STANFORD UNIVERSITY

RPH-PR 4.7, PROCEDURE

Procedure on Institutional Conflict of Interest in Research Involving Human Subjects

Effective Date:	05/04/2026
Last Revision:	N/A
Contact:	Cindy Kiel, Chief Conflicts Officer Office of the Vice Provost and Dean of Research Ronda Anderson, Director, Conflict of Interest and Conflict of Commitment, Office of the Vice Provost and Dean of Research
Related Policy:	RPH 4.7 – Institutional Conflict of Interest in Research Involving Human Subjects

1. Summary

These procedures describe how Stanford University identifies, reviews, and manages Institutional Conflicts of Interest (ICOI) related to human subjects research and the exchange of significant or sensitive human health data. They outline responsibilities of institutional offices, Institutional Leaders, and the Institutional Conflict of Interest Committee (ICOIC), and they provide mechanisms for appeal and sanctions. The procedures are intended to ensure transparency, protect research integrity, and safeguard the welfare of human participants.

2. Definitions

For purposes of these procedures, terms such as Institutional Conflict of Interest (ICOI), Human Subjects Research, and Institutional Leaders have the same meanings as in the ICOI policy (RPH 4.7, Policy on Institutional Conflicts of Interest in Human Subjects Research).

3. Procedures for the Identification of Institutional Conflicts of Interest Arising from Stanford Financial Holdings or Investments

The following steps describe how potential ICOI is identified within the University's research, contracting, and development processes:

a. **Protocol Disclosure:** The Stanford Human and Animal Research Compliance Office requires all new Human Subjects Research protocols (exempt or non-exempt) to indicate the nature and sources of drugs, devices, or biologics or human health data that are intended to be used or exchanged in the proposed research. Information on the sources of funding for the research is also required, including support from unrestricted school, department, or individual accounts.

b. **Contract Review:** The Industrial Contracts Office (ICO) and the Office of Research Administration (ORA) review data use and data transfer agreements that pertain to

identifiable and de-identified human subjects clinical or research data, including secondary use of “significant” or “sensitive” human subjects data. ICO and ORA will identify when such data exchanges occur with a company with which Stanford has a financial interest as a result of licensing or investment activities, and alert the CCO in the Office of the VPDOR when such an exchange is identified.

c. **Licensing Review:** If the Office of Technology Licensing (OTL) identifies a situation in which Stanford-licensed technology or technology related to University investments or licensing activities is used or evaluated in Human Subjects Research (regardless of whether a data exchange with the licensee occurs) or involves a significant exchange of human health data, OTL will inform the CCO.

d. **CCO Review:** When the CCO receives such a notification from the Institutional Review Board (IRB), Stanford Management Company (SMC), Office of Technology Licensing (OTL), Industrial Contracts Office (ICO), Office of Research Administration (ORA), or any other University office, the CCO will review available information to identify if the reported activities have or will create an ICOI. This review should be conducted prior to entering into external agreements with the potential to create an ICOI whenever possible. The CCO will initiate a process to determine if an ICOI exists, and if so, to either eliminate or manage the conflict in accordance with Section 5 of these procedures.

e. **School and Department Funds Threshold Trigger:** When a school or department fund’s cumulative investment in a company exceeds the policy threshold, and that company provides products or services that could be evaluated in Human Subjects Research (e.g., therapeutics, medical devices, biologics, diagnostics, or healthcare services), Stanford Management Company (SMC) will notify the Chief Conflicts Officer (CCO) in the Office of the Vice Provost and Dean of Research (VPDOR). The CCO will review all such notifications for potential ICOI and, where a conflict is identified, will initiate a process to eliminate or manage it in accordance with Section 5 of these procedures.

f. **Invention Accelerator Program Notification:** Prior to the conduct of Human Subjects Research related to licensed technology, the faculty or staff director of the accelerator program will notify the CCO of the names of all companies in which the accelerator holds a financial interest. The CCO will review the notification to determine whether an ICOI exists and whether management is required, and if so, will initiate a process to eliminate or manage it in accordance with Section 5 of these procedures.

g. **Equity Gift Notification:** When Stanford receives a gift consisting of equity in a privately held company or 1% or more equity in a public company, and the company directly uses Stanford intellectual property to produce a product deployed in Human Subjects Research at the University, Financial Management Services (FMS) will notify the VPDOR and the CCO. Normally, Stanford will sell such equity as soon as possible following receipt of the gift. The CCO will review the notification to determine whether an ICOI exists and whether management is required, and if so, will initiate a process to eliminate or manage it in accordance with Section 5 of these procedures.

