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PURPOSE

To document specific CVS Health financial conflict of interest requirements and responsibilities to assure professional and commercial integrity in human subject research.

SCOPE

This policy applies to any CTS employee, or any individual meeting the definition of a Research Colleague, who is planning or actively involved in any research activities. This policy applies to commercially and federally funded research.

POLICY

CVS Health establishes requirements for Clinical Trial Services (CTS) staff disclosures of financial interests and professional relationships in outside entities that would reasonably appear to be related to their Institutional Responsibilities and for certifications of policy compliance on an annual and ad hoc basis. The intent of this policy is to ensure responsible stewardship of federal funds, and to promote research free from any real or perceived conflicts of interest that could harm patients, the reputation of CVS Health or the government funding agency.

PROCEDURE

The Research Financial Conflict of Interest (FCOI) Program must approve a Research Colleague's participation or continued participation in research when a Significant Financial Interest (SFI) exists.

If it is determined that a SFI exists, approval to begin or continue research may be granted only if the Research FCOI Program and or Financial Conflict of Interest (FCOI) Committee determines that a management plan will, to the extent possible, ensure that the design, conduct or reporting of the research will be free from bias that may result from the FCOI or Public Health Services (PHS) reportable FCOI. The approved management plan is subject to modification by the Institutional Review Board (IRB), as applicable. The Research FCOI Program will monitor compliance with management plans.

Determination of the existence of a Financial Conflict of Interest (FCOI)

A FCOI occurs when:

- The Research Colleague and/or Relative(s) has a SFI in the sponsor of the research or any other financially interested company including the manufacturer of the products under investigation or in use in the study; or
- The Research Colleague and/or Relative(s) has a SFI that could affect or be affected by the research.

A SFI from a financially interested company is defined as one or more of the following:

- For a publicly traded entity, a SFI exists if the aggregate value of any Remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any Equity Interest in the entity as of the date of disclosure exceeds $5,000.

- For a non-publicly traded entity, a SFI exists if the aggregate value of any Remuneration received from the entity in the twelve months preceding the disclosure exceeds $5,000 or any Equity Interest in the non-publicly traded entity as of the date of disclosure exceeds $5,000.

A SFI that could affect or be affected by the research include the following:

- Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- The occurrence of any Reimbursed or Sponsored Travel that alone, or when aggregated with any other Remuneration, exceeds $5,000.

The term SFI **does not** include the following types of financial interests:

- Any ownership or Equity Interest held by the Research Colleague and/or Relative(s) in Clinical Trial Services (CTS) or CVS Health or its subsidiaries and affiliates.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Research Colleague and/or Relative(s) does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an 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 an institution of higher education.
- Income from service on advisory committees or review panels for a federal, state, or local government agency, an 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 an institution of higher education.
- CVS Health/CTS Clinical Trial Services salary or any other payment such as bonus and/or equity tied to salary compensation package.

PHS reportable and non-reportable FCOI

A PHS reportable FCOI exists if the Research FCOI Program finds that the FCOI could directly and significantly affect the design, conduct or reporting of the research that is funded by PHS in any amount.

Note that while the following situations could create a FCOI, they do not create a PHS reportable FCOI:

- Royalties to be paid by CTS or CVS Health or CVS Health subsidiaries and affiliates to the Research Colleague and/or Relative(s) if the Research Colleague and/or Relative(s) is employed by CTS or CVS Health.
- A Research Colleague has an ownership, investment or other pecuniary interest in CTS, CVS Health or its subsidiaries or affiliates.

Compelling Circumstances

In addition to the approval and management requirements above, the Research FCOI Program must find compelling circumstances to justify the Research Colleague's participation in the research when a FCOI or PHS Reportable FCOI exists. Compelling circumstances are those facts that convince the Research FCOI Program that the Research Colleague may participate in the research despite the FCOI or PHS reportable FCOI.

