

**Whiting School of Engineering
and
Krieger School of Arts and Sciences**

Divisional Policy on Conflict of Commitment and Conflict of Interest

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1 Preamble

The missions of the Whiting School of Engineering and the Krieger School of Arts and Sciences (WSE and KSAS) are to create new knowledge and to propagate this knowledge through publications, patents, and educational programs. Essential to fulfilling this is the active participation of Academic Staff in research, which often involves interactions with government, industry, business, and other institutions. Hence, WSE and KSAS encourage their Academic Staff members to participate in activities outside the University that enhance their professional skills, promote the transfer of technology, or provide a public service. These activities can benefit WSE and KSAS and its Academic Staff, and often contribute to the richness and diversity of the academic community. Moreover, as a result of such activities, society may benefit from the dissemination of knowledge and technology developed within the University. Yet such activities can lead to conflicts of commitment or interest. Whether actual or perceived, such conflicts raise questions about the integrity and ethics not only of the individual, but also of WSE, KSAS, the University, and all their Academic Staff. The WSE and KSAS Policy on Conflict of Commitment and Conflict of Interest provides a framework for identifying conflicts of commitment or interest, and, when appropriate, resolving or managing situations in which a conflict may exist or appear to exist. The Policy seeks not only to identify and eliminate or manage actual conflicts of commitment or interest but, whenever possible, to prevent even the appearance of conflicts. In so doing, this Policy protects the excellent reputation of the University's Academic Staff as well as its unique research culture and traditions.

The Policy builds upon and implements the Johns Hopkins University Policy on Disclosure and Professional Commitment and the University Policy on Individual Financial Interests and Financial Conflicts of Interest in Research.

2 Summary

- This Policy applies to Academic Staff of the Whiting and Krieger Schools including faculty, researchers, postdoctoral fellows, research associates and assistants (including graduate students), teaching assistants, as well as other professional and senior staff who are compensated for their services or otherwise supported by WSE and KSAS.
- A Conflict of Commitment arises when the external activities of Academic Staff are so demanding of time or attention that they interfere with the individual's responsibilities to the University.
- A Conflict of Interest occurs when Academic Staff are in a position to advance their own interests, or that of their family or others, to the detriment of students, colleagues, funding agencies, or the University.
- Conflicts are common and practically unavoidable in a research university. However, as noted above, the relationships that lead to these conflicts often enrich the University and intellectual environments. Therefore, it is WSE and KSAS policy that conflicts be managed, supervised, or monitored whenever practical. However, some conflicts carry significant risks and therefore may not be manageable. In these cases, either the conflict is eliminated or certain activities are prohibited.
- Reports of potential conflicts of commitment or interest are reviewed by the WSE and KSAS Conflict Review Committee (CRC), comprised of senior WSE and KSAS faculty members, as

well as ex-officio non-voting members from various JHU administration offices. The CRC makes recommendations for conflict management or elimination to the Vice Dean for Faculty for WSE and the Vice Dean for Natural Sciences for KSAS. Issues solely related to employment status are forwarded directly to the Dean of the appropriate School.

- The CRC is governed by the *Krieger School of Arts and Sciences Whiting School of Engineering Conflict Review Committee By-Laws*.
- Academic Staff may appeal recommendations of the Conflict Review Committee or decisions of the Vice Dean for Faculty or Vice Dean for Natural Sciences to the Dean of the appropriate School. Decisions of the Dean are final.
- Sanctions for violating this Policy depend on the severity of the violation and range from reprimand to dismissal.

3 Who Is Covered

This Policy covers the Academic Staff of the WSE and KSAS. Academic Staff includes tenured and tenure track faculty, members of the research staff (professors, scholars, scientists, and engineers with research titles), teaching staff (senior lecturer/lecturer/junior lecturer, teaching professor/associate teaching professor, adjunct professor/adjunct associate professor/adjunct assistant professor), postdoctoral fellows, research associates and assistants (including full-time graduate students), teaching assistants, as well as other professional and staff who are compensated or otherwise supported by WSE and KSAS for their services or who appear to act as agents of WSE and KSAS in using, controlling, or assigning to others the use of WSE and KSAS facilities and resources.

- Full-time or salaried part-time JHU faculty members (tenured and tenure track faculty and members of the research staff including professors, scholars, scientists, and engineers with research titles) are required to disclose outside activities and financial interests whether or not they participate in research.
- Non-salaried part-time faculty must disclose outside activities and financial interests if they are related to their Johns Hopkins Institutional Responsibilities (defined below) and if they participate in research at JHU.
- Other individuals involved in research at Johns Hopkins who are Investigators *are* considered Academic Staff under this Policy and must disclose outside activities and financial interests if they are related to their Johns Hopkins Institutional Responsibilities.
 - ***Institutional Responsibilities are those responsibilities and roles assigned to an individual in the course of their appointment or employment with the institution. These may include, among other things, research, teaching, clinical care/practice, and administrative responsibilities.***
 - ***An Investigator is the project director or principal investigator and any other person responsible for the design, conduct, or reporting of research, including collaborators and consultants, and all study team members on IRB applications.***
- JHU staff members are considered Academic Staff under this Policy and must disclose financial interests if they are related their Institutional Responsibilities. All Academic Staff must report the outside activities of their immediate family members if the activity relates to the Institutional Responsibilities of the Academic Staff member. The immediate family of an Academic Staff member includes her or his spouse, domestic partner, and/or dependent children.

- Subrecipient investigators on PHS-funded research must disclose occurrences of reimbursed or sponsored travel that are related to subrecipient's work for JHU, regardless of the relationship of the travel to PHS funding, when the amount of travel during the 12 months preceding the disclosure reaches or exceeds \$5,000 in the aggregate for a particular entity. (Note: This aggregate value includes travel for spouses, domestic partners and dependent children unless the travel occurs in the course of their employment by the entity.)
 - This does not include travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, teaching hospital, medical center, U.S. institution of higher education, or related research institute. Exceptions also include travel reimbursements to Johns Hopkins, travel payments made by Johns Hopkins, or travel charged to a Johns Hopkins account.

This Policy acknowledges that potential conflicts of interest also may exist, for both Academic Staff and the University, with respect to activities that do not involve research. An example of such activity would be procurement. Accordingly, although Conflict of Interest in research is the focus of the WSE and KSAS Conflict Review Committee (CRC), the Dean may request that the CRC review and provide advice concerning financial interests related to other activities.

The Policy on Conflict of Interest also applies to WSE and KSAS itself, insofar as specific financial or fiduciary interests of WSE and KSAS as an institution may represent a source of bias or perceived bias in the conduct and reporting of research. Such interests include, but are not limited to, royalties or equity obtained as a result of licensing technology to outside entities and income or other financial interests obtained in other ways. This Policy will be interpreted in a manner consistent with the Johns Hopkins University's Intellectual Property Policy and the Johns Hopkins University Policy on Institutional Conflict of Interest.

