



Conflict of Interest and Conflict of Commitment

Policy: GOV033
 Responsible Executive: Provost & VP
 of Human Resources
 Responsible Office: Office of the
 Provost
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Policy Statement

As an internationally renowned center of academic excellence, the Johns Hopkins University (“University” or “JHU”) understands that teaching, scholarship, and clinical care is conducted at the highest levels when its faculty and students regularly and continuously interact with communities, entities, and individuals outside the University.

Regular interaction with outside parties such as for-profit entities, governments, other not for profit organizations, and the public is critical to informing and advancing research, knowledge, and public service. The University encourages these independent activities and seeks to be creative and flexible in creating faculty relationships that advance the University’s non-profit missions while also protecting the integrity of University teaching, research, and scholarship, and ensuring the safety of human research subjects. This policy is an integral part of the University’s efforts to support the members of the University community in conducting themselves in accordance with the highest ethical standards and producing the best research, education, and clinical care.

Who Is Governed By This Policy

All units of the University except the Applied Physics Lab are governed by this policy.^{1,2} This Policy shall apply to, and be uniformly applied by, all schools and divisions of the University.

¹Covered Individuals who are clinical faculty must also follow the conflict of interest policies of relevant Johns Hopkins affiliated hospitals.

²Employees of the Applied Physics Lab are directed to review and comply with the conflict of interest and conflict of commitment policies of the Applied Physics Lab.

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Policy Purpose

The University recognizes that its faculty must by necessity engage with non-University entities, communities, and people to perform research, teach, and conduct clinical practice at the highest levels. The University also recognizes that public confidence in the integrity of the University ranks among its greatest assets. Accordingly, decisions made on behalf of the University by faculty, staff, and agents of the University must reflect the best interests of the institution, not be in competition with the University, and not be motivated by a desire for personal gain.

As a recipient of federal funding, the University complies with certain regulatory conflict of interest requirements, including: (i) Public Health Service Regulations at 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94; (ii) the National Science Foundation Conflict of Interest Grants Policy Manual at Section 510; (iii) Food and Drug Administration regulations at 21 C.F.R. Parts 54, 312, 214, 320, 330, 601, 807, 812, 814, and 860; and (iv) the Uniform Grant Guidance at 2 C.F.R. Part 200.318. This Policy ensures that the University is in compliance with all applicable regulatory conflict of interest requirements.

Definitions

Conflict of Commitment	An Outside Activity that may interfere with a Covered Individual's responsibilities to the University or is of a nature that the activity may only be performed through the Covered Individual's University role.
Conflict of Interest	A Financial Interest or Outside Activity that could compromise or appear to compromise the integrity or objectivity of the Covered Individual's decision making. An individual need not act against the University's interests for a Conflict of Interest to exist; the mere fact that the individual has the Financial Interest or Outside Activity is sufficient to create a Conflict of Interest.
Covered Individuals	University officers, faculty, staff, and others who: (i) are compensated or otherwise supported by the University for their services; (ii) use, control, or assign to others the use of University facilities and resources, (iii) participate or engage in University Research, or (iv) teach at the University. Students and part-time faculty and staff are considered Covered Individuals when they meet any of the aforementioned categories.

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Financial Interest

Income, honoraria, or other compensation including, but not limited to, equity, stock or stock options, royalties or other distributions, the right to future royalties or other distributions, proprietary interests in intellectual property that has been licensed by Johns Hopkins Technology Ventures, or in-kind interests received by a Covered Individual or that Covered Individual's spouse, domestic partner, or dependent children that reasonably appears to be related to the Covered Individual's University responsibilities or activities. In addition, a Financial Interest exists when a Covered Individual or a Covered Individual's spouse, domestic partner, or dependent children maintain fiduciary obligations to an outside entity when those fiduciary obligations reasonably appear to be related to the Covered Individual's institutional responsibilities or activities.

