

Controlled Access to Radiation Exposure On-line Submission for MRSC and RDRC Applications

Instructions and Process

Welcome to the Controlled Access to Radiation Exposure (CARE) system! This submission process is for the Medical Radiation Safety Committee (MRSC) and/or the Radioactive Drug Research Committee (RDRC) to review protocols that included administration of radiation and/or radioactive materials to human subjects. The primary concern is for human subject protection, but operator exposure may be a concern in some studies. Research studies that involve patient or operator exposure that is different than that which would be received by a patient or operator not participating in the study are the main focus of the MRSC.

***PLEASE NOTE:** This application is distinct from the Institutional Review Board (IRB application). MRSC applications must be also submitted when human subject protocols use radiation-producing machines and/or radioactive materials and it is recommended that it be submitted concurrently with the HPSC/IRB application. It should be noted in the application if the human protocol involves the use of a new radiopharmaceutical because RDRC review is typically necessary in these circumstances.*

CARE REVIEW PROCESS:

1. **Required Information** - Complete ALL Required Information for each protocol being submitted through the CARE on-line system. The following are REQUIRED fields:
 - a. **Standard of Care and Non-standard of Care Procedures** – Please specially describe with procedures are considered standard of care and which are considered non-standard of care. Separate your description for Radiation-Producing Machines, Radioactive Material and Radiation Therapy.
 - b. **Internal Radiation Dosimetry** – Internal radiation dosimetry MUST be provided for radiation producing machines, radioactive material and radiation therapy if the protocol is to be processed as RDRC. Otherwise, dosimetry will be provided during the review process.
 - c. **Informed Consent Form** – The Informed Consent form must include information on potential risks to the research subject from exposure to radiation. Since the degree of risk depends on the magnitude of the dose, it may be necessary to obtain information on the expected radiation doses before the Informed Consent form is finalized. **Guidelines can be found in the Informed Consent portion of the on-line application.**
 - d. **Completed Application Form with All Required Signatures**
2. **Initial Review** - Initial Review will be required once the protocol is submitted. This is done to ensure that required protocol information is completed. If necessary, the protocol will be returned to the Principal Investigator for revisions. Once the Initial Review process is completed the protocol will then receive an official entry date.
3. **Medical and Technical Review** – In the interest of protecting human subjects, a technical review will be performed in order to determine if the protocol conforms with legal requirements concerning radiation exposure to humans. The committee will assess radiation dosimetry for human subjects and review the informed consent language. If necessary, the committee will request revisions from the Principal Investigator.
4. **Decision Letter** – Shortly after review and revisions, as needed, a decision letter will be sent to the Principal Investigator.