RDRC - Monitoring RDRC Approved Studies

The purpose of this document is to outline how studies will be monitored by the Radioactive Drug Research Committee (RDRC)

Upon approval by the RDRC and the IRB, an RDRC approval letter will be sent to the investigator. This will include information about the PI's responsibilities with regard to the RDRC. The investigator will also be provided with a copy of the FDA's most recent version of "Guidance for Industry and Researchers" regarding the RDRC.

The Clinical Research Support Center, Quality Assurance and Education team (the QA Team) will be notified of the new approval. The QA Team will contact the principal investigator of the study to arrange a site initiation visit. The purpose of the visit is to confirm that the PI has the tools necessary to manage the study from initiation to completion. The QA team will provide the investigators with the "RDRC Principal Investigator Responsibilities" document. This document will be reviewed and data collection templates will be provided to the investigator to assist in the specific data collection required for these protocols. The QA team will also review IRB requirements and confirm that the study team has appropriate tools in place. After the QA visit has been completed, the QA team will write a report summarizing the events that occurred during the visit and send the investigator as well as the RDRC a copy of this report. The study may begin enrollment at this time, if HuCIR approval has been given. These site initiation reports will be reviewed at the next RDRC committee meeting.

Within 90 days of administering the radioactive drug to the first subject and at least annually, the QA team will visit the PI to confirm compliance with the RDRC and IRB approvals, the relevant regulations, and local policies. The QA team will provide the PI with a report summarizing what occurred during the visit and send a copy of this report to the RDRC with any corrective action plan by the PI.

The RDRC will review progress on each open RDRC protocol on at least a quarterly basis including continuing review information, QA reports, amendments, and adverse events, regardless of whether these were related to use of radioactivity.

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