4 Guiding Principles

As the first research university in the United States and the largest recipient of federal grants and contracts, Johns Hopkins has a research culture that is unique. The University has a tradition of excellence in both teaching and research that is based on scholarly creativity and intellectual rigor, with minimal rules and regulations. These aspects of Johns Hopkins' culture are valued highly and contribute to the creative spirit of the institution. As inheritors of this tradition, Academic Staff recognize that with this freedom comes the responsibility to conduct themselves in accordance with the highest standards of integrity and ethics. Johns Hopkins also has a strong tradition of faculty governance within departments, Schools, and across the University. Hence, when limitations must be placed on certain professional activities to protect the academic freedoms and reputation of Johns Hopkins and its faculty, this is done by the faculty themselves through faculty councils or committees. This Policy respects these traditions by utilizing a faculty committee to review conflict cases on an individual basis and allowing for considerable flexibility in implementation.

Changes in federal law encouraging technology transfer, as well as increased research support from private sources, have made Conflicts of Interest common and practically unavoidable in a modern research university. Conflicts of Interest can arise because a mission of the University as well as WSE and KSAS is to promote the transfer of knowledge gained through University research and scholarship to the private sector. It is appropriate for Academic Staff to be rewarded for their participation in activities supporting this mission, whether through consulting fees or sharing in royalties resulting from the commercialization of their work. It is inappropriate, however, for actions or decisions made in the course of an Academic Staff member's University activities to be influenced by considerations

of personal financial gain. Such conduct calls into question the professional objectivity and ethics of the Academic Staff member, and also reflects negatively on all other Academic Staff and on the University. This Policy assists Academic Staff in recognizing situations that may lead to conflicts and in ensuring that these situations are properly reviewed and, if necessary, managed. The mere existence of a conflict, whether real or potential, will not necessarily exclude Academic Staff from a particular activity. Conflicts span a wide spectrum, from those that are relatively minor and inconsequential to those that carry the potential for significant risks to research integrity or to the rights of others and, therefore, may not be allowed.

This Policy also addresses conflicts that may emerge from technology transfer and entrepreneurial activities. Over the last several years, WSE and KSAS have experienced growth in entrepreneurial endeavors among Academic Staff and students. While WSE and KSAS encourage entrepreneurship, the primary responsibilities of its Academic Staff and students are academic and not commercial. Conflicts may arise between the University's academic missions of teaching and research and the commercial interests of Academic Staff. These types of conflicts may occur in connection with Academic Staff members' complex financial interests in start-up companies, whether or not such companies are created around University licensed technology. These situations raise a number of difficult issues, including those involving research integrity when Academic Staff hold significant financial or management interests in companies sponsoring University research. These and other similar situations (e.g., Academic Staff serving as board members for start-ups sponsoring their research) also pose the risk of exploiting staff and students as well as redirecting University resources for commercial ends. After over a decade of attempting to manage these situations, the University has found that some conflicts generally cannot be managed and therefore usually should not be allowed. This Policy delineates the limits necessary to prevent these conflicts and to protect the academic mission of the University as well as the reputation of its Academic Staff.

An integral part of the Policy is the review of activities that may pose a conflict. Conflict of Commitment and Conflict of Interest issues are reported to the WSE and KSAS Conflict Review Committee (CRC) for review and its recommendations are implemented by the Vice Dean for Faculty (WSE) or Vice Dean for Natural Sciences (KSAS) (hereinafter, the term "appropriate Dean" will be used). Conflict of Commitment cases relating solely to employment status are negotiated with the Dean of the appropriate School. As discussed in detail below, activities that may raise questions of Conflict of Commitment or Conflict of Interest must be reviewed *before* the activity is undertaken. The reporting and review of all potential conflicts outlined in this Policy serves several important purposes. First, it helps protect the intellectual property rights of Academic Staff and may help shield Academic Staff from costly legal liability. Second, the review process provides Academic Staff with meaningful guidance for the continued development and future structuring of relationships with industry. Finally, this process provides assurance to students, colleagues, the University, sponsors, and the public that activities that may pose a conflict have been examined in accordance with the highest academic and ethical standards

The responsibility for reporting potential Conflicts of Commitment or Conflicts of Interest rests with the covered party. The CRC is responsible for determining if the disclosed interests could affect the Academic Staff member's research or performance of University responsibilities and, if so, to suggest to the appropriate Dean the management, reduction, or elimination of the conflict.

5 Activities and Interests to be Disclosed

Academic Staff must disclose any of the following time commitments and/or financial interests that reasonably appear to be related to his/her Institutional Responsibilities:

- a. **Services to outside entities that may be reasonably related to one's Institutional Responsibilities.**
 - i. This includes, but is not limited to: consulting, scientific advisory board service, speaking/teaching/lecturing, editing/authoring/publishing, and compensated legal ("expert witness") consulting and testimony.
 - ii. Services must be disclosed whether they are undertaken by agreement with for-profit or not-for-profit organizations or with non-U.S. government agencies.
 - iii. Services to U.S. government agencies, other than those services listed below as exclusions, must be reported.
 - iv. Services to 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 Institute of higher education, other than those services listed below as exclusions, must be reported.
 - v. Disclosures should specify the name of the entity to which the service was provided, not the name of an intermediary organization engaged to handle logistics or payment.
- b. **Intellectual property.** Academic Staff's financial interests in University and third party intellectual property (e.g., patent applications, patents, copyrights) that is licensed to an outside entity or that is the subject of agreements involving potential income or other valuable consideration. This includes intellectual property that is licensed by the Johns Hopkins University, the covered party, or any other entity.
- c. **Equity and other financial interests.** Financial interests, such as investments, that reasonably appear to be related to Academic Staff's Institutional Responsibilities. This does not include income from investment vehicles, such as mutual funds and retirement accounts, if the Academic Staff does not directly control investment decisions in these vehicles.
- d. **Fiduciary and management roles in non-Hopkins entities.** This includes but is not limited to service on boards of directors, or as an officer, manager, or medical director of a for-profit company or non-profit organization, including charitable foundations.
- e. **Travel.** Academic Staff who are investigators on PHS-funded research projects or applications for PHS funding must disclose each occurrence of reimbursed or sponsored travel related to a covered party's institutional responsibilities if the value of the reimbursed or sponsored travel occurring during the 12 months prior to the disclosure, when aggregated for a particular entity, is \$5,000 or more. This includes the value of sponsored or reimbursed travel for the covered party's spouse, domestic partner, and dependent children, if applicable. Disclosure must include the purpose, sponsor/organizer, destination and duration of each occurrence. Disclosures should specify the name of the entity to which the service was provided, not the name of an intermediary organization engaged to handle logistics or payment.
 - i. **This does not include** travel paid for by Johns Hopkins University, the Johns Hopkins Health System Corporation, or any of their constituent entities, or travel that is sponsored or reimbursed by U.S. local, state, and federal government entities; U.S. institutions of higher education as defined at 20 U.S.C. 1001(a); U.S. academic teaching hospitals, medical centers; or U.S. teaching hospitals, medical centers, or research institutes affiliated with a U.S. institution of higher education.
 - ii. **This does not include** travel sponsored or reimbursed for the spouse, domestic partner, or dependent children if the spouse, domestic partner, or dependent child is employed

by the entity or if the travel relates to the spouse, domestic partner, or dependent child's own employment responsibilities.

f. **Activities exempt from disclosure and review:**

- i. Services to the Johns Hopkins University, the Johns Hopkins Health System Corporation, or any of their constituent entities.
- ii. Services governed by an agreement between the Johns Hopkins University, the Johns Hopkins Health System Corporation, or any of their constituent entities and a third party.
- iii. Seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with an Institution of higher education.
- iv. Services on advisory committees or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with an Institution of higher education.
- v. Services provided by spouses, domestic partners, and dependent children without income or remuneration.