For scientific investigators who receive funding from the Public Health Service agencies, Financial Interest shall also include reimbursed or sponsored travel related to the Covered Individual's institutional duties, except when such reimbursed or sponsored travel is reimbursed or sponsored by a U.S. federal, state, or local government agency, a domestic institution of higher education as defined at 20 U.S.C. 1001(a), or a research institute that is affiliated with such a domestic institution of higher education.

For University Research that is regulated by the U.S. Food and Drug Administration ("FDA"), Financial Interest shall also include status as an inventor of intellectual property that comprises the clinical investigational product to be studied in the University Research. Status as an inventor of intellectual property that is not yet covered by an issued patent shall be determined by inclusion on a report of invention to Johns Hopkins Technology Ventures.

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Outside Activity

The provision of services and time commitments for non-University activities that: (i) are based on the expertise and knowledge of the Covered Individual and reasonably appear to be related to the Covered Individual's University responsibilities or activities; or (ii) may reasonably be deemed to significantly impact the Covered Individual's ability to satisfy his or her University responsibilities and activities.

Outside Activities include, but are not limited to, consulting, service on governing boards (e.g., board of directors of for-profit and non-profit entities) or scientific advisory boards, outside speaking, professional or academic society work, outside administrative responsibility such as serving as an officer or employee of an outside entity, expert witness activity, and outside teaching.

The following activities are considered Outside Activities but are excluded from the disclosure requirements of this Policy when undertaken at, for, or on behalf of a U.S. federal, state, or local government agency, or a domestic institution of higher education as defined at 20 U.S.C. 1001(a), or a U.S. academic teaching hospital, medical center, or research institute that is affiliated with such a domesticity institution of higher education ("U.S. Institutions of Higher Education"): Seminars, one-off or invited lectures, and service on an advisory committee or review panel.

The following activities are not considered Outside Activities:

1. Uncompensated, domestic, scholarly activities that are traditionally undertaken in the Covered Individual's academic field, including but not limited to service on academic journals. For the avoidance of doubt, any compensation received for such traditional academic activity—including honorariums and travel reimbursement—is a Financial Interest and must be reported under this Policy.
2. Service to the University, the Johns Hopkins Health System ("JHHS"), or any of their constituent entities, and performance of services under an agreement between JHU, JHHS, or any of their constituent entities and an external party.

Research

A systematic investigation, study, or experiment designed to develop or contribute to generalized knowledge, whether basic or applied.

Startup Company

A privately held company that (i) is based on intellectual property developed by Covered Individuals at the University, or (ii) is founded by Covered Individuals and relates to the Covered Individuals' University responsibilities and activities.

Startup Companies do not include small limited liability corporations or partnerships created for the sole purpose of facilitating faculty expert consulting.

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University Research

University Research is Research and other sponsored activity conducted with support that flows from or through the University, including non-financial support.

Policy

JHU faculty regularly engage with the outside world in furtherance of the University's scholarship and service; outside faculty Activity shall be managed as stated in this Policy. In contrast, and because their University responsibilities differ significantly from faculty, Covered Individuals who are non-faculty staff are generally prohibited from engaging in Outside Activities or Financial Interests that create Conflicts of Interest or Conflicts of Commitment.

I. Identification and Management of Conflicts of Interest and Conflicts of Commitment

The University shall determine whether a particular Covered Individual's Financial Interest or Outside Activity creates a Conflict of Interest or Conflict of Commitment. If the University determines that a Conflict of Interest or Conflict of Commitment exists, the University shall institute a plan to manage the Conflict of Interest or Conflict of Commitment or prohibit the activity if the Conflict of Interest or Conflict of Commitment is deemed not manageable. Primary responsibility for making these determinations falls to divisional and school deans, in the case of full and part-time faculty, and the specific employee's supervisor and Human Resources in consultation with the Office of General Counsel as needed, in the case of staff. University officer Conflicts of Interest and Conflicts of Commitment shall be managed in accordance with the Johns Hopkins University and Johns Hopkins Health System Policy on Institutional Conflicts of Interest.

