University of Colorado
Denver | Anschutz Medical Campus

COMMITTEE FORM #4

Materials for Review of New RDRC Application

In order for the Radioactive Drug Research Committee (RDRC) to consider an application for review, the committee must receive a complete packet of materials.

This packet must include the following documents:

- The RDRC application
- A copy of the protocol submitted to the IRB
- A copy of the research consent form submitted to the IRB
- A copy of the labels to be used for the radioactive material
- A copy of the package insert (if manufactured drug)
- A copy of the batch records demonstrating successful manufacture of the materials to be used if produced locally (for example by the UCD cyclotron team) and a copy of the Radiopharmaceutical Oversight Committee's (RPOC) approval letter
- A copy of the Scientific Advisory Review Committee (SARC) approval, if applicable
- A copy of the PI's human subjects training (pulled from InfoEd)
- A copy of the authorized user's qualifications (keep annually updated copy on file, to be added to each protocol file)

Without a complete packet of materials, the RDRC will not review the study.

History of SOP	Date
Initial approval	12/16/15
Review by the RDRC	
Re-review:	