

Guideline G1-006A: Determining “Relatedness” to Research

I. Purpose and Scope

- A. To provide guidelines for the Individual Conflict of Interest Committee (“Committee”) to determine whether an Investigator’s Significant Financial Interest is related to Research conducted in whole or in part under the auspices of the University, including Research funded by the Public Health Service, and, if so related, whether the Significant Financial Interest is a Financial Conflict of Interest.

II. Definitions

The definitions provided in Policy 1-006 and Rule 1-006C apply for purposes of this Guideline.

III. Guidelines

- A. To determine whether an Investigator’s Significant Financial Interest is related to Research, and if so, whether the Significant Financial Interest is a Financial Conflict of Interest, the Committee shall consider:
 - 1. The role of the Investigator and the Investigator’s opportunity, if any, to bias the results of the Research;
 - 2. The nature of the Research being proposed; and
 - 3. The value of the Significant Financial Interest in relation to the size and value of the Business Entity.
- B. In making the determination in Section III.A., the Committee may also consider the following factors:
 - 1. Whether the Business Entity in which the Investigator has a Significant Financial Interest is also the sponsor of the Research;
 - 2. Whether the Business Entity in which the Investigator has a Significant Financial Interest is the manufacturer of a drug, device, or product being used or evaluated in the Research;
 - 3. Whether the outcomes of the Research could have a financial impact on the Business Entity in which the Investigator has a Significant Financial Interest;
 - 4. Whether the Research is of a basic or fundamental nature directed at understanding basic scientific processes;
 - 5. Whether the degree of replication and verification of Research results is such that immediate commercialization or clinical application is not likely;

6. Whether the goal of the Research is to evaluate an invention linked to the Significant Financial Interest (such as where the Significant Financial Interest is a patent, or an interest in a company that has licensed the invention);
 7. In the case of Human Subjects Research, whether there are double blind conditions or the involvement of a data and safety monitoring board;
 8. Where the Significant Financial Interest is in a privately held company, whether the researcher's Significant Financial Interest could result in the Investigator having influence over company decisions, or whether the Research could have a significant impact on the Business Entity's business or financial outlook;
 9. The magnitude of the Significant Financial Interest (e.g., the amount of consulting, or the percentage or value of equity);
 10. Where the Significant Financial Interest is in the sponsor of the Research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future;
 11. The number and nature of relationships an Investigator has with a Business Entity (multiple relationships can create a relationship with a Business Entity that is stronger than the sum of the parts);
 12. Whether the goal of the Research is to validate or invalidate a particular approach or methodology that could affect the value of the Significant Financial Interest;
 13. Whether other scientific groups are independently pursuing similar questions;
 14. Whether sufficient external review of the Research conducted and the reporting of Research results exist to mitigate undue bias;
 15. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a Significant Financial Interest; or
 16. Whether the project involves a sub-award to a Business Entity in which the Investigator has a Significant Financial Interest.
- C. The Committee will consider an Investigator's Significant Financial Interest to be related to the Research when the Committee reasonably determines that the Significant Financial Interest:
1. Could be affected by the Research; or
 2. Is in a Business Entity whose financial interest could be affected by the Research.

IV. References

- A. University of Utah Policy 1-006: Individual Financial Conflict of Interest Policy

- B. University of Utah Rule 1-006C: Individual Financial Conflict of Interest in Research
- C. U.S. Department of Health and Human Services, Promoting Objectivity in Research, 42 C.F.R. pt. 50, Subpart F (for NIH Contracts, 45 C.F.R. pt. 94, Responsible Prospective Contractors)
- D. U.S. Department of Health and Human Services, Financial Disclosure by Clinical Investigators, 21 C.F.R. pt. 54

V. Contacts

Policy Owner: Questions about Policy 1-006 and any related Rules, Procedures, and Guidelines should be directed to the Conflict of Interest Officer.