The divisions and schools shall uniformly apply this Policy as outlined in more detail in the Procedures section herein, and shall communicate regularly with the University regarding general issues and specific matters.

II. Specific Prohibited Activities

There are certain types of Financial Interests and Outside Activities that create such strong appearances of or actual Conflicts of Interest and Conflicts of Commitment that management conditions are insufficient to protect the integrity of the University and are prohibited under this Policy. The most common types of prohibited Financial Interests and Outside Activities are listed below.

- A. Outside Activities are prohibited if they involve the use of University proprietary information or intellectual property without a license to such University intellectual property that is executed by Johns Hopkins Technology Ventures.
- B. Outside Activities that compromise the basic scholarly independence and freedom of action that are central to University life are prohibited (this includes Outside Activities that restrict a faculty member's ability to conduct University Research or other academic activity).
- C. Outside Activities that prevent full-time staff or faculty from fulfilling their primary responsibilities to the University are prohibited.
- D. Outside Activities that involve the non-incidental use of University resources are prohibited. Non-incidental use of University resources includes but is not limited to: (i) extensive use of University electronic mail for Outside Activity purposes; (ii) any use of University laboratory space or equipment for Outside Activity purposes, and (iii) any use of University administrative services for Outside Activity purposes.

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- E. Unless specifically approved by their primary academic division, Covered Individuals who are full-time employed by JHU may not provide patient care at a facility or practice other than a Johns Hopkins facility or practice unless the patient care services are the subject of a contract between Johns Hopkins and the outside facility, practice, or sponsoring or funding entity.
- F. A Covered Individual may not serve as principal investigator of any human subjects research protocol or as principal investigator or sponsor-investigator of an FDA-regulated clinical trial when a Covered Individual has a Financial Interest that is related to the human subjects research as stated in Sections III and VII of this policy.
- G. A Covered Individual may not have any involvement in a University business decision (including but not limited to subaward, procurement, licensing, and sponsored research decisions) when the Covered Individual's Financial Interest or Outside Activity may create the appearance of a Conflict of Interest or Conflict of Commitment in that decision-making.
- H. Direction of compensation for Outside Activity to a University account is prohibited. Covered Individuals are not allowed to direct their personal consulting income to any University account, including a University research or discretionary account.
- I. Full time School of Medicine faculty and salaried part-time School of Medicine faculty may not conduct Research outside of JHU.
- J. Investigators may not participate in a "malign foreign talent recruitment program," as that term is defined by the Federal Government.

III. Special Areas of Focus**A. University Research**

University Research is an area of University activity that requires careful attention to real and perceived Conflicts of Interest. Federal regulations and policy statements require the University to maintain this Policy and take the actions described herein to prevent actual or perceived bias in federally funded University Research. Covered Individuals who have Financial Interests related to University Research may participate in that University Research only when the resulting Conflict of Interest has been appropriately and timely disclosed and a formal, approved management plan has been instituted by the applicable official. If University Research involves human subjects, the management plan must also be accepted by the responsible Institutional Review Board ("IRB").

B. Human Subjects Research

Financial Interests and Outside Activity require additional and very careful scrutiny when related to human subjects research. The University and its investigators are obligated by federal law to protect the rights and safety of individuals who participate in University Research. When Covered Individuals who have Financial Interests or Outside Activities related to human subjects University Research wish to participate in that University Research, the applicable official shall either recommend a management plan to the responsible IRB to manage the Conflict of Interest or, if the Conflict of Interest cannot be adequately managed, shall prohibit the participation in University Research. The IRB must accept the recommendation of the applicable official before the Covered Individual may participate in the University Research; the IRB may require additional management steps if the IRB deems them necessary for human subject safety or data integrity. For more information about the process of reviewing and managing Conflicts of Interest in University Research involving human subjects, please see the Procedures section of this policy.

