

Title: The Institutional Official's Authority and Responsibilities – Human Subjects Research

Purpose

The purpose of this policy is to outline the authority and responsibilities of the Jefferson Institutional Official.

Policy

The Institutional Official (IO) is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federal-wide Assurance (FWA).

RESPONSIBILITIES

The responsibilities of the Institutional Official include:

- Ensure there is a robust structure and framework to support human subjects protection.
- Sign all Federal-wide Assurances under the purview of Jefferson and ensure that all elements agreed to in the assurances are fully supported and met.
- Ensure there is a proper procedure for appointing and evaluating Institutional Review Board (IRB) members. IRB appointments are made primarily by the Director and Associate Director of the Office of Human Research.
- Setting the “tone” for an institutional culture of respect for human subjects.
- Providing sufficient resources for the Office of Human Research and the IRBs to operate effectively.
- Empower the Office of Human Research to review and approve individual IRB policies, providing input as appropriate.
- Ensure effective institution-wide communication and guidance on human subject research.
- Ensure there are educational activities in place for all staff engaged in the conduct of or oversight of human subject research.
- Ensure that investigators fulfill their responsibilities for the ethical conduct of human subjects research.
- Consulted and copied on correspondence, as appropriate, generated by Jefferson's Human Research Protection Program Directors in response to on-campus visits and audits performed by federal oversight agencies.
- Communicate with and advise other senior management officials on human subjects protections issues as necessary.