

BIOSAFETY AND RADIATION SAFETY REVIEW

In addition to the requirement for IRB review for research projects at Prisma Health, ancillary reviews may also be required for the following instances:

- 1) The Radiation Safety Committee is responsible for reviewing and approving certain clinical research studies involving exposure of human subjects to ionizing radiation.
- 2) The Radioactive Drug Research Committee is responsible for reviewing and approving the use of certain “non-approved” radioactive drugs for research purposes in humans that would otherwise require review by the FDA in the form of an Investigational New Drug (IND). Use of radioactive drugs in such studies is generally intended to obtain basic research information and is “not intended for immediate therapeutic, diagnostic or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).” (21CFR361.1(d)(7)).
- 3) The Institutional Biosafety Committee (IBC) oversees a review and registration process and addresses concerns regarding the Dual Use research of Concern nature of proposed research. The committee provides recommendations for safety policy to the Prisma Health ORHP and reviews all infectious disease research performed at Prisma Health. This includes research projects involving recombinant DNA, including human gene transfer, or potentially infectious/toxic materials.