Disclosure to Compliance

Research Colleagues must submit disclosures of all financial interests in non-CVS Health entities, annually, prior to application for funding from PHS agencies, and within 30 days of a material change in their financial interests. The initial disclosure must occur prior to participating in research. The Research FCOI Program will review all disclosures and determine whether any of the financial interests that are SFIs constitute a FCOI or PHS Reportable FCOI. This disclosure is in addition to any disclosure requirements of the IRB or CVS Health corporate policies.

Coordination with an IRB
The IRB may not approve participation in research that has been disapproved by the Research FCOI Program. The IRB may not approve monitoring procedures or other conditions that are less protective than those imposed by the Research FCOI Program. No authorization granted by the Research FCOI Program may supersede the authority of the IRB. The IRB may impose more stringent restrictions upon research than those imposed by the Research FCOI Program. The IRB may disapprove research participation despite a determination by the Research FCOI Program that compelling circumstances exist.

Failure to Comply
Failure to comply with the provisions of this policy may result in loss of research privileges or disciplinary action up to and including termination from employment in accordance with applicable CTS and CVS Health policies and procedures. Failure to comply with this policy includes but is not limited to failing to file a disclosure form, knowingly filing an incomplete, erroneous or misleading disclosure form, and/or non-compliance with prescribed monitoring procedures or management plan.

Retrospective Review and Mitigation Reports

PHS Funded Research
When the Research FCOI Program becomes aware of a PHS reportable FCOI that was not disclosed timely or, for whatever reason, was not previously reviewed by the Research FCOI Program, the Research Colleague will be allowed to participate in the research only pursuant to a PHS reportable management plan. In the case of such noncompliance involving PHS funded research, the Research FCOI Program will have a PHS reportable management plan in place within 60 days of the disclosure of the SFI.

In addition, within 120 days of the finding of such noncompliance, or a finding of noncompliance with a PHS reportable management plan, the Research FCOI Program will complete and document a retrospective review of the Research Colleague’s activities and the PHS funded research project to determine whether any PHS funded research, or any portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. If bias is found, the Research FCOI Program will provide the required notification and mitigation report to the PHS awarding entity.

Non PHS Funded Research
In cases of such non-compliance involving non PHS funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Research Colleague is thereafter required to disclose the FCOI in each public presentation of the results of the relevant research and also request an addendum to previously published presentations of the relevant research.

Public Accessibility
This policy shall be provided to the public via CTS' public website, and any future revisions will be posted on the website within 30 days of approval.

For PHS funded research, the Research FCOI Program will make available via a written response within 5 business days of the receipt of a request for information concerning any PHS reportable FCOI with respect to senior/key personnel as identified by the institution. Written requests for information must specifically name the individual for which the information is requested.

Management Plan
If the FCOI Committee determines a management plan is needed, the committee will develop a plan to manage, reduce, or eliminate the FCOI. FCOI management plans are strategies designed to mitigate the potential for an FCOI to impact or bias research objectivity and/or the safety or welfare of human research participants. FCOI management plans can include, but not be limited to:

- Disclosure to study staff
- Disclosure in publications and presentations
- Disclosure in the informed consent
- Recusal from data collection or data analysis
- Recusal from negotiations and/or final sign off on a contract
- Reduced role in the research

Research Colleague must acknowledge agreement to the FCOI Management Plan. A copy of the management plan will also be provided to the Research Colleague's manager.

Training
Pursuant to Federal conflict of interest regulations, each Research Colleague must complete training regarding this policy on financial conflicts of interest and their responsibilities regarding disclosure of financial interests. Training must be completed prior to engaging in research related to any PHS funded research project and refreshed at least every 4 years.

Additional training must be completed:

- Immediately (at the next available training session) when FCOI policies are revised in a manner that change Research Colleague requirements.
- When a Research Colleague is new to CTS
- When a Research Colleague is not compliant with FCOI policies and procedures or a PHS reportable management plan.