4. Procedure for Disclosing Conflicts of Interest Arising from the Financial Interests of Institutional Leaders

The following procedures implement the requirements of the Institutional Conflicts of Interest (ICOI) Policy. They describe the operational steps by which schools, departments, and Senior Institutional Leaders fulfill their responsibilities in RPH 4.7, Policy on Institutional Conflicts of Interest in Human Subjects Research, Section 4. These procedures ensure that prior approval requests and financial disclosures are managed consistently, that potential ICOI are reviewed in accordance with established criteria, and that determinations are properly documented and escalated when required.

a. Identification and Prior Approval Requirements of Potential ICOI by Institutional Leaders

To implement the policy requirements, the following process is followed as outlined in RPH 4.7, Policy on Institutional Conflicts of Interest in Human Subjects Research, Section 4. The following steps outline the required process:

1. Institutional Leaders (as defined in the policy) are required to obtain prior approval for outside professional activities, including consulting, company equity holdings, and service on a board of directors for a company, consistent with RPH 4.1, Policy on Conflict of Interest and Conflict of Commitment.
2. Prior approval requests are managed in accordance with school procedures through OPACS.
3. The school-designated COI reviewer enters or confirms the request in OPACS.
4. The school-designated COI reviewer will determine whether Stanford is conducting human subjects research associated with the outside entity or whether there are known sensitive or significant human data exchange agreements with the entity. Reviewers document their determinations in OPACS. If the reviewer identifies human subjects research associated with the outside entity or known sensitive or significant human data exchange agreements with the entity, they will refer the situation to the CCO.
5. Conflicts identified through these procedures, regardless of the value of the interest, are considered significant as defined in the policy.
6. Any ICOI related to an Institutional Leader that is found to be significant by applying these criteria must be reviewed by the CCO prior to the conduct of human subjects research at Stanford. If the human subjects research is already underway at Stanford, the review must precede an Institutional Leader accepting or conducting outside activities identified above.
7. OPACS automatically flags potential ICOI cases for the CCO, who records determinations.
8. If needed, the CCO escalates the matter to the ICOIC for review based on established criteria.

b. Identification, Disclosure, and Prior Approval by Senior Institutional Leaders and Approval Requirements

Senior Institutional Leaders must disclose financial interests as set forth in RPH 4.7, Policy on Institutional Conflicts of Interest in Human Subjects Research, Section 4. The following steps outline the required process:

1. As part of their annual conflict of interest disclosure, Institutional Leaders must disclose all of their direct financial interests, and the CCO will determine whether any of the disclosed interests are significant and related to human subjects research at Stanford.
2. For these purposes, a direct financial interest is deemed significant as outlined in the policy.
3. Senior Associate Deans for Research (or equivalent) must disclose to the School Dean.
4. The School Deans and the Vice Provost and Dean of Research must disclose to the Provost.
5. The Provost must disclose to the President.
6. The President must disclose to the Chair of the Board of Trustees.
7. The annual disclosures are provided to the Human and Animal Research Compliance Office by the person responsible for receiving the individual's annual COI disclosure.
8. If any human subjects research at Stanford involving one of these disclosed companies is proposed during the ensuing year, the Human and Animal Research Compliance Office notifies both the affected Institutional Leader and the CCO.
9. If, at any time during the year, an Institutional Leader becomes aware of actual or proposed human subjects research involving a company, or the use in human subjects research of the product of a company in which they have a significant financial interest, they must advise the Human and Animal Research Compliance Office and the CCO of the possible ICOI.
10. Any questions of whether a significant conflict triggers ICOIC review under the policy are assessed by the CCO before the CCO convenes the ICOIC.
11. Potential ICOIs involving Institutional Leaders are reviewed by the CCO and, where appropriate, by the ICOIC.

c. Disclosure and Review of Certain Senior Administrative Staff Financial Interests

1. Certain senior administrative staff who are not Institutional Leaders under RPH 4.7, Policy on Institutional Conflicts of Interest in Human Subjects Research, but who hold roles that may influence research-related decisions or oversight (e.g., Office of Technology Licensing (OTL), Office of Research Administration (ORA), Office of the General Counsel (OGC)), are governed by Stanford's Administrative Guide 1.5.2, Staff Policy on Conflict of Commitment and Interest.
2. When such a staff member's personal financial interests could reasonably be imputed to Stanford in a manner that may affect, or reasonably appear to affect, human subjects research, those interests must be disclosed to the Chief Conflicts Officer (CCO).

