

RDRC SOP for Review of Amendments to Approved Research

The Radioactive Drug Research Committee (RDRC) is required to review and approve, prior to implementation, changes to approved protocols as follows:

1. Change in PI
2. Change in Radiopharmaceutical/ tracer use in the Protocol
3. Change in the consent language used to describe the risks of the radiopharmaceutical material or agent
4. Change or addition of radiopharmaceutical material or agent
5. Change in dose of/exposure to radiopharmaceutical material or agent
6. Change in number or dose of radiation exposure related to other procedures (e.g., CT scans, X-rays)
7. Change in the number of subjects to be studied
8. Adverse Events involving the radiopharmaceutical material or agent
9. Changes in location of the research
10. Changes in vendor providing the radiopharmaceutical material or agent
11. Changes in the authorized user of the radiopharmaceutical material or agent

The PI is required to submit any proposed changes in the research prior to implementing those changes. The RDRC Administrator will receive notice of a proposed change through InfoEd. The RDRC Chair and RSO will review the proposed amendment and compare it to the list of items above to determine whether or not further RDRC review is required. Proposed changes detailed above will be sent to the RDRC for review at a convened meeting.

The RDRC will receive a copy of the proposed amended protocol as submitted to the IRB, the consent form, the RDRC application, a written rationale for the proposed change as well as any relevant labels, and batch records in order to undertake their review. When the amendment is approved which involves exposure either of more than 30 research subjects, or of any research subject under 18 years of age, the committee shall immediately submit to the Food and Drug Administration (FDA) a special summary report regarding this information. Such reports will be submitted to FDA utilizing their required format.

The meeting minutes will document the rationale for the change and the RDRC's decision. The PI will be notified of the RDRC's decision and shall not institute the changes until both the RDRC and the IRB have approved the amendment

History of SOP	Date
Initial approval	12/16/15
Amended	05/12/16
Re-review:	