

Series 207 The IRB & Undue Influence | Institutional Review Board

Independence of the IRB

The Institutional Review Board is required to conduct its business independent of other institutional interests. This includes business interests of the university, conflicts of interest, or general pressures to conduct research absent a thorough review. IRB members, the Institutional Official, HRP staff, and others receive training on the importance of the IRB's independent nature, and the Institutional Official (IO) is specifically charged with ensuring that the IRB is protected from these kinds of pressures.

Reporting Compromised Independence

Any person who has reasonable belief or evidence that the independent nature of the IRB is threatened, should report the basis for their concerns and/or evidence to the Institutional Official, who is the Vice President for Research. The Vice President for Research (IO) will review the information, and determine whether to move forward with an investigation or action. If it is appropriate, given the nature of the concern, to share this information with the IRB Chair and HRP Director, such information shall be shared so that the IRB Chair or HRP Director can work to reduce any inappropriate influence. The IO should take appropriate steps to investigate the nature of the undue influence, and remedy those effects where appropriate. This might include asking Internal Audit to conduct an investigation, removing a member of the IRB who is inappropriately representing outside interests, or working with the Director of Research Integrity and Compliance to develop a management plan for a conflict of interest that is inappropriately impacting the work of the IRB.

If the individual who holds reasonable belief or evidence that the independent nature of the IRB is threatened cannot report to the IO, the individual should, at a minimum, report their concerns to Utah State University Internal Audit. It may also be appropriate to report these concerns to the Office for Human Research Protections, if implicated projects are receiving federal funding and are reviewed under the Common Rule. Otherwise, reporting to an external sponsor may be necessary.

Responsibility to Maintain Independence

Institutional Leadership, as defined in USU Policy 584, shares the responsibility to maintain the independence of the IRB with the Institutional Official and IRB Chair. These individuals shall, at all times, work to avoid even the perception that the IRB is not an independent entity whose primary purpose is to promote the safety, welfare, and protection of human participants in research. At no time shall this SOP be construed to prohibit the HRPP's requirements to continuously improve its efficiency and effectiveness. However, effectiveness should never be compromised solely for the sake of efficiency.