3. Upon receipt of such a disclosure, the CCO will conduct an initial assessment to determine whether the interest presents a potential Institutional Conflict of Interest in human subjects research.
4. If the CCO determines that the disclosed interest may constitute an ICOI, the matter may be referred to the ICOIC for review and management in accordance with Section 5 of these procedures.
5. The CCO will document the assessment and any resulting determinations or management actions.

5. Institutional Conflict of Interest Committee

a. Structure and Operations

The Institutional Conflict of Interest Committee (ICOIC) is the body responsible for reviewing complex cases involving actual or potential ICOI. The following procedures govern its role and operations:

1. The ICOIC establishes criteria for determining which ICOI cases may be dealt with administratively by the CCO and which involve sufficiently complex issues as to warrant full ICOIC review.
2. The CCO will include a list of cases being managed administratively on the consent calendar at each ICOIC meeting; a committee member may move to have the Committee discuss any of them.
3. For cases that receive full ICOIC review, the ICOIC will recommend disposition or resolution options to the VPDOR, who will make the final decision about the course of action to be taken to address the conflict.
4. The Provost is responsible for appointing members of the ICOIC. The VPDOR will appoint the chair and designate staff to support the Committee.
5. The ICOIC members will include the VPDOR-appointed Chair, a Senior Associate Dean of Research or a senior faculty member with relevant expertise from at least three (3) Schools, and at least one additional member. One or more members who are not otherwise affiliated with the University may be added to the committee. The dean of the school (or designee) in which the ICOI arises may be invited to serve as an ad hoc member for the discussion of any case pertaining to their school.
6. ICOIC members must abstain from involvement in Committee matters in which they have a personal COI, other than answering any questions the Committee may have.
7. When an ICOIC matter involves a significant financial interest of an Institutional Leader in relation to Human Subjects Research within their unit, the relevant school dean or designee will prepare a case document describing the nature of the ICOI and a proposed management or elimination approach.
8. The case document must include a statement from the institutional official whose personal financial interests have created the conflict, and, when possible, from the faculty member(s) whose research is potentially affected, and from the IRB as to the level of risk to human subjects.

9. This case document will be submitted to the CCO for initial review, and then shared with the ICOIC members and the VPDOR.
10. When an ICOIC matter arises from the University's financial holdings or investments (as described in Section 3 of RPH 4.7, Policy on Institutional Conflicts of Interest in Human Subjects Research), rather than from the personal financial interests of an Institutional Leader, the CCO will first determine whether the matter may be addressed administratively or requires full ICOIC review, applying the same criteria used for all ICOI cases under item 1 above.

In cases requiring full ICOIC review, the CCO typically prepares a case document describing the nature of the financial interest, the human subjects research at issue, and the relationship between them, together with a proposed management or elimination approach. The case document must include: a description of the University's financial interest (e.g., the nature of the licensing arrangement, investment, accelerator interest, or gift equity); a summary of the human subjects research activity at issue and the investigator(s) involved; input from the Human and Animal Research Compliance Office as to the level of risk to human subjects; and, where applicable, input from OTL, SMC, or other relevant University offices regarding the nature and value of the financial interest.

The case document is provided to the VPDOR (and to the ICOIC members for cases requiring full ICOIC review), the dean of the school in which the affected research is being conducted, or their designee, may be invited to serve as an ad hoc member of the ICOIC for the discussion of the case. The ICOIC will review and assess the case using the criteria in Section 5.B and recommend a course of action to the VPDOR in accordance with Section 5.C.

11. The ICOIC may delegate certain cases to the CCO where the circumstances are similar to other cases that have previously been adjudicated by the ICOIC. In those cases the CCO will act on behalf of and record and report outcomes to the ICOIC.
12. The ICOIC members treat as confidential any information provided to them in the course of ICOIC review and discussion.

b. Criteria for Evaluation of Potential COI

When determining how best to address a potential ICOI, the following evaluative criteria are applied to guide decisions about risk and management, including:

1. The level of risk to human subjects in the research, as determined by the IRB.
2. The level of risk to the integrity and objectivity of the research.
3. The risk to individuals and the institution from the use or transfer of significant and sensitive human health data.
4. The level and type of the financial interests or relationship held by the Institutional Leader.
5. Directness and immediacy of the Institutional Leader's authority over the research, including the people engaged in conducting the research.

