

Series 201 The Institutional Official | Institutional Review Board

Authority of the Institutional Official

Utah State University maintains a Federalwide Assurance (#00003308) on file with the U.S. Department of Health and Human Services. The Federalwide Assurance (FWA) assures the federal government that Utah State University will comply with applicable provisions of federal law, policy, and regulations related to the protection of human research participants. The FWA is executed by an official with sufficient standing and resources at USU to ensure compliance with these policies, called the Institutional Official (IO). At Utah State University, the Institutional Official is the Vice President for Research. In line with those assurances and responsibilities, the Vice President for Research is also the Responsible Organizational Official, tasked with ensuring that the Human Research Protection Program at Utah State University has the resources necessary to ensure compliance with these provisions.

Responsibilities of the Institutional Official

The Institutional Official has many responsibilities related to the Human Research Protection Program. They must be a high-level official at Utah State University, with legal authority to commit USU to the terms of its FWA. They must have sufficient power at the institution to promote a culture of compliance and the prioritization of ethical research practices. Critical among the responsibilities of the IO are the following:

1. Ensuring that the IRB operates independently from outside or executive pressures regarding the institution's other interests, and especially its business interests;
2. Ensuring sufficient resources for the operation of the IRB and HRPP, including office space, supplies, meeting space, budget, electronic management systems for the effective and efficient review of protocols, and sufficient staffing to ensure the compliance and ethics aims of the HRPP can be met;
3. Serving as the point of contact for reporting responsibilities to the federal government;
4. Maintaining an active FWA;
5. Maintaining an active IRB Registration (IORG);
6. Evaluating, at least annually, the strengths and weaknesses of the HRPP, and seeing to its continuous improvement;
7. Leading by example in modeling ethical behavior and embodying a spirit of care and concern for the rights and welfare of human research participants;
8. Staffing an Institutional Review Board (IRB) that has sufficient expertise to review the types of research that USU commonly engages in, and ensure its members prioritize the rights and welfare of human research participants over other priorities;
9. Negotiating the terms of reliance between institutions working on a single, collaborative project to be overseen by a single IRB;
10. Staying up-to-date on activities delegated to other officials or offices; and
11. Remaining knowledgeable regarding HRPP requirements and best practices.

Ensuring these requirements are met can be a full-time job in and of itself. For that reason, many of these tasks are able to be dedicated to professional staff or faculty of sufficient standing to ensure they are carried out thoroughly and efficiently in a day-to-day manner. The IO is encouraged to seek out educational resources, such as membership in Public Responsibility in Research & Medicine (PRIM&R) and CITI educational modules relating to the responsibilities of the IO, in order to ensure sufficient knowledge of these requirements and appropriate delegation, outlined in the next section.

Maintaining accreditation of the HRPP is a strongly encouraged manner of ensuring a high-quality HRPP.

Delegation

Because the Institutional Official is a high-level administrator with many important responsibilities, they are empowered to delegate several of the day-to-day tasks relating to the oversight of the HRPP to other individuals. At Utah State University, most of these responsibilities reside with the Director of Human Research Protections, and/or the IRB Chair, who is hired and/or appointed by the IO. These delegations should be clearly outlined in a job role or position description for the individuals to whom such responsibilities are delegated.