REGULATORY TIPS AND UPDATES– DID YOU KNOW?

UNIVERSITY OF Cincinnati

IM Regulatory Newsletter

In this issue:

Radiation Safety Committee (RSC) and Institutional Biosafety Committee (IBC) Reviews – When are they required?

Institutional Biosafety Committee (IBC) Review is required if your study involves:

- **Human derived materials that will be handled within a UC Research Lab (does not apply to clinical diagnostic lab)**
- **Introduction of recombinant nucleic acids, infectious agents and/or genetically modified cells into human patients**

If IBC review is required, the PI or delegate will need to complete the IBC REDCap submission at the following link:

https://redcap.research.cchmc.org/surveys/?s=LLP3CEJWNRFE43P7

The following documents will need attached in the submission:

a. Protocol
b. IB
c. Pharmacy Manual (if applicable)
d. Any other supplemental documents

NOTE: UC IBC accepts external IBC reviews if your study is going through a central IRB that is also performing IBC review at the study level. UC IBC review is not needed if you are utilizing an external IBC, however, a MOU must be established with the external IBC and UC IBC.

Radiation Safety Committee (RSC) review

Radiation Safety review is required for all studies involving ionizing radiation exposure even if it is SOC. (X-rays, DEXA scans, etc.)

- **If a research study involves ionizing radiation, you must check that RSC review is required on your HRP form for your RAP submission.**
- **You will need the PI to complete and sign the RSC form (if SOC it requires an additional physician signature to verify)**
- **Once completed and signed, submit the form, protocol, Informed Consent risk language, and imaging manual to Rich Anderson for review.**
- **Rich will determine if additional or modified risk language needs added to the ICF.**
- **If it does, make those ICF changes and get sponsor approval (if Industry)**
- **Once the sponsor approves, attach the correspondence from Rich in your RAP submission showing his determination. If no changes were required attach that determination.**
- **If Investigator Initiated, follow the same process, but get investigator approval on ICF changes before submitting to IRB.**

There are very few that require a full Radiation Safety Committee (RSC) review.

The ones that have to go to the full RSC would be any that involve some use of an RGE or radiopharmaceutical that is outside of any of our current internal authorizations or even less likely, is not currently allowed by our state radioactive material license.

If you have any questions, please do not hesitate to reach out to: IMRegulatory@uc.edu

For more information, please click: Tools and Templates

Thank you!