Additional reporting for full-time and salaried part-time faculty: Additional information about outside activities and/or interests, including those listed above as exclusions, may be requested at any time by the or the appropriate Dean in connection with any of the following: appointments, promotions, administrative assignments, performance reviews, requests for institutional clearance, certification of research, application for support of academic endeavors, purchases of equipment, relevant inquiries or investigators, or disciplinary reviews.

6 Conflict of Commitment

Despite the increasing frequency and complexity of the relationships of the University and its Academic Staff with industry, government, and other entities, these relationships are governed by one basic principle:

Full-time Academic Staff (including full-time, funded graduate students) of the Whiting School of Engineering and Krieger School of Arts and Sciences recognize that their primary responsibility is to The Johns Hopkins University. To fulfill this responsibility they are expected to devote their energies to activities that further the academic objectives of the Schools.

Acceptance of a full-time appointment or position entails a commitment to give one's best efforts to this end and to assign first priority to the needs and goals of The Johns Hopkins University. Similarly, WSE and KSAS expect full-time funded graduate students to be engaged full-time in their academic activities. ***A "Conflict of Commitment" occurs when the time and attention devoted to external activities negatively affects an Academic Staff member's ability to fulfill her/his University responsibilities.***

Outside commitments are reviewed for compliance with institutional policies and standards, including:

- Time commitment
- Conflict of commitment with Johns Hopkins duties

- Use of the Johns Hopkins name by or in connection with an outside activity
- Use of Johns Hopkins facilities and resources
- Academic freedom

6.1 Special Area of Consideration: Outside Consulting

Public and private institutions alike may call on Academic Staff to provide their expertise, whether through consulting or other forms of professional service. Consulting can provide Academic Staff with valuable experience in their professional fields outside the context of the University. Participation of Academic Staff in external professional activities for pay also may benefit the University and society as a whole, and is therefore allowed. Yet consulting also has the potential to divert Academic Staff from their primary responsibilities to the University. Hence, University policy has long limited the time that Academic Staff may spend consulting. In general, consulting is defined as compensated professional activity related to an Academic Staff member's field or discipline or Institutional Responsibilities that is not Research.¹ In this Policy, consulting includes a fee-for-service or equivalent relationship with a third party. It does not include service on national commissions, on governmental agencies and boards, on boards or committees of nonprofit professional associations, on granting agency peer-group review panels, on visiting committees or advisory groups to other universities, and on analogous bodies. It also does not include "moonlighting" that is not related to an Academic Staff member's field or discipline. These efforts are part of the Academic Staff member's private life and do not come under University regulation or this Policy. Such endeavors, however, may only be pursued after the commitment to the University and the Schools has been fulfilled.

Consulting is permitted provided the Academic Staff member's full-time obligations to the University are met. University policy allows Academic Staff members supported by University funds to conduct outside consulting, commercial, and other external compensated professional activities up to 52 days per year or one day per week during the academic year and at times they are receiving their full-time salary. Academic Staff who are supported entirely by grants or contracts generally are not allowed to consult. Academic Staff who are compensated at less than their full-time equivalent salary are allowed to consult additionally during time they are not compensated by the University. The total number of days per year that faculty on part-time appointments may consult may be determined by the formula $[52 \times F] + [(1-F) \times 6 \times 52]$, where F is the fraction of full-time equivalent salary that the Academic Staff member receives. In deriving this formula, it is assumed that Academic Staff are not likely to spend more than six days per week on professional activities during periods they are off duty at the University. For consulting carried out by the hour and not by the day, a formula of one consulting day equaling ten consulting hours should be used in calculating the total consulting time. This does not derive from accounting principles, but rather from subjective judgments about the average length of faculty workdays.

¹ As defined in the University Policy on Individual Financial Interests and Financial Conflicts of Interest in Research, Research is "a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. Research includes basic and applied research for product development. Research includes, but is not limited to, any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement; for example, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and research resource awards."

6.2 Other Activities Requiring Review

- Faculty members who receive their full-time salary from the University are allowed to consult or engage in entrepreneurial activity one day (ten hours) per week. Entrepreneurial activity should not be interpreted to mean Research, teaching, speaking, and/or lecturing. Faculty members who receive less than full-time salaries are allowed to consult beyond the one-day per week limit (as described above) when classes are not in session. Faculty who wish to pursue outside activities that exceed these limits must receive approval from the Dean of the appropriate School.
- **Academic Staff may not hold a substantive appointment at another academic institution without prior approval of the Dean of the appropriate School.** Further, full-time faculty cannot accept a teaching position at another academic institution without the consultation and approval of the appropriate Dean.
- Significant management roles (e.g., officer in company or positions that involve supervision of the work of others and/or day-to-day responsibility for operating decisions) usually are demanding in terms of both time and energy. Accordingly, Academic Staff who wish to accept significant managerial responsibilities in a company or another organization must negotiate an appropriate reduction in University responsibilities and compensation with the Dean of the appropriate School.

6.3 Agreements for Professional Services

Faculty are personally responsible for ensuring that these agreements and outside activities comply with Johns Hopkins University (JHU) policies, including the JHU Intellectual Property Policy and all applicable conflict of interest and conflict of commitment policies.

WSE/KSAS will not review private consulting or advising agreements that faculty may enter into in their personal capacity. Faculty are encouraged to append the ***Johns Hopkins University Rider to Faculty Private Consulting or Advising Agreement*** to their consulting agreement contracts. This Rider, if entered into without any modifications or edits, will cause a private agreement to be in compliance with the policies referenced above.

Prior to signing any private agreement and/or providing the consulting or advising services, faculty must disclose the proposed arrangement for review in the JHU online system, eDisclose. This disclosure requirement is applicable regardless of whether faculty use the Rider. WSE/KSAS will review the information disclosed by faculty to ensure the proposed arrangement adheres to the policies referenced above. Additionally, the faculty member's department chair, department director, or division director will have access to the submitted disclosure and has the authority to limit the faculty member's outside activity from the standpoint of professional commitment.

7 Conflict of Interest

WSE and KSAS seek to foster creativity and scholarly activities and facilitate the translation of discoveries into technologies and products that benefit society. The Bayh-Dole Act obligates the University to attempt to commercialize inventions resulting from federally funded research and to distribute a portion of the royalty income to inventors. However, the financial incentives that accompany such activities may lead to Conflicts of Interest. ***A "Conflict of Interest" may take many forms, but generally occurs when the conduct of research, the reporting of research results, or other professional norms could be compromised by an Academic Staff member's interests or commitments, especially financial.*** For example, a Conflict of Interest occurs whenever Academic

Staff propose to do research within the University that is sponsored by or related to the activities of a company in which they have a financial interest or fiduciary responsibility. Conflicts of Interest have the potential to harm research integrity by causing bias in the recording and reporting of results or by inappropriately redirecting University resources or the activities of students. Such conflicts also may place human research subjects at additional risk as well as reduce public confidence in research programs at WSE and KSAS.

This Policy is designed to maintain the trust of the public and the scientific community in WSE and KSAS's research enterprise and to support University compliance with applicable government regulations.² This Policy assists Academic Staff who have a financial interest or fiduciary responsibility in an outside entity in identifying arrangements that may represent a conflict or an appearance of a conflict in the conduct and reporting of research. The review and conflict management measures described below directly benefit Academic Staff by promoting academic integrity, protecting intellectual property rights, facilitating the technology transfer process, and helping reduce the risk of legal liability.