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Service as a principal investigator of any human subjects research protocol or as principal investigator or sponsor-investigator of an FDA-regulated investigational new drug application or investigational new device application is prohibited when a Covered Individual has any of the following Financial Interests in an entity that is related to the human subjects research:

1. Fees, honoraria, gifts, or in kind compensation (or entitlement to the same), whether for consulting, lecturing, or any other purpose, that exceed \$25,000 in the aggregate in any twelve-month period;
2. Equity interest of any amount (including ownership interests, options and warrants) in a private entity (or entitlement to the same);
3. Equity interest (including ownership interests, options and warrants) in a publicly-traded entity that exceeds \$25,000 in value as determined through reference to current prices (this does not include diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund);
4. Service as an officer, director, or in any other fiduciary role in a company that has an interest in the outcome of the research.

Service as a principal-investigator or sponsor-investigator of a more-than-minimal risk human subjects research protocol (as determined by the IRB) is prohibited when a Covered Individual has any of the Financial Interests listed in Section III.b.i-iv above or is an inventor of intellectual property that is licensed to an entity and that is related to the human subjects research.

Service as a principal-investigator or sponsor investigator of a more-than-minimal risk human subjects research protocol (as determined by the IRB) that is regulated by the FDA is prohibited when a Covered Individual has any of the Financial Interests listed in Section III.b.i-iv above or is an inventor of intellectual property, whether licensed or unlicensed, that comprises the clinical investigational product to be studied in the FDA-regulated University Research. Status as an inventor of intellectual property that is not yet covered by an issued patent shall be determined by inclusion on a report of invention to Johns Hopkins Technology Ventures.

C. Startup Companies

Relationships between Covered Individuals and Startup Companies present opportunities for development and commercialization of inventions and may also create Conflicts of Interest and Conflicts of Commitment. Covered Individuals must comply with all University Policies, including the University Intellectual Property Policy, when founding or otherwise engaging with Startup Companies. Staff are generally prohibited from founding, receiving compensation from, or engaging in Outside Activities with Startup Companies.

Covered Individuals who are faculty may engage with Startup Companies in the following ways, provided such engagement is appropriately and timely disclosed and approved in compliance with the Procedures outlined in this Policy:

1. Founder. Faculty may generally be a founder of a Startup Company.
2. Equity Interests. Faculty may generally hold equity in Startup Companies.
3. Membership on Boards of Directors. Faculty may generally serve on the board of directors of a Startup Company.
4. Service as an Operating Officer. Service as an operating officer of any entity, including Startup Companies, is a time-intensive position. Faculty who are employed full-time by the University may, upon appropriate review

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and approval as stated in this Policy, serve as an operating officer of a Startup Company for a period of two years from either (a) the date of incorporation or legal creation of the Startup Company, or (b) a date no later than six months after the date of incorporation or legal creation of the Startup Company. If a Faculty member desires to continue to serve as an operating officer after their two-year period or service has expired, he or she must request an extension in writing. The request shall be directed to the dean of the Faculty member's primary division and must be made sufficiently in advance of the end of the two-year period of service to allow the dean to consider the request prior to expiration of the time period. Such request must be supported by specific information about the Startup Company and justification for continued service as an operating officer. Requests by full-time faculty to serve as a Startup Company operating officer in excess of a period of two years will rarely be approved and only in those situations when such continued service is in the best interest of the University. It is expected that most Faculty members who desire to continue to serve as an operating officer of a Startup company beyond the two-year period of service will take a leave of absence to continue working as an operating officer for the Startup Company. In rare instances, after review by the Faculty member's department director and the appropriate dean or dean's designee, Faculty members may be permitted to reduce their University employment and also work part-time as a company officer after their two-year period of service expires, provided there is clear distinction between the faculty member's JHU duties and the objectives and focus of the Startup Company.

5. Service as a Consultant. Faculty may generally consult for Startup Companies.
6. Student Employment. Students under the academic direction of a faculty member, paid for by a faculty member's grant, or in a faculty member's research group shall not be employed part-time or full-time, whether as an employee or consultant, by a Startup Company in which the faculty has a Financial Interest.

