

TITLE	SOP Manual(s)	Legacy Document Number(s)
Conflict of Interest in Research Policy	Privacy and Security Practices	

**PURPOSE** This policy defines the minimum requirements for disclosing, identifying, and managing conflicts of interest in research.

**SCOPE** This policy applies to all research at Bloodworks and all subsidiaries and organizations under its control. It also applies to the Covered Individuals as defined in the policy.

**RESPONSIBILITIES** All Bloodworks staff are required to follow this policy.

**DEFINITIONS**

**Covered Individual:** Investigators (as defined within this policy) and Institutional Decision Makers (others can be added to the list of Covered Individuals depending on the extent to which Bloodworks wishes the policy to extend beyond investigators and institutional decision makers.)

**Domestic Partner:** An individual permanently residing with a Covered Individual, both considering themselves life partners and who can show financial interdependence and joint responsibility for each other’s common welfare.

**Conflict of Interest (COI):** A significant financial interest or outside relationship that Bloodworks determines could directly and significantly influence (or be perceived to directly and significantly influence) the Covered Individual’s performance of the Covered Individual’s institutional responsibilities, including patient care or the design, conduct, and/or reporting of research.

**Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.

**Immediate Family:** For the purpose of Conflict of Interest in Research disclosures, immediate family is defined as spouse/domestic partner, dependent and/or minor children.

**Institutional Decision Maker:** Means the following Bloodworks Covered Individuals: (The highlighted list below is a sample--Bloodworks should confirm who they want to include as Institutional Decision Makers)

President, including President ad interim, Executive Vice Presidents, Vice Presidents, Chief Officers, Directors, and Managers within Bloodworks organized business or Research support units (e.g., purchasing, sponsored projects, compliance, asset management, business affairs, etc.), Professionals in Research or Bloodworks Bio with the authority to bind, negotiate on behalf of, or execute agreements for Bloodworks, and any other person designated by Bloodworks’ President as an Institutional Decision Maker for the purposes of this policy.

**Institutional Official (IO):** The official designated by Bloodworks to solicit and, with assistance from the Conflict of Interest Committee (COIC), review disclosures of Significant Financial Interests by Covered Individuals to determine whether a Financial Conflict of Interest (FCOI) exists and, if so, determine actions to be taken to manage, reduce, or eliminate such conflict of interest.

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**Investigator:** An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of Research, including a Principal Investigator, a co-Investigator, collaborator, consultant, or project director.

**Manage:** Taking action to address a financial COI, which can include reducing or eliminating the financial COI, to ensure, to the extent possible, that the design, conduct, or reporting of Research will be free from bias.

**Research:** A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge including human subjects protocols and all laboratory Research disciplines, as well as behavioral and social-sciences Research. The term encompasses basic and applied Research, product development, and Research that is subject to regulation by the U.S. Food and Drug Administration. As used in this policy, the term includes any such activity for which Research funding is available from any source, including any Public Health Service Awarding Component through a grant or cooperative agreement.

## POLICIES

1. Bloodworks is committed to conducting research in a manner that ensures the integrity of the research process and Bloodworks programs. Bloodworks requires all Covered Individuals to promptly disclose financial interests to the best of their knowledge as well as other situations that present a conflict of interest or an appearance of a conflict of interest. Bloodworks ensures that situations giving rise to the appearance or an actual conflict of interest are appropriately managed.
2. Covered Individuals must not:
  - a. Accept outside commitments of time, effort, or employment - temporary or regular, that actually or potentially results in any COI with or interferes with the Covered Individual's independence of judgment or institutional responsibilities to Bloodworks;
  - b. Accept or solicit any gift, favor, or service that might reasonably tend to, or is being offered with the intent to, influence the Covered Individual in the performance of his/her institutional responsibilities;
  - c. Accept outside employment or engage in a business or professional activity that might reasonably require or induce the Covered Individual to disclose confidential information acquired in the performance of his/her institutional responsibilities;
  - d. Accept outside employment or compensation that could reasonably impair the Covered Individual's independence of judgment in the performance of his/her institutional duties;
  - e. Make personal investments that could reasonably create a substantial conflict between the Covered Individual's private interest and the interests of the institution; or
  - f. Intentionally or knowingly solicit, accept, or agree to accept any benefit for having exercised the Covered Individual's official powers or performed the Covered Individual's official duties in favor of another.