Under PHS regulation, when the institution determines that a financial interest is related to PHS-supported research and “could directly and significantly affect the design, conduct or reporting” of the research, the institution has identified a financial conflict of interest (FCOI). The FCOI must be eliminated or managed to protect the integrity and objectivity of the research. In most cases, a finding of conflict of interest will result in the imposition of conditions associated with participating in the research. In some cases, participating in the research will be conditioned on reducing the investigator's financial interest. In some instances the conflict of interest will be deemed "unmanageable," and the investigator will be required to eliminate the financial interest as a condition of participating in the research. If the arrangement involves a PHS grant or contract and the institution determines that there is a FCOI, the FCOI must be reported to the PHS awarding agency and other conditions apply. In cases where the arrangement is not determined to be an FCOI according to PHS standards, the arrangement nevertheless may be subject to administrative conditions.

All arrangements may be re-reviewed if circumstances change or there is new information.

7.1 Activities Requiring Review

7.1.1 Research Sponsored by Companies with Ownership by Academic Staff

The participation of Academic Staff in research, sponsored by companies in which they have an ownership interest is subject to limitations, although exceptions may be made in rare circumstances. Generally the Academic Staff member may not participate in or supervise research that is sponsored by a company in which he or she or a member of his or her immediate family has one or more of the following relationships with a company:

- A. Holds a management or senior leadership position (e.g., officer, scientific director) in the company, whether or not compensated; or
- B. Serves on the company's board of directors, whether or not compensated; or
- C. With the exception of equity or other ownership interest received through the University's licensing distribution policy³, maintains beneficial ownership of more than ten percent (10%) of

³ Such ownership interest remains subject to applicable University policies on intellectual property and Conflict of Interest.

the company or one of its affiliates, where beneficial ownership is defined as the aggregate of stock, options, warrants, and other ownership instruments.

7.1.2 Contracts and Subcontracts

Only in exceptional circumstances, and only with explicit approval of the sponsor, may an Academic Staff member have University contracts, subcontracts, or purchase orders to companies in which he or she or a member of his or her immediate family has one or more of the following relationships with that company:

- A. Holds a management or senior leadership position (e.g., officer, scientific director) position in the company, whether or not compensated;
- B. Serves on the company's board of directors, whether or not compensated; or
- C. Holds equity greater than 0.1% or \$25,000 of a company's outstanding stock.

This limitation on contracts, subcontracts, or purchase orders applies even when the equity received is through the University licensing distribution policy.

7.1.3 Research Sponsored through Other Organizations

Academic Staff may not serve as principal investigators or co-investigators on sponsored projects submitted and managed *solely* through other academic, federal, or commercial institutions. Exceptions may be granted only with the prior written approval of the appropriate Dean. This stipulation does not apply to subcontracts awarded to the University; it is not intended to limit the participation of Academic Staff in multi-site training or research programs, nor is it intended to apply to circumstances in which the Academic Staff member's research requires access to facilities not available at the University.

7.1.4 University Research Sponsored by Others but “in the field” of a Company in which an Academic Staff member has a Significant Interest

University research “in the field” of a company in which an Academic Staff member has a significant financial interest (with the exception of equity or other ownership interest received through the University's licensing distribution policy) or has a significant managerial role has the potential for a conflict of interest to arise. The term “in the field” means research involving the licensed technology, research on products or processes used by the company, research on similar products or processes but targeting different systems, or University research involving complementary or competitive approaches if the financial interests of the company would reasonably appear to be affected by the conduct or outcome of the research. By examining the company's business and the scope of research conducted by the Academic Staff member, the CRC will judge whether the research is “in the field.”

7.1.5 Student Involvement

Academic Staff must ensure that the activities of students are not subordinated to the personal commercial interests of the Academic Staff member, and that the work of students is not exploited. Situations can arise in which an Academic Staff member's commercial activities can influence, however unwittingly, his/her academic roles to the detriment of the student. Examples of such

difficulties include pressuring students to pursue research not in keeping with their own educational goals or transmitting students' research results to an external organization before the research is completed. Therefore, the involvement of students in the external commercial activities of Academic Staff is *not allowed* when there is a supervisor/subordinate, teacher/student, advisor/advisee, or other academic relationship within the University.

If Academic Staff already are associated with students in commercial activities (e.g., common involvement in a start-up company), they must disqualify themselves from becoming research supervisors, academic program advisors, or examiners for an advanced degree for those students.

7.1.6 Support Staff Involvement

When a supervisor/subordinate relationship exists within the University, the involvement of support staff in the external compensated or commercial activities of Academic Staff is not permitted. Further, when no such relationship exists, the involvement of support staff in the external commercial activities of Academic Staff is not permitted. Academic Staff may not require support staff to perform duties related to their personal and nonprofessional activities.

7.1.7 Technology Transfer

Whenever an Academic Staff member, or a company in which he/she has a financial interest, wishes to license intellectual property from the University that the Staff member has had a part in developing, the Academic Staff member must be recused from the licensing negotiations (e.g., by involving a professional management team) and/or by being compensated solely by the company (i.e., by forfeiting his/her right to distributions under the University's Intellectual Property Policy.)

7.1.8 Royalty

Entitlement to royalties under the Johns Hopkins University's Intellectual Property Policy creates a conflict of interest in proposed or existing related University research (regardless of the source of external research support, if any) that may affect the value of the Johns Hopkins University intellectual property. This includes arrangements involving licensing-related payments, royalty, or future royalty, whether such payments are received by Johns Hopkins and distributed to the inventor or received by the inventor from another source.

7.1.9 Equity

A Conflict of Interest arises whenever research is conducted that could affect the value of equity owned by an Academic Staff member. For the purposes of this Policy, the term equity applies to stock, stock options and warrants, as well as to ownership interests. The term equity does not include ownership of diversified mutual funds. The following equity arrangements must be reported and reviewed.

- A. Any proposal for licensing an Academic Staff member's invention when the Academic Staff member, either directly or through WSE and KSAS, holds equity or will hold equity (e.g., stock options) in the licensee;

- B. Any proposal to conduct research (regardless of the source of research support) involving an Academic Staff member who, either directly or through WSE and KSAS, holds equity or will hold equity (e.g., stock options) in a company supporting the research and the value of the equity may be affected by the research. This includes equity received or to be received by any means, including but not limited to the following: for consulting or advisory services, through a JHU-based or personal licensing agreement, through inheritance, or as the result of an arms-length purchase;
- C. Any proposal by an Academic Staff member to acquire equity in the sponsor of an ongoing research project or in a company that controls technology that is the subject of ongoing research, where the technology may reasonably appear to be materially affected by the research.

7.1.10 Income and Other Payments

A Conflict of Interest may arise when Academic Staff propose to conduct research that may affect the value of a company or entity from which Academic Staff receive or are entitled to receive income (e.g., income for consulting, advisory or lecturing services, honoraria, and in-kind support, but not grants or contracts). Hence, any proposal to conduct such research must be reviewed.

7.1.11 Appointment Letters

Academic Staff receiving annual appointment letters must confirm that they reported all applicable outside commitments as required during Annual Certification. Such reports must be updated as information changes.

