

The Compliance Manager serves as the primary contact for compliance issues involving human subject's research at Yale University. The Compliance Manager is responsible for the continued development and implementation of a post-IRB approval monitoring program of research studies involving human subjects, as well as other quality improvement activities.

Responsibilities of the Compliance Manager

- Conduct reviews in response to allegations and findings of noncompliance with Human Research Protection Program (HRPP) and sponsor requirements.
- Conduct systematic reviews that evaluate researchers' and their study team's compliance with approved protocols, federal regulations and guidance regarding the protection of human subjects, and relevant University and HRPP/IRB policies relating to the protection of subjects participating in research.
- Review protocol review processes performed by the Yale Institutional Review Boards (IRBs) to ensure compliance with federal regulations and guidance and University and HRPP/IRB policies and procedures regarding the human subject protection programs and protocol tracking integrity.
- Compile reports on audit/monitoring findings. Recommend corrective actions to researchers and the IRBs as required. Report findings when appropriate to the IRB Leadership, the Associate Vice President for Research Administration (the Institutional Official), the University Research Compliance Officer, the Office of the General Counsel, the University's Chief Privacy Officer and other University compliance offices and authorities.
- Receive and handle compliance issues and complaints, and may refer such items, as appropriate, to the University Research Compliance Officer, Yale Medical Group, appropriate Deans' offices and other Yale University offices for investigation and resolution.
- In conjunction with other HRPP leadership, develop and implement written policies and procedures that foster and enhance compliance in research involving human subjects.
- Generate reports requested by federal agencies. Assist representatives from sponsors and federal agencies conducting audits of Yale human research activities.
- Develop and conduct seminars and lectures, distributing literature, and other programs to educate and facilitate compliance of Yale's human research activities.
- Notify the HRPP and research community of important research ethics and human subject protection issues as they arise. Monitor changes in federal regulations and state laws and

assess their impact on research compliance. Provide guidance to operations staff and IRB members on federal regulations and state laws as required.

- Serve as a compliance resource to the research community and other internal interested parties.