
**Optum Care Center for Research and Innovation (OCRI)
Standard Operating Policy**

Doc ID #: RP-40	Title: Financial Conflicts of Interest	Version #: 1.1
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PURPOSE:

The purpose of this policy is to establish and uphold the highest ethical standards of objectivity in research by identifying and evaluating financial conflicts of interest (“FCOI”) that may affect research decisions, transactions, and operations; and managing them so that important collaborations can be undertaken without compromising integrity. The policy is also intended to be complimentary to any Optum or UnitedHealth Group FCOI policies and procedures. Additionally, this policy is intended to comply with the requirements of the federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94 for research funded through the Public Health Service (PHS).

SCOPE:

This policy applies to any research conducted under the purview of the Optum Care Center for Research and Innovation (OCRI) and its Steering Committee.

DEFINITIONS:

- **Designated Official:** An institutional official designated to solicit and review disclosures of Significant Financial Interests from Investigators.
- **Financial Conflict of Interest (“FCOI”):** A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the Research.
- **Investigator:** The Project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of the Research, taking into account the degree of independence with which the person works, which may include, but is not limited to, graduate students, post-doctoral fellows, technicians, collaborators or consultants.
- **Non-PHS Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research, which is not funded by a PHS awarding component or other entity or organization that has incorporated the PHS rules with regard to FCOIs. The term encompasses educational activities funded or proposed for funding by NSF. Phase I and II Small Business Innovative Research (“SBIR”) or Small Business Technology Transfer (“STTR”) applications and awards are subject to the same disclosure requirements and reviews as all other Non-PHS-Funded Research.
- **PHS-Funded Research:** Research funded or proposed to be funded by the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, and any entity or organization that has incorporated the PHS rules with regard to FCOIs. The term includes but is not limited to

research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and research resources awards. Although the PHS regulations exclude Phase I Small Business Innovative Research (“SBIR”) or Small Business Technology Transfer (“STTR”) research from COI requirements, under this policy Phase I and II SBIR and STTR applications or awards are subject to the same COI disclosure requirements and review as all other PHS-Funded Research, including PHS-required COI training.

- **Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research, regardless of funding source. The term encompasses basic, sponsored, and clinical research, including applied research and product development.
- **Senior/Key Personnel:** The project director or principal investigator and any other person identified as senior/key personnel in the grant application, contract proposal, contract, progress report, or any other report submitted to the sponsor for the PHS-Funded or Non PHS-Funded Research.
- **Significant Financial Interest:** Anything of monetary value related to a study team member responsibility, including but not limited to:
 - Any remuneration or equity interest in a publicly or non-publicly traded entity, such as stock, stock options, or other ownership interests, where the interest is valued at over \$5,000 when aggregated with the interests of the team member’s spouse and dependent children for the twelve months preceding the disclosure. However, this does not include remuneration paid to the team member by the Institution. Examples of remuneration not included within this definition are ownership of securities in which the team member or team member’s spouse or dependent child has an interest solely through a mutual fund or Institutional investment fund (assuming the team member exercises no control over these investment vehicles), or investments in UnitedHealth Group, including common stock, restricted stock units, stock appreciation rights, or stock options (assuming the team member is currently employed within UnitedHealth Group).
 - Salary, consulting fees, honoraria, or any other form of compensation from any organization, if those payments are expected to exceed \$5,000 when aggregated with payments to the Investigator's spouse and dependent children for the twelve months preceding the disclosure. This does not include salary, royalties, or other remuneration from Institution, or payments from public or nonprofit entities for seminars, lectures, service on advisory committees, or service on review panels for a Federal, state or local government agency, institutions of higher education, and academic teaching hospitals or medical centers.
 - Any interest in intellectual property, including patents and copyrights, or any royalty or other payment or entitlement related to the intellectual property interest, regardless of its value.