7.1.12 Other

- A. Any proposal by an Academic Staff member to have a management position, board of directors seat, or other fiduciary role in any organization (non-profit or for profit) must be reviewed whenever the activities could reasonably be interpreted to be related to the role or activities of the Academic Staff member within the University.
- B. Any proposal to conduct research when one's spouse, domestic partner, or minor dependents have a financial interest that may be affected by the research must be reviewed.

7.1.13 Use of University Resources

The University's name, facilities, and equipment are to be used solely for the furtherance of University goals and not for the benefit of, or to imply the University's support of, non-University activities. Hence, Academic Staff may not solely or primarily use University resources, including facilities, equipment, or computers for non-University purposes. Minimal and discretionary use of one's office and office equipment such as computer, telephone, fax machine, etc. is permitted. University confidential information must not be used or shared. The University may grant permission to an Academic Staff member to use University facilities for outside activities, but only under very prescribed conditions that must be negotiated with the appropriate Dean in consultation with Homewood Research Administration and the Office of the General Counsel. Such permission will be granted through a written agreement between the University and the outside entity.

Inappropriate uses of University resources include the following and are not permitted:

- Using the University's name or letterhead in sponsoring or recommending any commercial service or product, regardless of whether the Academic Staff member has any interest in the promotion.
- Using the University's name or letterhead in connection with an outside organization, unless the participation in that organization is at the request of the University or is otherwise a part of the Academic Staff member's official University duties.
- Granting external entities access to Johns Hopkins facilities or services for purposes outside the University's missions, or offering favors to outside entities in an attempt to influence them unduly in their dealings with the University.
- Using confidential information acquired through conduct of University business or research activities for personal gain, or granting to others unauthorized access to such information.
- Providing preferential access to research results, materials, or products generated from University teaching or research activities to an outside entity for personal financial gain. (Appropriate licensing arrangements for inventions/creations or consulting on the basis of sponsored project results in accordance with this Policy is not precluded.)

8 Procedures for Disclosing and Review

8.1 How to Disclose

Login to eDisclose using your JHED ID and password: <http://edisclose.jhu.edu>.

Institutional policy and federal regulation mandate disclosure requirements to enable review for conflict of interest and professional commitment. The university's web-based disclosure system, eDisclose, is the sole means for disclosing outside activities and financial interests for review under policies on professional commitment and conflicts of interest. The system is accessible anytime and anywhere there is a working internet connection. You will need your JHED ID and password to enter the system.

8.2 When to Disclose

- Annually with your Annual Certification, as described in the next section.
- Prior to undertaking an outside commitment
- Prior to submission of an application for PHS-funded research on which you are an investigator
- Within 30 days of acquiring or discovering a financial interest related to your institutional responsibilities
- Whenever a disclosed interest or activity changes (*e.g.*, the amount or type of remuneration, type of service, or time commitment) or ends.
- **Faculty who do not have outside activities to disclose only need to complete the Annual Certification.**

8.3 Annual Certification

In addition to submitting “real-time” disclosures, all full-time and salaried part-time faculty are required to complete an Annual Certification. The purpose of the Annual Certification is to confirm that all your disclosures are complete, accurate, and up-to-date. The Annual Certification does not affect the obligation to disclose outside activities and interests as they arise and before proposing related research. Faculty members who are required to submit the certification will be notified via personal e-mail when their Annual Certifications are ready for submission. They will also receive weekly e-mail reminders during their submission period. The Annual Certification is accessible via eDisclose, the online disclosure system. Faculty members will be notified via e-mail when their Annual Certifications are ready for submission. Submitting an Annual Certification is mandatory for all full-time and salaried part-time faculty. Failure to submit a completed Annual Certification as required may be reviewed under the Procedures for Dealing with Issues of Professional Misconduct.

8.4 Changes to Disclosures

If your disclosed relationship with an entity changes in any way, you need to update your disclosure in eDisclose. To do so, find your original disclosure for the entity and then select the “Edit Disclosure” button on the left and add the change or new activity to the existing entry. Please note that the disclosure must be in the “Review Complete” state in order to be updated.

For example:

- Your relationship with the company/entity has ended
- Your service has changed (*e.g.*, type of service provided, time commitment, amount or type of remuneration)
- You propose to participate in research related to the entity (a new protocol or a new research grant or contract)
- Your intellectual property is licensed to the entity

8.5 Review of Disclosures

Disclosures of outside interests will be reviewed by designated divisional staff, Deans of the school, and/or the Conflict Review Committee.

Determining whether a particular outside activity or interest constitutes an acceptable or unacceptable time commitment is the responsibility of the Dean of the school. The Dean may place restrictions on or deny any activity or interest if they believe the activity or interest is likely to negatively impact a faculty member’s ability to fulfill his or her University responsibilities due to the amount of time required by, or the nature of, the outside activity or interest. For such a determination to be made, Deans may evaluate areas of faculty responsibility and productivity, including but not limited to research and teaching.

Determining whether a particular outside activity or interest constitutes an acceptable or unacceptable potential for conflict of interest is the responsibility of the designated divisional staff, the Conflict Review Committee, and the Dean of the school. Disclosures are reviewed in light of related research activity for the following:

- potential of disclosed interests to directly and significantly affect the design, conduct, or reporting of research funded by a PHS Awarding Component or other sponsor (“financial conflict of interest”, or “FCOI”); and
- risks to the rights and safety of human research subjects; and
- impact on the integrity of research data; and
- risks to the rights and obligations of collaborators, students and trainees participating in research; and
- impact on the availability of research results to the scientific community for use in the public interest; and
- impact on the academic, research, and educational missions of the University; and
- appearance of a conflict of interest.

The staff and/or Committee will determine whether or not the disclosed interests constitute a financial conflict of interest (FCOI). If the Committee identifies an FCOI, the Committee will recommend to the Dean that the proposed arrangements be either (a) prohibited, or (b) permitted, subject to specific management measures. In cases where the Committee does not judge the arrangement to be an FCOI, the arrangements nevertheless may be subject to administrative conditions. All arrangements may be reviewed again if circumstances change or there is new information. After reviewing the recommendation of the Committee, the divisional Dean will render a final decision and will communicate that decision, with a description of management measures or administrative conditions, to the involved covered party in writing. The Committee will be notified of the Dean’s decision if it differs from the recommendation of the Committee.

8.6 Management Recommendations

Upon completing its review, the CRC will recommend to the appropriate Dean that the proposed arrangements either be a) not allowed, or b) allowed, subject to specific management conditions. After reviewing the recommendation of the CRC, the appropriate Dean will render a final decision and will communicate that decision, with a description of any specific management conditions, to the Academic Staff member in writing. The appropriate Dean also shall report to the CRC whenever his/her decision countermands or disregards the CRC’s recommendations.

For proposed arrangements involving human subjects research, the CRC will make a recommendation to the appropriate Dean and the appropriate IRB. This procedure is described more fully in Appendix A.

