Does the IRB protocol involve the use or evaluation of a drug or device that emits ionizing radiation?

Yes

Is the drug or device currently approved by the FDA for commercial marketing?¹ (Note: This would exclude drugs and devices studied under IND or IDE applications or RDRC approval.)

Yes

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No

Do the objectives or specific aims of the protocol address an evaluation of the drug or device for an “experimental” indication or involving “experimental” procedures?²

Yes

Does the protocol involve the use of the drug or device for an “experimental” indication or involving “experimental” procedures?²

No

Does the protocol involve the use of the drug or device for an “experimental” indication or involving “experimental” procedures?²

No

Does the protocol involve research subjects (e.g., healthy controls) who would not normally receive the drug or procedure in association with the diagnosis or treatment of a disease or condition?

Yes

Yes

Yes

HUSC REVIEW/APPROVAL IS REQUIRED

No

No

No

NO

HUSC REVIEW/APPROVAL IS NOT REQUIRED

¹ Note: HUSC review/approval is required for all Humanitarian Use Devices that emit ionizing radiation.

² “Experimental” indications or procedures are those that are not consistent with standard clinical practice or the current FDA-approved product labeling.