POLICY/PROCEDURE:

- Each study team member who has a responsibility for the design, conduct or reporting of research must disclose all his/her Significant Financial Interests (SFI), and those of their spouse and dependent children, that reasonably appear to be related to the study team member's institutional responsibilities.
- The study team member is not responsible for deciding whether the SFI constitutes a conflict of interest or could affect the design, conduct or reporting of the Research. That determination is made by the Designated Official in accordance with Optum policies.
- In the instance of publication or presentation, authors are expected to disclose their financial interests to promote transparency. Interests that need to be disclosed may include:
 - Financial interests supporting or otherwise connected to the presentation, publication, or research.
 - The provision of legal consulting on the subject of the research
 - Any other interests that could be material to members of an audience or readers assessing the opinions, advice, or work presented
- Typical activities that may create a conflict of interest are detailed below. This is not a comprehensive list, there may be other situations that create a conflict of interest. Likewise, the below outlined situations may not always present a conflict. To ensure compliance, situations like the ones detailed below should be reviewed by the UnitedHealth Group Compliance & Ethics team by completing a disclosure through the [eGRC Enterprise Conflicts of Interest Management Tool](#) ("eGRC Tool"). Further details on these situations can be found in the [UHG Conflict of Interest policy](#).
 - Outside directorships
 - Working for a competitor/outside business partner
 - Ownership interest in a competitor's company
 - Defined as any remuneration or equity interest in a publicly or non-publicly traded entity, such as stock, stock options, or other ownership interests, where the interest is valued at over \$5,000 when aggregated with the interests of the Investigator's spouse and dependent children for the twelve months preceding the disclosure.
 - Ownership interest in business partners
 - Defined as 5% or more, even if the study team member has no interaction with the business partner in their Optum/UHG role, or
 - More than 5% of the study team family member's investment portfolio includes a business partner's stock, even if the study team member has no interaction with the business partner.
 - Positions of family members employed by competitors or business partners
 - Corporate opportunity
 - Seeking or holding a public office
- All personnel listed in the IRB application should complete either their local market or UHG corporate FCOI training prior to engaging in research.
- Each team member should review the categories of FCOI in the context of each protocol or individual IRB submission.
- Where required, a FCOI form should be completed in accordance with the governing IRB and/or study sponsor's policy. The form may be the sponsor template or a local template. The FCOI form must be filed in the regulatory binder (CTMS) for auditing and monitoring purposes.
- If utilizing the UHG IRB, a statement in the cover letter must be provided that details:
 - "Team member X may have a potential conflict for this protocol in the area of XXX."

- A member of the OHRA will act as the Designated Official. They will reach out to the team member and facilitate any necessary conversations or meetings to determine (a) who needs to be included in the conflict discussion based upon the scope, (b) determine with he identified subject matter experts if a conflict exists, and (c) provide decision and direction on how the team member may proceed in the conduct of the research.
- FCOI should be updated when new conflicts arise on a per project basis.
- If the research is PHS-funded, FCOI must be filed at least annually and within 30 days of discovering or acquiring a new Significant Financial Interest.
- Conflicts that do not need to be disclosed include:
 - Salary, royalties, or other remuneration paid by Optum, UHG or the local market to the study team member, if they are currently employed or otherwise appointed by, including intellectual property rights and agreements to share in royalties related to such rights.
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the study team member does not directly control the investment decisions made in these vehicles; and
 - Income from seminars, lectures, teaching engagements or service on advisory committees or review panels that are sponsored by a federal, state, or local government agency within the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

References:

[UHG Conflict of Interest Policy](#)

[Conflict of Interest in Public Health Supported Research](#)

REVISION HISTORY:

Version #	Description of Changes	Created/Reviewed By/Date	Approved By/Date	Date Adopted	Date Effective
1.0	Original	Alexa Richie	Stacy McNabb, Amy Nguyen-Howell	6.10.2021	6.10.2021
1.1	Administrative updates		A. Richie	1.17.2024	1.17.2024

APPROVALS:

Alexa Richie

Digitally signed by Alexa Richie
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National Executive Director of Research
 OCRI

January 17, 2024
 Date Approved