

An individual capable, both in experience and available resources, of overseeing the organization's human research protection program. The Director serves as the primary contact for OHRP regarding human research protection issues for the organization. The Director has responsibility for the organization's distributed program for protecting human participants in research. The Director should have comprehensive knowledge of all aspects of the organization's system of protections for research participants, as well as be familiar with the organization's commitments under the FWA, and play a key role in ensuring that the organization fulfills its responsibilities under the FWA.

Responsibilities of the Director, HRPP

- Maintain Yale's Federal wide Assurance (FWA) and ensure compliance with its terms, as well as Yale policies and procedures, federal regulations, and state and local laws relative to the conduct of human research studies.
- Provide guidance regarding the interpretation of regulations, laws, and policies to the organization's IRBs, researchers, staff, and administrators.
- Develop and implement Yale human research protection policies and procedures.
- Oversee and coordinate HRPP activities across the various offices and staff that have roles in protecting research participants.
- Complete all required human research protection training and HIPAA training.
- Ensure that human research protection training is available and completed by investigators, key study personnel, the Institutional Signatory Official, and all Yale staff who participate in the human subjects protection program.
- Oversee the quality assurance monitoring of the HRPP, including research protocols and investigation of matters of non-compliance. Ensure implementation of corrective action, as needed, in accordance with Yale policies and IRB policies and procedures.
- Maintain current knowledge of human research protection guidance and regulations as they evolve. Stay current on emerging issues. Monitor federal regulatory websites and other research-related resources so as to stay current with regulatory changes in human research protections guidelines and policies. Communicate pertinent information to staff in a timely manner.