D. Consulting

The University is not a party to private consulting agreements and it is the responsibility of Covered Individuals to ensure that all Outside Activity, including private consulting, complies with University policies. In general, consulting activity for large, established companies when the compensation provided for the consulting is a flat or hourly fee is less likely to be problematic than consulting activities for Startup Companies or consulting when the compensation is tied directly to the success of the third party entity or its products (i.e., compensation in equity, royalties, and other methods of deferred compensation). Proposed private consulting will be reviewed as specified under the Procedures of this Policy, and factors to be taken into account by the reviewing official shall include: (i) the remuneration provided to the Covered Individual; (ii) the relationship between the faculty and the third party entity; and (iii) the potential for confusion regarding the Covered Individual's University activities and the private consulting activity.

E. Sabbatical and Joint Appointments at other Academic Institutions

Faculty who engage in University approved sabbaticals and joint appointments at other academic institutions must be mindful that they continue to be University employees during their sabbatical and joint appointment periods and shall comply with all applicable University, school, and divisional policies, including the University Intellectual Property Policy. In particular, faculty shall not assign University intellectual property to outside entities in violation of the University Intellectual Property Policy during the sabbatical or joint appointment. Faculty shall comply with all applicable divisional and school sabbatical and joint appointment policies.

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F. Procurement and Sub-awards

Covered Individuals who are in a position to make or influence University purchasing, sourcing, procurement, or University Research subaward decisions must refrain from any activity related to University purchasing, sourcing, procurement, or granting of subawards that could create the appearance of a Conflict of Interest. When a Covered Individual has a Financial Interest or Outside Interest in a third party entity that may contract with the University for a specific procurement or subaward, the Covered Individual must notify the applicable University research administration or procurement official of the Covered Individual's Financial Interest or Outside Interest.

With respect to proposed procurement engagements, the Covered Individual is prohibited from (i) participating in the selection of the third party entity to provide goods or services to the University, (ii) negotiating with the third party entity on behalf of the University, (iii) negotiating with the University on behalf of the third party entity, and (iv) actively attempting to influence the procurement or subaward decision.

If a Covered Individual desires to subaward a portion of University Research to a third party entity in which the Covered Individual has a Financial Interest or Outside Interest, the University must conduct appropriate due diligence to confirm that the proposed subaward is scientifically appropriate and in the best interest of the University Research. If the University makes that determination in favor of issuing the proposed subaward, the Covered Individual is prohibited from negotiating for either the University or third party in the subaward contracting and subsequent business discussions related to performance of the subaward. Additional management conditions related to the subaward may be issued by the applicable divisional or University official at his or her discretion.

Non-Faculty Staff with Responsibilities Related to Technology Transfer, Business Development, and Entrepreneurial Activities.

Covered Individuals who are non-faculty staff and have University responsibilities related to business development, technology transfer, procurement, or entrepreneurial activity ("Business Development Staff") must be especially careful to avoid Outside Activities or Financial Interests that may create a Conflict of Interest with their University responsibilities. As with all staff, full-time Business Development Staff are prohibited from creating Conflicts of Interest or Conflicts of Commitment. Specific prohibited Outside Activities and Financial Interests for Business Development Staff include holding any Financial Interest in or engaging in Outside Activity with an outside entity (including a Startup Company) that: (i) has licensed, optioned, or entered into negotiations to license or option JHU intellectual property; (ii) has participated in or applied to participate in any JHU incubator program (including student incubator programs); or (iii) was founded by JHU undergraduate or masters students.

Business Development Staff may be required to submit regular reports to their supervisor of their Outside Activities and Financial Interests that may reasonably be deemed to relate to their University responsibilities.

Procedures

In addition to the Procedures outlined below, individual schools and divisions may have processes and procedures related to review and management of Conflicts of Interest and Conflicts of Commitment.

