinator will notify the PI via email and provide them with a link to where the application materials can be located and/or an application packet. (<http://www.ucdenver.edu/research/ORCS/RDRC/Pages/Application-Process-and-Materials.aspx>)
* The PI will then upload either the RDRC Application or the RDRC Exempt Letter into InfoEd so as to be able to complete their COMIRB submission. **Failure to upload the RDRC Application or the RDRC Exempt Letter into InfoEd at the time of COMIRB application will result in an “Incomplete Submission” from COMIRB.**
* The PI submits only the RDRC Application to COMIRB. The RDRC Application and all required supporting materials for RDRC application and review need to be sent directly to the Coordinator at rdrc@ucdenver.edu for formal application.
* The RDRC Application and all supporting materials required must be received no later than one week prior to the RDRC Meeting. The dates of the RDRC Meetings are posted on their website: <http://www.ucdenver.edu/research/ORCS/RDRC/Pages/default.aspx>

**\*\*\*\*\*\* IMPORTANT NOTE \*\*\*\*\*\***

**No incomplete applications will be submitted for Committee review. Please make sure that you have ALL required materials submitted ONE WEEK prior to the next scheduled RDRC meeting.**

* After the RDRC has reviewed the application and supporting materials, the determination of their review will be communicated to the PI and to COMIRB via InfoEd.
* Upon approval from RDRC, the Clinical Research Support Center (CRSC) will be notified. The CRSC will then contact the PI to schedule a Study Initiation Visit. After the completion of their visit, CRSC will send the RDRC a document of their findings.
* Environmental Health and Safety (EH & S) may also initiate a site evaluation, upon their discretion.
* Enrollment in the study cannot occur until:
* Signed RDRC Authorization has been uploaded into InfoEd and sent to the PI
* COMIRB has issued a Certificate of Approval
* CRSC has completed the Study Initiation Visit, and has determined that the PI has all necessary materials and resources available to him/her to conduct studies, understands reporting requirements, and is registered and trained in Oncore.
* EH & S evaluation, if done, has determined that the PI has all postings, disposals, and emergency procedures in place to safely carry out the protocol procedures.