

A federally mandated committee charged with responsibility to review proposed research in order to ensure that the rights of research participants are protected and that risk of harm to participants is minimized.

Responsibilities of the Institutional Review Board

- Review all research activities involving human participants and document its findings regarding ethical considerations, scientific merit, and adherence to federal regulations and IRB policies and procedures.
- Responsible for ensuring compliance with the terms of the Institution's Federalwide Assurance (FWA) as well as Yale policies and procedures, federal regulations, and state and local laws related to the review of human research.
- Review research activities to ensure that:
 - 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;
 - Subjects' privacy and confidentiality are protected; and
 - Appropriate additional safeguards are incorporated for any vulnerable subjects.
- Review research protocols with the authority to:
 - Approve;
 - Require modifications to secure approval;
 - Disapprove; and
 - Terminate or suspend.
- Conduct continuing reviews of approved research. Review proposed amendments, adverse events, protocol deviations, and matters of non-compliance.
- Determine if and when it will:
 - Require research progress reports;
 - Audit and/or monitor the research and researchers for adherence to the federal regulations and policies and IRB policies and procedures; and
- Report suspensions, terminations, and non-compliance to IRB officials, Yale officials, and the federal government.