I. Training

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All Covered Individuals who engage in University Research shall complete University conflict of interest training (i) before engaging in University Research, (ii) at least every four years thereafter, and (iii) whenever this Policy is substantively revised. Conflict of interest training will be provided by the applicable dean's office. Whenever the University or a school or division determines that a Covered Individual is not in compliance with this Policy, that individual shall be required to immediately complete conflict of interest training.

Additionally, all Covered Individuals who do not engage in University Research must read this policy before engaging in any Outside Activity or accepting a Financial Interest

II. When to Disclose

Covered Individuals must timely disclose all Financial Interests and Outside Activities in writing or through an established electronic disclosure system, as specified by the applicable school or divisional policy or procedure. Disclosures must be made:

- A. Before a Covered Individual engages in an Outside Activity or acquires a Financial Interest.
- B. When a previously-disclosed Financial Interest or Outside Activity changes or ends.
- C. At the time a Covered Individual applies for funding from a Public Health Service agency.
- D. Within 30 days of reimbursed or sponsored travel related to a Covered Individual's institutional responsibilities, for all Covered Individuals who are investigators on Public Health Service funded research if the value of the Covered Individual's (including his/her spouse, domestic partner, and dependent children) reimbursed travel from any third party exceeds \$5,000.00 in the previous 12 months.

In addition to these disclosure requirements, full-time and salaried part-time faculty must complete an annual certification to ensure that their disclosures are accurate and up to date

III. What to Disclose

The following activities must always be disclosed by Covered Individuals:

- A. Proposed Outside Activities, whether or not they are compensated.
- B. Proposed Financial Interests.
- C. For Covered Individuals who engage in Public Health Service-funded research, all reimbursed or sponsored travel related to the Covered Individual's institutional responsibilities, if the value of the Covered Individual's (including his/her spouse, domestic partner, and dependent children) reimbursed travel from any third party exceeds \$5,000.00 in the previous 12 months.

IV. How to Disclose

Full and part-time faculty and Covered Individuals engaged in University Research shall disclose using the University's eDisclose system. University officers and officials shall comply with the disclosure and reporting procedures of the Johns Hopkins University and the Johns Hopkins Health System Corporation Policy on Institutional Conflict of Interest. All other staff, unless covered by a division or unit policy, shall disclose proposed Financial Interests and Outside Activities to their supervisor in writing.

V. Review of Disclosed Financial Interests and Outside Activities

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A. Covered Individuals Engaged in University Research

In the case of Covered Individuals who engage in University Research, disclosures will be reviewed by the relevant dean, who may be advised by a standing faculty committee on conflicts of interest. Review will generally occur in the division or school of an individual's primary appointment or employment. In some cases, however, review will occur in the division or school with the primary responsibility for the affected University Research. The University may conduct additional review as it deems appropriate. Disclosures will be reviewed for the following:

- Presence of a Conflict of Interest or Conflict of Commitment.
- Risk to the rights and safety of human subjects in research.
- Impact on integrity and objectivity of academic scholarship and research data.
- Risk to the rights and obligations of students—including undergraduate, graduate, post-graduate, and continuing education—and trainees studying, taking classes, and participating in University Research.
- Risk to University independence and objectivity in business transactions.
- Impact on the independence of clinical care or other professional practice judgments.
- Impact on a Covered Individual's ability to devote professional loyalty, time, and energy to teaching, research, patient care or administrative responsibilities in accordance with the Covered Individual's responsibilities to the University.

B. University Officers and Officials

Disclosures made by University Officers and Officials, as defined in the Johns Hopkins University and Johns Hopkins Health System Corporation Policy on Institutional Conflicts of Interest shall be reviewed and managed according to the procedures outlined in that Policy.

C. All Other Covered Individuals

Disclosures made by other Covered Individuals will be reviewed by the Covered Individual's supervisor. The supervisor may consult with Human Resources in determining whether a Conflict of Interest or Conflict of Commitment exists.

