

Columbia University
JRSC and IRB Review Requirements

For Human Subjects Research that Involves Ionizing Radiation Exposure for Subjects

Ionizing Radiation Exposure	SOC	Non-SOC
Internal (Imaging at Columbia)	No CU HUS review	CU HUS review
	CU IRB review	CU IRB review
External (Imaging at non-Columbia facility)	No CU HUS review	CU HUS review
	No request for documentation or approvals from imaging site	<p>Verification that the facility is licensed by the appropriate authority to use ionizing radiation. RAM and/or RPE license when appropriate</p> <p>If radioactive materials will be administered: AU name and certification</p> <p>When an investigational radiologic device, radiopharmaceutical, radionuclide or ionizing radiation exposure setting or sequence, is involved:</p> <ul style="list-style-type: none"> • Radiation Safety approval from imaging site • IRB approval for imaging site when the imaging site is engaged in the research (approval from site IRB or approval from CU IRB through reliance agreement)*
	CU IRB review	CU IRB review

- AU Authorized User
HUS Human Use Subcommittee of the Columbia/NYPH/NYSPI Joint Radiation Safety Committee
IRB Institutional Review Board
RAM Radioactive Material
RPE Radiation Producing Equipment
SOC Standard of Care

*To be “engaged in research” at the external site means that the investigator at the site (a) is considered to be a scientific collaborator with the applicable CU investigator, (b) has intellectual input into the study and (c) may merit professional recognition or publication privileges. The relationship between CU and the external site is usually evidenced by a subcontract. In contrast, to “provide services” at the external site means that (a) the site normally performs the services for a fee for non-research reasons, (b) there is no collaboration or shared intellectual input with the site and (c) the services performed by the site do not merit professional recognition or publication privileges. The relationship between CU and the external site is usually evidenced by a service agreement.