FCOI training will be provided to other Research Colleagues as deemed appropriate by the Research FCOI Program.

Confidentiality
Access to information collected in connection with this policy will be limited to those with a need to know and will only be shared in accordance with CVS policies and federal regulations.

Records

CVS Compliance will maintain records relating to all Research Colleague disclosures of financial interests, review of and response to such disclosures regardless of the FCOI Committee's determination of a FCOI. CVS Compliance will also maintain a record of all actions taken, management plans and retrospective reviews under this policy. These records will be maintained for at least 7years from the date of final activity on the disclosure. For PHS funded studies, records will be maintained for at least 3 years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in PHS regulations.

DEFINITIONS:

1. **Equity Interest:** Equity Interest includes any stock, stock options, or other ownership interest as determined through public prices or other reasonable measure of fair market value.

2. **Financial Conflict of Interest (FCOI):** Financial Conflict of Interest means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct or reporting of research.

3. **Institutional Responsibilities:** Institutional Responsibilities means a Research Colleague's professional responsibilities on behalf of CTS, CVS Health or its subsidiaries and affiliates. These responsibilities can include research, research consulting, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRB) or Data and Safety Monitoring Boards (DSMB).

4. **Management Plan:** A document that outlines and implements measures to actively reduce, mitigate or eliminate actual, potential, or perceived financial conflicts of interest held by the Research Colleague.

5. **Public Health Service (PHS)**: A collection of agencies of the U.S. Department of Health and Human Services concerned with public health. PHS components include the National Institutes of Health (NIH), Centers for Disease Control (CDC), the Food and Drug Administration (FDA), Indian Health Service, Agency for Health Resources and Services Administration, Agency for Healthcare Research and Quality, Health Resources and Service Administration, Substance Abuse and Mental Health Service Administration.

6. **Reimbursed Travel**: Travel by a Research Colleague relating to the Research Colleague's Institutional Responsibilities where expenses are reimbursed to the Research Colleague by an entity other than CTS or CVS.

7. **Relative(s)**: For the purposes of this policy, Relative(s) is defined as spouse and dependent children of the Research Colleague.

8. **Remuneration**: Remuneration includes salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria, paid authorship, and payments not described in the research contract.
9. **Research Colleague:** Includes any individual employed by CVS Health Clinical Trial Services (CTS), any individual employed by CVS Health or any official, employee, consultant, agent, student, trainee, or administrator who is planning or actively involved in any human subject research activities.

10. **Significant Financial Interest (SFI)**: SFI means anything of monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property (e.g., patents, copyrights, and royalties from such rights).

11. **Sponsored Travel**: Travel by a Research Colleague relating to the Research Colleague's Institutional Responsibilities where travel expenses are paid by an entity other than CTS or CVS on behalf of the Research Colleague.

EXTERNAL REFERENCES

- 42 CFR 50 Subpart F-Promoting Objectivity in Research

REVIEW AND REVISION HISTORY

Date	Revision No.	Reason for Change	Sections Affected
4/18/23	1	Changed "Investigator" to "Research Colleague" throughout the policy for clarification.	Entire policy
4/18/23	1	Removed section Donating SFI to Charitable Organizations.	Donating SFI to Charitable Orgs.
4/18/23	1	Separated out PHS Funded and Non PHS Funded retrospective review	Retrospective Review
4/18/23	1	Add Management section and removed Disclosures to Scientific Community section for policy clarity. Disclosure to Scientific Community section revised and incorporated in new Management section.	Disclosures to Scientific Community

4/18/23	1	Revised records maintenance time from 3 to7 years and added for PHS funded records to be maintained for 3 years per regulations.	Records
4/18/23	1	Changed “Covered Individual” to Research Colleague and removed “Investigator” for clarity. Added definition of “Relative” for clarity. Revised definitions of Reimbursed Travel and Sponsored Travel for clarity.	Definitions