VI. Outcome of Review of Disclosed Financial Interests and Outside Activities

If it is determined that a Conflict of Interest or Conflict of Commitment exists, the relevant University official shall determine whether the Conflict of Interest or Conflict of Commitment can be sufficiently managed, or whether the Conflict of Interest or Conflict of Commitment so threatens the integrity of the University that the Conflict of Interest or Conflict of Commitment can only be mitigated by terminating the relationship, activity, or Financial Interest that generates the Conflict of Interest or Conflict of Commitment. If the University official determines that the Conflict of Interest cannot be managed, that decision shall be communicated to the Covered Individual in writing.

VII. Management of Conflicts of Interest and Conflicts of Commitment

When a Conflict of Interest or Conflict of Commitment is deemed manageable by the relevant University official, the University shall create a plan to manage the Conflict of Interest or Conflict of Commitment in a way that allows

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the Covered Individual to pursue the Financial Interest or Outside Activity while protecting the integrity of the University. Management plan conditions may include:

- A. Disclosure of the Conflict of Interest, which may include: public disclosure of the Conflict of Interest of the Covered Individual in, among other things, human subject research consent forms and all relevant publications and presentations, including internal University presentations.
- B. Limiting the Covered Individual's role in University Research, which may include restrictions on the Covered Individual's ability to serve as principal investigator, serve as sponsor-investigator of a U.S. Food and Drug Administration investigational new drug application or investigational device exemption, analyze data or results, participate in the conduct of the study, or obtain consent from human research subjects.
- C. Oversight, including appointment of a disinterested individual or group to monitor the University Research activity.
- D. Limitations on University business activity, which may require prohibiting the Covered Individual from, among other things: (i) negotiating on behalf of the University; (ii) receiving certain confidential or proprietary University information; or (iii) discussing information related to the Conflict of Interest with University officers, faculty, or staff.
- E. Divestiture of specified Financial Interests.
- F. Severance or limitation of Outside Activities or Financial Interests that create actual or potential Conflicts of Interest or Conflicts of Commitment.
- G. Disclosure to certain individuals who participate in University Research, including, but not limited to, students, staff, and collaborators, which may require: (i) informing these individuals in writing of the Conflict of Interest; (ii) signed acknowledgements by affected students, staff, or collaborators indicating they fully understand the circumstances of their work for or with the Covered Individual; (iii) subjecting the work to periodic, disinterested review to ensure freedom to publish, to discuss research, and to adjust the research direction in ways that are of benefit to student education and independent of any benefit to a third party; or (iv) determining if the Covered Individual may have a role in supervising a student thesis, dissertation, or other academic work.

Once the University official has created a management plan, that management plan shall be conveyed to the Covered Individual in writing. All arrangements may be reviewed again if circumstances change or there is new information.

The University shall monitor compliance with faculty management plans until the completion of related University Research. Divisional deans and department directors shall have the primary responsibility of monitoring compliance with faculty management plans. Central, divisional, and departmental HR shall monitor compliance with staff management plans in the rare event that a staff conflict of interest is approved.

VIII. Management of Conflicts of Interest in Human Subjects Research

When a Covered Individual discloses a Financial Interest or Outside Activity that is related to proposed human subjects research and it is determined that there exists a Conflict of Interest with respect to the human subjects research, the University shall determine whether such participation is in the best interest of the University, considering factors such as (i) the nature of the Financial Interest or Outside Activity, (ii) whether the Covered

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Individual is uniquely qualified to participate in the human subjects research, (iii) and the degree of risk to human subjects posed by the research.

If the participation is judged to be permissible, the University shall determine the appropriate course of action to manage the Conflict of Interest, promote research integrity, and achieve transparency. The course of action shall be set forth in a formal management plan and shall include some or all of the measures listed below, and may include other measures deemed appropriate. At a minimum, all management plans for Conflicts of Interest in human subjects research shall include the disclosure condition and prohibition on obtaining consent condition described below. The applicable official's decision shall be communicated to the responsible IRB, which shall have full and final authority for determining the role of the Covered Individual in the human subjects research protocol and the content of any informed consent form.