6. The status of the company (e.g., privately-held start-up company, small publicly-traded, large publicly-traded, etc.), and the importance or perceived importance of the research to the finances of the company.
7. Feasibility and effectiveness of implementing a management plan separating the institutional official from oversight of people conducting the Human Subjects Research, while the official maintains their position.
8. The risk to the academic freedom and unbiased treatment of the faculty member who has proposed the research.
9. The actual or perceived risk to the reputation of the institution.

c. Review and Disposition

In general, the University should seek to significantly reduce or eliminate any ICOI, or appearance of an ICOI, for research involving a meaningful risk to human subjects or the transfer of sensitive or significant human health datasets.

1. The ICOIC will review and assess the case document using the criteria listed below.
2. As a result of this assessment, the ICOIC may recommend to the VPDOR one or more of the following courses of action:
    - Prohibit the research from proceeding at or under the auspices of Stanford.
    - Prohibit Stanford from taking an interest in an external entity or terminate Stanford's financial relationship with the external entity.
    - Propose a plan to manage the conflict.
3. In cases where the ICOI arises from financial interests of an Institutional Leader, but not the University:
    - Remove the Institutional Leader from such leadership position; and/or
    - Require the Institutional Leader to divest or terminate the financial relationship; or
    - Recommend other measures as appropriate.
4. If the ICOIC makes a recommendation for management, the report to the VPDOR must provide a management plan that includes some or all of the following elements:
    - Identification of the individual, usually the School Dean or his or her designee, who will be directly responsible for ensuring that the requirements of the management plan are implemented and monitored for continued compliance.
    - Formal recusal of the conflicted Institutional Leader from the chain of authority over the project and from authority over salary, promotion, space, and trainee assignment decisions affecting the investigator(s) conducting the human subjects research or conducting research impacted by the institutional conflict, including the exchange of significant or sensitive human health data.
    - Direct communication of the recusal arrangements to the Institutional Leader's superior and affected faculty, staff, and students.
    - Designation of a "safe haven," e.g., a non-conflicted senior individual, with whom the investigator can address ICOI-related concerns.

- Instructions to the investigator(s) involved in research impacted by the institutional conflict to disclose the ICOI in public presentations and publications.
- Disclosure of the ICOI in the informed consent process of the human subjects study associated with the conflict and review of the consent by the IRB at each annual renewal of the study protocol.
- Use of an external IRB or data safety monitoring board as applicable.
- In multi-site trials, disclosure of the ICOI to PIs at the other sites.
- Any other requirements that the ICOIC deems necessary.

5. If the ICOIC's management recommendations do not include divestment or a reduction in investment, the VPDOR will make the final decision about whether a proposed ICOI management plan is acceptable.
6. If the conflicted Institutional Leader is a dean, vice provost, or provost, the case document and the VPDOR's decision will be transmitted to the Provost and President.
7. If the conflict involves the President or Provost, then the final decision will be made by the President (in the case of the Provost) or the Chair of the Board of Trustees' Audit and Compliance Committee (in the case of the President).
8. The CCO will communicate the VPDOR's decision to the Human and Animal Research Compliance Office for notification to the IRB and to the Office of Sponsored Research (if the ICOI involves a sponsored research project) and/or the Industrial Contracts Office (if the ICOI involves a data agreement), and to the relevant dean or designee so that the recommendations can be implemented by the school.

6. Appeal Process and Sanctions

If an Institutional Leader disagrees with a decision made by the VPDOR to eliminate, reduce or manage an ICOI, the leader may, within thirty (30) days of notification of the decision, submit a written appeal to the Provost for reconsideration. The appeal shall include all information that the Institutional Leader considers relevant to a reconsideration of the decision.

In the event an Institutional Leader fails to disclose external interests in accordance with this policy and with RPH 4.1, Policy on Conflict of Interest and Conflict of Commitment, or in the event an individual fails to adhere to requirements of a VPDOR decision or adopted management plan, appropriate action as set forth in Stanford's applicable code of conduct policies shall be applied. See, e.g., Stanford Administrative Guide, Section 1.1, available at https://adminguide.stanford.edu/chapter-1/subchapter-1/policy-1-1-1.