

The IRB is charged with review of proposed research protocols in order to ensure that the rights of human subjects are protected and that risk of harm to subjects is minimized. The framework for protection of human subjects is set in Federal regulation. Committee members work with IRB staff to ensure compliance with Yale policies and procedures, federal regulations, and state and local laws relative to the review of human subject's research studies.

The Community Member has the particular responsibility of bringing the perspective of the volunteer research participant to the review of protocols.

- General Member Responsibilities
- To review all assigned research protocols to ensure that:
 - Research design is sound and study hypothesis is reasonable
 - Risks to subjects are minimized
 - Risks to subjects are reasonable in relation to anticipated benefits
 - Selection of subjects is equitable.
- Informed consent is obtained or appropriately waived from all prospective subjects and documented
- The research protocol includes a plan for data and safety monitoring
- Subject's privacy and confidentiality are protected
- Appropriate additional safeguards are incorporated for any vulnerable subjects
- To attend all Committee meetings and to notify IRB staff in advance if there is a need to be absent from a scheduled meeting
- To complete required human subjects protection training and HIPAA training, if applicable
- To maintain confidentiality regarding reviewed protocols
- To act as primary or secondary reviewer for specific assigned protocols
- To act as a resource for researchers in the design of human subjects protection aspects of protocol development.
- To participate in Committee discussion of protocols
- To comply with Committee conflict of interest policy and procedure
- Specific Application of Responsibilities
 - To consider the risks and benefits of the study
 - To consider the inclusion/exclusion criteria, and determine if it has an ethical basis.
 - To consider the consent document to determine if the consent matches the protocol, if it is clear, and if it is understandable for research participants.

