

Review by specific scientific or safety oversight committees may be necessary before submitting a protocol to the IRB. The need for this review is dependent on specific protocol attributes which may include children as subjects, area of research, resource utilization and/or exposure to radioactive agents or interventions for research purposes.

Oversight committees that must review the protocol prior to its being submitted to the IRB

- **Institutional Biosafety Committee (IBC):** Reviews the scientific and safety aspects of research involving gene transfers, human pathogen and other biologic agents.
- **Magnetic Resonance Research Center Protocol Review Committee (MRRC):** Reviews and approves all human research protocols that will make use of the facilities of the MRRC. The Committee evaluates each proposed study for the level of supervision that must be available, based primarily on risk stratification.
- **Pediatric Protocol Review Committee (PPRC):** Reviews the scientific aspects of all research at the Yale School of Medicine that involves children, with the exception of Pediatric Oncology, which is reviewed by the Yale Cancer Center's Protocol Review Committee.
- **Protocol Review Committee (PRC):** Reviews the scientific aspects of all oncology research to be conducted at Yale, regardless of department.
- **Psychology Subject Pool Committee:** Oversees the process for ensuring that research proposals intending to recruit introductory psychology students meet education standards set for the course.
- **Radiation Safety Committee:** Reviews, on the basis of safety, and approves or denies, consistent with the limitations of the regulations and the license, all requests for authorization to use radioactive material within the institution.
- **Yale Diagnostic Clinical Research Committee:** All research studies utilizing Diagnostic Imaging hospital/affiliated facilities imaging equipment or research studies requesting a Diagnostic Radiology clinical research coordinator must be reviewed and approved by the YDR Clinical Research Committee.
- **Yale New Haven Hospital Radioactive Drug Research Committee:** Oversees the use of radioactive materials to be used in human participants, prepared at the Yale Medical Center, which require neither an Investigational New Drug (IND) nor Food and Drug Administration (FDA) approval.
- **Yale Center for Clinical Investigation (YCCI):** The YCCI participates in the review of research that is fully or partially supported with YCCI funds. The scientific aspects of

research supported by the YCCI may be reviewed by the YCCI's Science and Safety Committee (SSC).

- **Other HRPP Partners With Oversight Responsibilities**
- **IRB Leadership:** Provides oversight and guidance to the IRBs. Reviews and approves institution-wide IRB policies, and, if applicable, Good Clinical Practice Guidelines as adopted by the Food and Drug Administration (FDA) for the conduct of human research.
- **Committee on Conflict of Interest and Conflict of Commitment:** Collaborates with the Yale IRBs in the review of protocol-specific conflict of interest disclosures and ensures that conflicts are either reduced, managed or eliminated.
- **Office of the General Counsel:** Interprets regulations related to the protection of human research participants and advises and guides Yale personnel in the protection of research participants.