The CRC may recommend that management of the Conflict of Interest be implemented using, for example, one or more of the following:

Disclosure - Disclosure is required in every case approved by the appropriate Dean, including: i) public disclosure of the financial interests of the investigator and of WSE or KSAS, if applicable, in all relevant publications, presentations (whether or not academic presentations), including presentations at the level of the Academic Staff member’s primary department or higher, ii) disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees, and iii) disclosure on human subject consent forms;

Limiting the Role of the Investigator with a Financial Interest - requiring that the role of the investigator with the financial interest be limited in some way (e.g., the investigator may not be allowed to serve as principal investigator, analyze data or results, or solicit consent from human research subjects);

Oversight - appointment of a disinterested individual or group to monitor the relevant research activity. An oversight committee will be charged with ensuring that the research is conducted and reported according to scientific and ethical standards and that Conflict of Interest management measures are observed. In cases concerning the Deans or Associate/Vice Deans, the individual or group monitoring the activity shall be appointed by and report to the Vice Provost for Research.

Divestiture - the sale or disposal of specified financial interests to eliminate or reduce the financial Conflict of Interest by a certain date;

Severance of Relationships That Heighten or Create Actual or Potential Conflicts - for example, relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce the financial or fiduciary conflict of interest.

Informing and managing conflicts when working with students, staff and collaborators – examples include: informing students, staff or collaborators in writing of their personal commercial interests in a research project; signed agreements between the Academic Staff member and students, staff or collaborators indicating they fully understand the circumstances of their work for the Academic Staff member; 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 a student's education and independent of any benefit to the company; and determining if the Academic Staff Member may have a role in supervising a student's thesis or dissertation.

The CRC may recommend other conditions or limitations on the proposed arrangements if, in its view, such conditions or limitations will contribute to the elimination, reduction, or management of the conflict.

8.7 Implementation of Recommendations

The Committee's recommendations will be presented to the Academic Staff member in the form of a management plan in eDisclose. The Academic Staff member will be asked to review the management plan in eDisclose and indicate his/her acceptance of the CRC's recommendations.

8.8 Reporting to Funding Agencies

If the review involves a proposal for funding from a Public Health Service (PHS) agency, the appropriate School's Research Administration Office will report to the PHS Awarding Component when it identifies the existence of a conflicting interest (but not the nature of the interest or other details), prior its expenditure of any funds under the award. The appropriate School will assure that the interest has been managed, reduced, or eliminated in accordance with 42 CFR Part 50 Subpart F. For any interest that is identified as conflicting subsequent to the School's initial report under the award, the report will be made and the conflicting interest managed, reduced, and eliminated, at least on an interim basis, within sixty days of that identification.

8.9 Appeals

If an Academic Staff member believes that a recommendation made by the CRC in a specific case or decision by the appropriate Dean is not appropriate or is based on erroneous information, the Academic Staff member may request an appeal by submitting a written request in eDisclose. If, after a

second review by the CRC and second decision by the appropriate Dean, the Academic Staff member still wishes to appeal, then he/she may appeal to the Dean of the appropriate School. The decision of the Dean shall be final.

In the event the appropriate Dean decides to countermand or reject a CRC recommendation and the CRC wishes to appeal that decision, it may appeal to the Dean of the appropriate School. The decision of the Dean shall be final.

9 Sanctions

Late disclosure and failure to disclose may have serious consequences. Failure to comply with the WSE and KSAS Policy on Conflict of Commitment and Conflict of Interest and with CRC recommendations adopted by the Deans or Vice Dean for Faculty (WSE) or Dean of Research and Graduate Education (KSAS) and, if warranted, IRBs, is subject to review under WSE and KSAS's "Procedures for Dealing with Issues of Professional Misconduct" and "Procedures for Dealing with Issues of Research Misconduct." Potential sanctions under these policies range from a reprimand by the Dean of the appropriate School and placement of a letter in the Academic Staff member's file, to suspension for a specified period of time, to termination.

Under federal conflict of interest regulation, if the failure of an investigator to comply with this conflict of interest policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with 42 CFR Part 50 Subpart F, Section 50.606, the institution must undertake a retrospective review of the research for bias. The appropriate School will promptly notify the PHS Awarding Component of the findings and corrective action(s) taken or to be taken. The PHS Awarding Component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, potentially including directions on how to maintain appropriate objectivity in the funded project.

Failure to comply with this policy and with Committee recommendations adopted by the Dean and IRBs is subject to review under the applicable division's policies and procedures on professional or research misconduct. Potential sanctions under these policies range from a warning from the Dean and placement of a letter in the covered party's file, to suspension for a specified period of time, to termination.

In the event of any of the following, 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 of the research: failure to disclose in a timely manner financial interests that are determined to constitute an FCOI with PHS-funded research; failure by the institution to review or manage an FCOI; or failure by a covered party to comply with a management plan. If bias is identified, the institution will develop and implement a mitigation plan.

If the failure of an investigator to comply with this conflict of interest policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with PHS regulations, the institution must promptly notify the PHS Awarding Component of the findings and corrective action(s) taken or to be taken. The PHS Awarding Component will consider the situation and make take appropriate action or refer the matter to the Institution for further action, potentially including directions on how to maintain appropriate objectivity in the funded project.

10 Required Training

Covered parties must complete Johns Hopkins University conflict of interest training. In accordance with federal regulation, all faculty are required to receive training related to conflict of interest prior to engaging in research at Johns Hopkins and at least every four years. Training also must be completed when any of the following occur:

- o Johns Hopkins revises its policy on conflict of interest in research;
- o A covered party is new to Johns Hopkins; or
- o Johns Hopkins determines that a covered party is not in compliance with this policy or his/her assigned management plan

11 External Reporting

To comply with federal regulations, the Institution will make available to the public within 5 days of a request the following information with respect to financial conflicts of interest with PHS-funded research:

- Investigator's name
- Investigator's title and role with respect to the research project
- Name of entity in which a significant financial interest is held
- Nature of the significant financial interest
- Approximate dollar value of the significant financial interest within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), 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

To comply with federal regulations, the Institution will report to the PHS Awarding Component the following information with respect to financial conflicts of interest with PHS-funded research:

- Project number
- Program director/principal investigator
- Name of investigator with financial conflict of interest
- Name of entity in which a significant financial interest is held
- Nature of the significant financial interest
- Approximate dollar value of the significant financial interest within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), 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
- Description of how the financial interest relates to the PHS-funded research and basis for the Institution's determination of a financial conflict of interest
- Description of key elements of the Institution's management plan, including:
 - o Role and principal duties of the conflicted Investigator in the research project
 - o Conditions of the management plan
 - o How the management plan is designed to safeguard objectivity in the research project
 - o Confirmation of the investigator's agreement to the management plan
 - o How the management plan will be monitored
 - o Other information as needed

Covered parties must abide by other disclosure requirements and standards, such as for journals and professional societies; in publications, presentations, and to colleagues, students and trainees -- even if an interest is not identified as a FCOI with research.

Appendix A: Special Considerations for Review and Management of Conflicts of Interest in Human Subjects Research

Financial interests in human subjects research require additional scrutiny because they may present real or perceived risks to the welfare and rights of human subjects, in addition to presenting risks to research integrity.⁴

Academic Staff are required to report all financial interests related to any human subjects research they plan to conduct. Whenever there is more than “minimal risk” to human subjects, it is presumed that individuals (faculty, staff, students, administrators, and researchers) may not participate in research projects involving human subjects while they have a significant financial interest in the research project or in a financially interested company. Exceptions may be made in specific cases only when, in the judgment of the CRC, individuals with financial interests provide the CRC with a compelling justification for being permitted to simultaneously hold the financial interest and participate in the human subjects research project.

