

**HOWARD UNIVERSITY (HU)  
OFFICE OF REGULATORY RESEARCH COMPLIANCE (ORRC)  
INSTITUTIONAL REVIEW BOARD (IRB)**

**ADDENDUM TO IRB STANDARD OPERATING PROCEDURE (SOP)  
SUPPLEMENT-2: PROTOCOLS INVOLVING IONIZING RADIATION or EQUIPMENT**

Currently, the **Institutional Review Board (IRB)** and the **Radiation Safety Committee (RSC)** operate under a centralized **Office of Regulatory Research Compliance (ORRC)** to ensure coordinated regulatory oversight. Below is a structured framework describing communication, roles, referral procedures, approvals, and training requirements. The key principles of this document are that: there will be no IRB approval without RSC clearance for radiation-involved research; the Radiation Safety Officer (RSO) will serve as a formal bridge between committees; radiation risk must be scientifically justified and minimized; training and authorization must be verified before study activation; and clear documentation and audit trails are essential. When possible, Investigators are encouraged to engage the RSO at the study planning stage. ***This addendum to the IRB Policy and Procedures (P&P) does not override the standard OHRP/ORRC and NRC P&P.***

## **2.0 Oversight Framework**

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### **Organizational Placement**

- IRB and RSC function as separate regulatory committees under the ORRC.
- Each committee retains independent regulatory authority (e.g., human subjects protection vs. radiation use authorization) but will act cooperatively to address radiation safety concerns.
- The Radiation Safety Officer (RSO) serves as the operational link between committees and, thus, is an Ex-Officio member of the IRB.

## **2.1 Communication and Interaction Framework Between IRB and RSC will occur as enumerated below:**

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### **2.1.2 Trigger-Based Communication: Procedures for Referring the Protocol to the RSC.**

#### **Protocols are flagged for RSC review when they involve:**

- Use of ionizing radiation beyond the standard of care
- Research-related CT, fluoroscopy, PET, and nuclear medicine procedures
- Administration of radiopharmaceuticals
- Use of radiation-producing devices for investigational purposes

#### **The IRB administrative pre-review process screens submissions using:**

- The radiation-use questions in the IRB application
- Automatic routing in the electronic IRB system (iRIS)

- If radiation is involved, the protocol is referred to the RSC before final IRB approval.

**Sequential Review:**

- IRB receives protocol.
- If radiation is involved, IRB defers final approval pending RSC review.
- RSC evaluates radiation risk, dosimetry, and regulatory compliance.
- RSC approval letter issued.
- IRB reviews/accepts RSC approval and finalizes approval.
- No protocol enrollment must occur before final approval by the IRB.

**Protocols Utilizing External (non-HU) Facilities:**

For protocols utilizing external (non-HU) facilities for radiation procedures, the Investigator must provide the RSC with the facility's current licensure and/or safety certifications. The IRB/RSC will evaluate the adequacy of these external protocols to ensure they meet the required safety standards. The IRB will verify that the Informed Consent clearly identifies the external location and any site-specific risks associated with that facility.

**Formal Communication Channels:**

- Shared electronic protocol tracking will occur in iRIS
- Cross-committee meeting minutes when relevant
- The Compliance Officer will include related protocol in the standing IRB meeting agenda
- Direct communication between the IRB Chair and the RSC Chair when risk concerns arise

**NOTE:** Alternatively, and for protocols in which the Investigator initially acknowledges that RSC's review would be required, the Investigator may submit the protocol to the RSC in parallel with review by the IRB. Following RSC approval, the Investigator will submit the RSC approval letter to the IRB before the IRB can issue final protocol approval. The IRB shall not finalize or stamp an Informed Consent Form until any RSC recommendation has been addressed and approval has been issued.

## **2.2 Radiation Safety Officer**

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**The role of the Radiation Safety Officer is as outlined in the Radiation Safety Policy and Standard Operating Procedures.** Nonetheless, the RSO plays a critical compliance and advisory role. Thus, as an **Ex Officio Member of the IRB**, the RSO will:

- Attends IRB meetings (or provides written comments in lieu) when radiation safety-related protocols are on the agenda
- Provides technical expertise on:
  - Radiation dose estimates
  - Risk categorization (minimal risk vs. greater than minimal risk)
  - Regulatory thresholds (e.g., 21 CFR 361, state radiation control regulations)

- Advises on appropriate radiation risk language in consent forms as necessary
- Ensures consistency with the institutional radioactive materials license
- As an Ex Officio member of the IRB, the RSO will not vote but serves in a consultative capacity.

## 2.4. Training Requirements

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Training is tiered based on role and radiation exposure, as specified in the HU ORRC CITI training guide. Staff whose daily responsibilities include interactions with the radiation source will additionally follow the HU Radiation Safety Policy. Full attendance at the HU Annual Radiation Safety Seminar may substitute for the CITI radiation safety module.

## 2.5. Documentation and Compliance Monitoring

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**Continuing Review:** IRB continuing review includes verification that: i) radiation exposure remains within approved limits, and ii) the RSC may require periodic dose reports.

**Amendments:** Per the IRB and RSC Policy and Procedures, all amendments must be submitted for review and approval, including: i) increased radiation dose, ii) additional imaging procedures, or iii) a change in radiopharmaceutical.

**Adverse Event Reporting as per IRB and RSC P &P, and specifically if:** Unanticipated radiation overexposure must be reported to: i) RSO immediately; ii) IRB per reporting policy; and iii) State regulators by the appropriate officer as required

## 2.6. Risk Integration in Informed Consent

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The IRB, with input from the RSO and RSC:

- Ensures radiation dose is expressed in understandable terms (e.g., comparison to background radiation)
- Distinguishes clinical vs. research-related exposure
- Clearly states cumulative dose and potential risks

## 2.7. Quality Assurance and Auditing

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- Joint audits between IRB (ORRC Director) and Radiation Safety Office (RSO)
- Random monitoring of high-dose protocols
- Verification of ALARA, DC-Health, and NRC compliance
- Training documentation audits

## 2.8. Process and Oversight

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Function	IRB	Radiation Safety Committee	RSO
Human subjects protection	Primary authority	Advisory	Advisory

<b>Function</b>	<b>IRB</b>	<b>Radiation Safety Committee</b>	<b>RSO</b>
Radiation dose review	Consults	Primary authority	Technical expert
Consent language	Approves	Recommends edits	Drafts/Advises
Investigator authorization	Confirms	Verifies	Oversees
Ongoing monitoring	Continuing review	Dose monitoring	Inspections