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3. Covered Individuals shall:
  - a. Read, understand and abide by this policy and follow procedures set forth by Bloodworks to gather COI disclosures.
  - b. Consider in advance whether any contemplated actions might create a COI.
  - c. Cooperate with the Conflict of Interest Committee and IRB to manage any COI situations.
  - d. Complete COI training and education on a regular basis and not less than annually.
  
4. No Covered Individual may serve as a member of a Board of Directors, executive, or as an officer (paid or unpaid) of any for-profit legal entity, competitor of Bloodworks, or any other legal entity related to one's institutional responsibilities or general area of professional expertise (this requirement would be a business decision and some organizations are moving in this direction while others are more comfortable in allowing Covered Individuals to serve on for-profit boards). Serving as a member of a Scientific Advisory Board or board of a professional or philanthropic society is permitted, provided that it is disclosed and does not conflict with this policy.
  
5. No Covered Individual will accept pay from private persons or corporations for any work that is part of his/her institutional responsibilities.
  
6. A Covered Individual who is employed 50% or more by Bloodworks or receives 50% or more of his/her salary from Bloodworks may not receive income for services during a 12 month period from a single entity and their subsidiaries in the form of cash amounting to more than \$40,000 or 25% of his/her total base salary, whichever is greater.
  
7. Institutional resources, such as the property of Bloodworks, will not be utilized for purposes of consultation or employment with an entity other than Bloodworks unless permission has been obtained in advance from the President and provision has been made for compensation to the institution.

#### Disclosure of Interests

1. Covered Individuals must report all of their financial interests at least annually by submitting an annual conflict of interest form.
  
2. Covered Individuals are required to report any reimbursed or sponsored travel when the travel is related to their institutional responsibilities and is being reimbursed or sponsored by a non-Bloodworks entity. The disclosure should specify the purpose of the trip, the identity of the sponsoring entity, the destination and duration. Note: This does not apply to travel that is reimbursed by a Federal, state or local government agency, or institution of higher education including academic teaching hospitals, medical centers or a research institute affiliated with an institution of higher education.

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3. No externally sponsored project application will be approved for submission to a sponsor unless each Investigator has completed an annual disclosure for and COI training.
4. Prior to conducting human subject research, each Investigator must have a current COI disclosure on file.
5. Each Investigator must update their annual COI disclosure form within 30 days of discovering or acquiring a new financial interest.

#### Research

1. It is the policy of Bloodworks that all Research, including PHS-funded Research, must be conducted in compliance with federal requirements, including those set forth in 42 CFR Part 50, Subpart F (PHS regulations) to ensure there is a reasonable expectation that the design, conduct, or reporting of Research will be free from bias resulting from Investigator COI.
2. The IO(s) must review all financial disclosures required under this policy (including those that meet the definition of Significant Financial Interest as defined in 42 CFR Part 50, Subpart F) to determine whether a Financial COI in Research (FCOIO-R) exists, and, if so, to determine what actions, if any, should be taken by the institution to Manage such COI
3. If the IO(s) in consultation with the COIC (and the IRB, if involving human subjects Research) determines that an Investigator has an FCOI-R, the IO(s), in cooperation with the Investigator and other appropriate individuals as designated by the IO(s), shall develop a written COI management plan governing that FCOI-R.
4. Neither the institution nor an Investigator may expend Research funds unless the IO(s) have determined that no FCOI-R exists or that any FCOI-R is manageable in accordance with the terms of COI management plan that has been adopted and implemented.
5. The institution will follow all requirements for management and reporting of a FCOI-R (including any instance where an FCOI-R was not properly identified or Managed prior to expenditure of federal funds) as outlined in 42 CFR Part 50, Subpart F.
6. For PHS-covered Research projects, FCOI-R identified subsequent to an earlier report are required to be reported to the PHS Awarding Component within 60 days and also require annual updating of reports regarding previously disclosed FCOI-R in compliance with 42 CFR Part 50, Subpart F.
7. Additionally, if an FCOI-R was not timely identified or Managed, or if an Investigator fails to comply with a COI management plan, the institution shall, within 120 days of identification of a FCOI-R, complete a retrospective review of the individual's activities conducted during the period of noncompliance to determine whether such

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noncompliance biased the design, conduct, or reporting of related Research. This retrospective review shall be conducted and documented in accordance with the requirements of 42 CFR Part 50, Subpart F and in accordance with the institution's standard operating procedure. For PHS-covered Research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating a COI disclosure, notifying the PHS, and submitting a mitigation report, as required by federal regulations. I