If an Academic Staff member proposes to conduct research which is determined by the responsible IRB (in accordance with 45CFR 46.110) to entail "no more than minimal risk" to subjects and the Academic Staff member has a significant financial interest, as defined below, the research project may be allowed; however, the research project still will be subject to review by the CRC.

Significant Financial Interests

Significant financial interests are presumed to be prohibited in regard to human subject research. (N.B.: Financial interests below the thresholds listed below are not exempt from reporting.) Significant financial interests include:

- i. Fees, honoraria, gifts or other emoluments, or "in kind" compensation from a financially interested company (or entitlement to the same), whether for consulting, lecturing, or any other purpose, that in the aggregate exceed \$25,000 within a twelve month period, excluding reimbursement of expenses such as travel expenses incurred as a direct result of performing consulting services;
- ii. An equity interest of any amount, including stock options or warrants, in a non-publicly-traded financially interested company (or entitlement to the same);
- iii. An equity interest, including stock options or warrants, (or entitlement to the same) in a publicly-traded financially interested company that exceeds \$25,000 in value as determined through reference to current prices. (Should the value of the equity interest increase to more than \$25,000 during the conduct of the research project, the Academic Staff member must notify the IRB.) This limit will be reviewed every two years, beginning in 2004, to determine whether an increase is warranted in light of any increase in the cost-of-living index. This does not apply to diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund. Equity holdings worth less than \$25,000 and rights to acquire additional equity will nevertheless be subject to restrictions;

⁴ This section of the WSE Policy is adopted from the School of Medicine’s revised procedures. In preparing its policy on conflicts of interest in human subjects research, the School of Medicine acknowledges the document titled "Preserving Trust, Promoting Progress: Guidelines for Developing and Implementing A Policy Concerning Individual Financial Interests in Human Subjects Research," issued in December 2001 by the Association of American Medical Colleges.

- iv. Royalty income or the right to receive future royalties from commercialization of research results, including entitlement to any "milestone" payments conditioned upon specified research-related dates or events, whether such payments are received from a financially interested company or via the University. Royalty interests arising from post-marketing sales of approved products are an example of a financial interest that promote translational research and may be amenable to successful management.
- v. Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the applicable research agreement). This includes any bonus or milestone payments (other than those addressed in this Policy) to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested company or from the University;
- vi. Service as an officer, director, or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service. A researcher's time-limited service as an officer or director of a company formed to obtain a grant under the federal Small Business Innovation Development Act or the Small Business Technology Transfer Program may be treated analogously to royalty interests arising from post-marketing sales of approved products, as described above.
- vii. Royalty income and the right to receive future royalties as a result of traditional academic publishing activity, such as the publication of textbooks, are excluded.

Reporting

Conflicts of interest in relation to human subjects research generally are brought to the attention of the CRC by one of the following mechanisms:

- i. *Local IRBs*: Application forms submitted to the Homewood, School of Medicine or Bloomberg School of Public Health Institutional Review Boards include a question concerning relevant financial interests. If an Academic Staff member has a relevant financial interest, as described above, the question on the application form must be answered in the affirmative. All applications containing an affirmative answer to the question concerning relevant financial interests will be referred to the WSE and KSAS CRC for review.
- ii. *External IRBs*: For proposals involving human subjects research at Johns Hopkins (or administered through Johns Hopkins) which are submitted to outside IRBs for review, the principal investigator must obtain CRC review by submitting the proposed protocol directly to the CRC. CRC review must be completed before the principal investigator submits the protocol to the outside IRB. Procedural questions should be directed to the appropriate Dean.

Review and Determination/Management

The CRC will review reports of proposed financial interests in human subject research projects. Recommendations concerning an Academic Staff member's relationship to the outside entity will be communicated in writing to the appropriate Dean and to the appropriate IRB. The appropriate Dean will communicate his/her decision concerning the Academic Staff member's relationship with the outside entity in writing. Nevertheless, to ensure the primacy of the welfare and rights of human subjects, the IRB will have the full and final authority for implementing the decision concerning the role of the involved Academic Staff member in the human subjects research protocol. Accordingly, the

IRB will communicate its decision concerning participation in the human subjects research protocol to the Academic Staff member and will provide a copy of that communication to the CRC.

If the IRB deems a specific research project involving human subjects to be exempt from IRB review, the Conflict of Interest issues associated with that project will remain subject to CRC review and the CRC may review the project as if it were "human subjects research" for the purposes of this Section.

The CRC's recommendation may involve either prohibition or management. These options are described below.

- i. Prohibition: If, upon reviewing specific evidence provided by the Academic Staff member with the relevant financial interest, the CRC believes that a Conflict of Interest is incompatible with human subjects research, it will recommend to the appropriate IRB that the involved Academic Staff member be required to eliminate the relevant financial interest before beginning the project or be barred from participation in the research.
- ii. Management: In cases involving minor (i.e., non-significant) financial interests, the CRC generally will recommend that the Academic Staff member be permitted to participate in a given human subjects research project, subject to certain specified management conditions. In a limited number of cases involving significant financial interests, if the CRC concludes that the justification provided by the Academic Staff member is sufficiently compelling and that the Conflict of Interest can be managed, it will recommend specific project-related management measures to the appropriate IRB.

In all cases involving human subjects research where a research consent form is required and in which an involved Academic Staff member has a relevant financial interest of any magnitude, a financial disclosure statement including the name of the financially interested individual and describing the source and nature of the relevant financial interests must be included in the consent form.

Additional project-related management measures may include, for example, one or more of the following: the Academic Staff member may not be allowed to (i) serve as principal investigator, (ii) analyze data or results, (iii) determine whether potential subjects are eligible for enrollment, (iv) solicit consent, or (v) determine whether an adverse event report is required. Other project-related management measures also may be recommended.

The CRC's recommendation, accompanied by a description of the nature and magnitude of the potential Conflict of Interest, will be communicated in writing to the appropriate IRB. The IRB, which is responsible for ensuring the ethical acceptability of the research, will evaluate the recommendations of the CRC and decide whether to a) accept the recommendations, b) accept the recommendations with additional management measures prescribed by the IRB, or c) conclude that the human subjects research cannot proceed. It then will communicate its determination to the Academic Staff member in writing. Upon concluding its evaluation, the IRB will inform the appropriate Dean and the CRC of its determination, but the IRB's decision will be final.

Appeals

Academic Staff who believe that the Conflict of Interest management measures adopted by an IRB are not appropriate or are based on erroneous information must follow applicable IRB procedures for requesting additional review.

Appendix B: Other Legal Obligations

Academic Staff should be aware that, as a result of their financial or fiduciary interest in a company, they may have obligations under various federal or state laws.

Public Health Service (PHS)/National Science Foundation (NSF)

Individuals who seek research funding from either PHS (including NIH) or NSF must comply with applicable regulations (Human Subjects Protection (45 CFR Part 46)) to (for PHS) "ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research." Under the regulation, investigators are required to disclose to an official(s) designated by the University a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding by the PHS."