Management plan conditions may include:

- A. Prohibition: The relevant dean or responsible IRB may require that the Covered Individual eliminate the Conflict of Interest before beginning the University Research or be barred from participation in the University Research.
- B. Disclosure: In all cases involving human subjects research where a written research consent form is required and in which an involved Covered Party has a Financial Interest, disclosure of the Conflict of Interest will be recommended to the responsible IRB for inclusion in the consent form.
- C. Prohibition on obtaining consent: In all cases involving human subjects research where a written research consent is required and in which an involved Covered Individual has a Conflict of Interest, the Covered Individual shall be prohibited from seeking or obtaining consent from prospective research subjects.
- D. Additional management conditions may be necessary to effectively manage the Conflict of Interest and ensure the primacy of the welfare and rights of human subjects, including requiring that the human subjects research be overseen by an independent data and safety monitoring board.
- E. Monitoring: The University shall monitor compliance with any management plan related to human subjects research on an ongoing basis until completion of the University Research.

IX. External Reporting of Conflicts of Interest

To comply with federal regulation, prior to the expenditure of funds from certain federal awards, including Public Health Service awards, the University will report to the awarding entity the following information with respect to Financial Interests:

- A. Project number.
- B. Program director/principal investigator.
- C. Name of investigator with financial conflict of interest.
- D. Name of entity in which a Financial Interest is held.
- E. Nature of the Financial Interest.
- F. Approximate dollar value of the Financial Interest within ranges, or a statement that the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- G. Description of how the Financial Interest relates to the federally funded research and basis for the University's determination of a Conflict of Interest.

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H. Description of the key elements of the University's management plan with respect to the Conflict of Interest, including: (i) role and principal duties of the conflicted investigator in the research project; (ii) conditions of the management plan; (iii) how the management plan is designed to safeguard objectivity in the research project; (iv) confirmation of the investigator's agreement to the management plan; (v) how the management plan will be monitored; and (vi) other information as needed.

X. Record Retention

All disclosures of Financial Interests related to University Research shall be retained by the office of the applicable University official for a period of at least three years following the termination of related University Research, including research funded by any awarding body of the federal government.

XI. Appeals

If a Covered Individual who holds a faculty appointment believes that a determination made under this policy in a specific case is not appropriate or is based on erroneous information, the Covered Individual may request additional review according to any applicable divisional policy or procedure. Faculty appeals from school or divisional decisions may be made to the Provost, whose review will be limited to review of whether the procedures set forth in this Policy were followed. The decision of the Provost will be final.

In the case of Covered Individuals who are staff, appeals of a determination under this policy shall be made in accordance with applicable Human Resources policies.

Policy Enforcement

Divisional deans' offices shall have the primary responsibility of (i) monitoring compliance with faculty Conflict of Interest management plans, and (ii) managing Conflict of Commitment Concerns. Failure to comply with this policy shall be subject to University review under applicable policies. In the case of human subjects research failure to comply with this policy may also be subject to responsible IRB policies on noncompliance. Potential sanctions under this policy and related divisional policies may range from a verbal warning to placement of a letter in the Covered Individual's employment file to suspension to termination.

If certain compliance failures occur with respect to Conflicts of Interest related to University Research involving Public Health Service agency funding, an interim management plan will be implemented and a retrospective review of ongoing research will be undertaken to determine whether bias is present in the design, conduct, or reporting the research. Those failures include: (i) failure to timely disclose Financial Interests; (ii) failure by the University to review or manage a Conflict of Interest related to University Research; and (iii) failure of a Covered Individual to comply with a management plan. If, after a retrospective review, the University determines that bias in research has occurred, the applicable dean or official will develop and implement a mitigation plan in accordance with the applicable divisional policy. The applicable dean or dean's designee shall promptly notify the federal funding entity of the findings and corrective actions that the University has taken or will take.

Related Resources

University Policies and Documents
Conflict of Interest FAQs

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Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Office of General Counsel	410-516-8128	http://jhu.edu/administration/general_counsel/