8. Certain information concerning each identified FCOI-R, as determined by the COIC in cooperation with the IO(s), shall be made available on a publicly accessible Web site in a manner consistent with 42 CFR Part 50, Subpart F.
9. Non-Clinical Trial Research:
  - a. If an Investigator for any non-clinical trial Research protocol or sponsored Research agreement or his/her spouse and/or dependent children holds any ownership interest in the Supporting Entity, review and approval by the COIC is required prior to beginning the Research in order to implement appropriate management or restrictions in order to ensure and maintain the objectivity and integrity of the Research.
  - b. An Investigator and/or his/her spouse and/or dependent children may not receive cash of \$25,000 or more within a 12-month period from a Supporting Entity that funds the Investigator's non-Clinical Trial Research, unless a COI management plan has been implemented to manage such conflict(s) of interest. (Some organizations put these restrictions in place while others do not. The dollar amounts and time periods are somewhat subjective.)
10. Clinical Trial Research:
  - a. No payment shall be received by an individual for enrolling patients on Clinical Trial Research. Payment to Bloodworks on a per-patient basis should be limited to costs incurred, reflect the fair market value of services performed, and be commensurate with the efforts of the individuals performing the Research.
  - b. A Covered Individual may not serve as an Investigator for Clinical Trial Research or sponsored Research agreement if he/she or his/her spouse and/or dependent children has:
    - Any ownership interest in any entity in which the IO in consultation with the COIC determines a COI or FCOI-R exists that cannot be Managed which is the supporting entity, or;
    - Received cash of \$25,000 or greater within the previous 12-month period from the supporting entity. Additional restrictions apply to any covered clinical study as defined by the FDA in CFR Title 21 Part 54.
  - c. The following must be disclosed in the informed consent document:
    - All financial relationships of an Investigator;

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- All ownership interests in the supporting entity of a faculty member involved as a collaborator in the Clinical Trial Research or his/her Family Members; c
  - Cash of \$10,000 or more received by an Investigator involved as a collaborator in the Clinical Trial Research or his/her Family Members from the supporting entity in the 12month period prior to the approval of each continuing review until termination of the protocol;
  - Any royalty income received by any of the foregoing from the supporting entity or their Family Members;
  - Any significant financial relationship held by Bloodworks itself in a supporting entity; and
  - The IRB may impose additional requirements in consideration of the interests of the Research subjects.
- d. Because of the unconditional priority of patient care, there may be exceptional situations wherein a Covered Individual who has a financial interest in the supporting entity that is prohibited by this policy, must serve as an Investigator on Clinical Trial Research. In such cases, the President may give written permission to a Covered Individual with a potential FCOI-R, authorizing that faculty member to act as an Investigator of that Clinical Trial Research. This information will be disclosed to all patients, prior to their being asked to enroll on that IRB Approved Protocol, in the informed consent document, and to the COIC. In all cases of Presidential waivers involving Clinical Trial Research, the waiver is subject to the approval of the IRB. The IRB may determine that an unmanageable conflict exists and the waived activity affecting the Clinical Trial Research cannot proceed.
- e. The Compliance Office maintains a database listing companies in which Covered Individuals their Family Members hold financial interests. Patients on any Clinical Trial Research, or their Immediate Family, will have access to pertinent information from this database upon request, and patients shall be notified of this right of access in the informed consent document.
- f. The IO(s) and the appropriate IRB shall cooperate in the consideration of whether an Investigator (including his/her Family Member) has an FCOI-R in regard to Clinical Trial Research and in the development and implementation of a COI management plan for that FCOI-R. The IRB may impose additional requirements or restrictions, and shall convey its final decision to Covered Individual, the COIC, the IO, and the Vice President of Research.
11. Any circumstances that alter existing disclosure reports must be brought to the attention of the COIC and IRB within 30 days of discovery. The 30-day grace period does not apply to consulting agreements or other relationships where a formal written contract is expected, which are to be reported and approved prior to signing or executing that contract.

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Non-Compliance

1. Failure to comply with this policy, including failure to comply with COI management plans, may result in disciplinary action up to and including termination.

**REFERENCES**

42 CFR Part 50

# SOP-02062 [1]: Conflict of Interest in Research Policy

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All Signature (Date and Time) shown in this report are in GMT.

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## Revision Notes ( )

Task Name	Action	Comment	Signature
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## Approval Information

<b>Note to Approver</b>	<input type="text"/>		
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