

# Series 203 Institutional Conflicts of Interest | Institutional Review Board

## Institutional Conflicts of Interest Scope

USU Policy 583 states that Utah State University is “committed to advancing knowledge through engagement in research and scholarship” and that USU provides “a creative and ethical environment that supports free inquiry... that will contribute to the economic, social, and cultural welfare of humankind.” In order to advance research-based discoveries in a manner that ensures public trust in the research enterprise, Utah State University must ensure that all research is beyond ethical reproach. Institutional Conflicts of Interest (ICOI) can, without appropriate management, threaten the validity and public confidence in the research enterprise. Therefore, all human subjects research in which an ICOI is present shall undergo a review process, and move forward under a management plan approved by the appropriate institutional-level conflict review committee as well as by the Institutional Review Board.

## Institutional Conflict of Interest Defined

An Institutional Conflict of Interest exists whenever the financial interests or holdings of Utah State University or the personal financial interests or holdings of institutional leaders might affect or reasonably appear to affect the design, conduct, reporting, review, or oversight of human subjects research. An institutional leader is any person with direct authority over the allocation of institutional resources, including, but not limited to: the President, the Provost, the Executive Vice President, Vice Provosts, Vice Presidents, Deans, Department Heads, and Center Directors (including Associate or Assistant Vice Provosts and Presidents). It also includes those holding positions in an interim capacity who are able to directly influence salaries, appointments, resource allocation, or oversight of human subjects research, including Chairs, Vice Chairs, and Directors of the Institutional Review Board, Conflict of Interest Committee, and other committees designated by the institution’s research compliance officers. Members of the USU Board of Trustees are governed by a separate conflict of interest policy, and are not governed by this policy.

Institutional Conflicts of Interest can be created by gifts, payments, royalty income, or other financial benefits provided to the university from for-profit or private entities. They can also be created by equity holdings held by the university or its entities. Examples of institutional financial interests that could bring about an ICOI include:

- Payments resulting from the transfer (licensing) of technology created at the university to an entity, including royalties, milestone payments, and/or other licensing fees;
- Rights to acquire an entity or right to receive an exit, change of control, or liquidation fee resulting from a university investment or the transfer of university technology;
- Equity of a certain amount in a company, resulting from the transfer of university technology or direct investment from the university;
- Gifts, including gifts-in-kind of goods or services, from a potential sponsor, from a philanthropic unit of a sponsor, or from an individual;
- Institutional Leader relationships where an institutional leader receives payments, honoraria, royalties, equity, options/warrants, company positions, or gifts; or
- Where a company or sponsor also sponsors research at USU or manufactures products to be studied or tested at USU or under its auspices.

## Institutional Conflict of Interest Identification & Management

It is the responsibility of the Investigators on any human subjects research project to identify, disclose, and seek review of any scenarios where an ICOI may be present. Such disclosure should take place, at a minimum, in the Quali Protocol

submission for any affected research project. All protocols affiliated with private sponsors will be screened for Institutional Conflicts of Interest. No protocol can be approved until ICOI screening and, when necessary, management, has been completed.

Any protocol impacted or potentially impacted by an ICOI must undergo Ancillary Review with, at a minimum, the Chief Research Compliance Officer or their designee. If an Institutional Conflict of Interest is present, the interest and its disclosure must also be reviewed by the relevant institutional-level conflict review committee. The results of those reviews shall be shared with the Institutional Review Board, and at that point, the protocol will be placed on the agenda for the next available meeting of the Convened IRB. The Institutional Review Board will review the protocol and associated ICOI management plan to determine whether the management plan adequately protects the interests of the prospective human research participants. The IRB may add elements of a management plan to adequately protect those interests prior to approval of the protocol.

Management plans should be preventative in nature. Conflicts generally do not arise as a result of actual bias or misconduct. Rather, they arise from the possibility of undue influence by the interest at stake. Management plans should be focused on preventing compromised decision making, or the appearance of compromised decision making, regarding a research project. The IRB's management plans, in seeking to prevent undue influence of the institutional interest on the conduct of the research, should consider:

- The nature of the interest
- The value and scope of the interest
- The extent of institutional accountability and discretion involved in decisions about the interest
- The seriousness of potential harms
- The potential benefits of the proposed research

## Existing Management Plans

Once the Institutional Review Board has reviewed and approved an ICOI management plan related to a specific interest, the IRB can determine whether it approves of the future use of that management plan for the same institutional interest. This shall be done at a meeting of the Convened IRB, following an approved motion by one of its members to permit the future application of an ICOI management plan to a protocol involving the same interest. Following such an approval, the Human Research Protections Director shall determine whether it is appropriate to apply the existing management plan to any subsequent protocols involving that interest. Factors the HRP Director shall consider include:

- The similarity of the research project's structure;
- Whether the nature of the institution's interest has changed since approval of the management plan;
- The characteristics of the human research participants;
- Staffing on the protocol;
- The applicability of the management plan to the current project's design; and
- Any other apparent similarities or differences that might impact the fit of the extant management plan to the protocol under review.

If the HRP Director determines that the management plan is appropriate for application to the current protocol, that plan shall undergo Expedited review procedures if the protocol is Exempt or Expedited. If the HRP Director determines that the management plan is not appropriate for application to the current protocol, it shall be placed on the next available IRB meeting's agenda for review by the Convened IRB.