In accordance with 42 CFR Part 50 Subpart F, Section 50.604 (a), the Institution must maintain an appropriate written, enforced policy on conflict of interest that complies with federal regulation. In addition, the Schools will comply with the regulation as follows:

- a) If the Schools carry out the PHS-funded research through subrecipients, such as subgrantees, contractors, or collaborators, the Schools will take reasonable steps to ensure that investigators working for subrecipients comply with 42 CFR Part 50 Subpart F, either by requiring those investigators to comply with the this policy or by requiring the subrecipients to provide assurances that will enable it to comply with the regulation. The Schools will require subreceptients to report identified conflicts of interest to Johns Hopkins and the appropriate Research Administration Office will report to the NIH the existence of any conflicting interests arising from those entities and assure that the interests have been managed, reduced, or eliminated in accordance with the regulation.
- b) The Schools will maintain records of all financial disclosures and all actions taken with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53 (b) for different situations.

U.S. Food and Drug Administration (FDA)

The FDA requires applicants, under various regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), to submit to the FDA a list of clinical investigators who conducted covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements. (Source: "Financial Disclosure by Clinical Investigators." FDA. <http://www.fda.gov/oc/guidance/financialdis.html>. March 20, 2001.

Securities and Exchange Commission (SEC)

The SEC enforces regulations concerning equity ownership, including insider trading, which may affect Academic Staff who hold equity in a financially interested company. For additional information,

Academic Staff members should seek advice from personal legal counsel. It is the obligation of the financially interested individual to ensure that he or she complies with applicable SEC regulations.

Other Sponsors

Outside sponsors may have specific requirements regarding the financial interests of covered parties. For more information, contact the sponsor or Research Projects Administration.

Appendix C: Glossary

Covered Party: Covered parties are investigators on all research conducted under the auspices of the Johns Hopkins University (JHU), including research that is funded by or through the university, its divisions, centers or institutes, or conducted under the aegis of any JHU or JHM IRB.

Days Per Year: Outside activities are measured in workdays where 1 day is equal to 10 hours. JHU eDisclose recognizes numeric entries up to one decimal place. Estimates should include travel time.

Department Reviewer: A department director, division director, division chief, or administrator who can access disclosures submitted by individuals in their department or division.

Dependent Children: A son, daughter, stepchild, eligible foster child, or legally adopted child who is primarily dependent upon a parent or guardian for financial support. The child must be (a) under age 19 at the end of the year, (b) under age 24 at the end of the year and a full-time student, or (c) any age if permanently and totally disabled.

Disclosure: A summary of information regarding an individual's financial interests and/or outside activities with an entity other than JHU, JHHS, or their constituent entities that must be submitted through JHU eDisclose.

Disclosure Requirements: Disclosure requirements are specific to each division. Covered parties should consult the JHU Policy on Financial Interests and Conflict of Interest in Research and the divisional policies on Disclosure and Professional Commitment (or, if the division does not have a professional commitment policy, the JHU Policy on Disclosure and Professional Commitment).

Domestic Partner: A partner with whom an individual is committed as a family, in a long-term relationship of indefinite duration, and are socially, emotionally, and financially interdependent on each other in an exclusive mutual commitment in which they agree to be responsible for each other's common welfare and share financial obligation.

Entity: A for-profit or not-for-profit organization or company, including private and governmental organizations.

Equity: Financial interests such as stock, stock options, warrants, and ownership interests in an entity. The requirement to disclose ownership of equity that relates to one's institutional responsibilities does not include income from investment vehicles, such as diversified mutual funds and retirement accounts, if the covered party does not directly control investment decisions made in these vehicles.

Fee: See Income.

Fiduciary/Founder Role: A legal and/or ethical obligation on the part of a covered party to act in the best interests (i.e., the financial and operational success) of another. Examples of fiduciary roles include membership on a board of directors and service as an officer, or manager, or medical director of a for-profit or non-profit company or organization.

Financial Interest: An interest in anything of monetary value, whether or not the value is readily ascertainable.

Gifts: Anything of value, whether a tangible item or a service, received from an entity (e.g., watches, briefcases, vacations, concert/theater tickets, golf club memberships, wine tastings).

Human Subject Research: Includes all research meeting the definition of “research” performed with “human subjects” as defined in the Federal Common Rule and the FDA (45 C.F.R. Part 46 and 21 CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.

Income: Includes, but is not limited to, monetary payment.

Institution: This includes JHU, JHHSC, and their divisions, centers, institutes and any other constituent parts.

Institutional Responsibilities: The responsibilities and roles covered parties are assigned in the course of their appointment or employment at JHU. This includes, for example, clinical practice, teaching, research, research consultation, professional practice, administrative roles, committee service, and service on panels such as IRBs.

Inventor: An individual who has conceived of an essential element or has contributed substantially to the conceptual development of Intellectual Property. Inventorship is a legal determination made by patent counsel for the University.

Investigator: Under JHU’s conflict of interest policy, an investigator is: (1) The project director or principal investigator and any other person responsible for the design, conduct, or reporting of research. (Includes collaborators and consultants.) (2) All study team members on IRB applications. This definition is independent of whether one is appointed or employed by the Johns Hopkins University. The phrase "responsible for the design, conduct, or reporting of research" should be interpreted to mean any individual involved in the research who works independently enough to affect the objectivity of the design, collection, or analysis of research data or reporting of research results. In addition to faculty members, this may include graduate and post-doctoral trainees, research staff, consultants, or other collaborators. The ultimate determination as to who is considered an investigator in PHS-supported research is the decision of the PI of the project.

Key Personnel: Members of the research team who will be responsible for the design, conduct or reporting of the research or other activities of the proposed project. This can include the principal investigator, project director or any other personnel, considered to be essential to work performance and identified as key personnel in the research funding proposal.

Management Plan: The conditions under which an individual’s financial conflict of interest is managed to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias. When there is a financial conflict of interest, participation in research is subject to compliance with management plan conditions.

Non-profit organization: Any organization that is not operating for the profit or gain of its individual members, whether these gains would have been direct or indirect, and therefore does not have individual stockholders.

Outside Activity: Involvement with non-JHU or JHHS entities and other activity conducted outside one’s institutional responsibilities.

Private Agreement: A personal agreement or contract between an individual and an outside entity.

Project Summary: A detailed description of research (e.g., abstract, scope of work).

Public Health Service (PHS): An operating division of the U.S. Department of Health and Human services, and any components of PHS, including: Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), and all institutes and centers of the National Institutes of Health (NIH).

Purchasing (role): The ability an individual may have to direct or influence purchases made by the University or Health System or one of their constituent entities. Remuneration: Payment or compensation received for services or employment. See also Equity, Income and Royalty.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. This includes basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). Includes, but is not limited to, any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, for example a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Retrospective Review: A process by which the institution reviews an investigator's research to determine if there was any bias in the design, conduct, or reporting of that research, pursuant to federal regulatory requirements. When a financial conflict of interest is not disclosed or reviewed in a timely manner, the institution must complete a retrospective review of the research.

Royalty: A payment for the rights to use intellectual property, especially patented or copyrighted works. Royalty usually, but not always, is a percentage of income from sales of the licensed technology.

Spouse: A marriage partner.

Travel Expenses: For the purpose of disclosure under university policies on disclosure and professional commitment and conflicts of interest, this includes amounts reimbursed to a covered party by an outside entity for transportation and hotel accommodations or the value of transportation and hotel accommodations purchased by an outside entity on behalf of the covered party. Travel disclosures must include the purpose of the trip, name of the sponsor/organizer, destination, and duration of each occurrence, as well as the amount of reimbursement, and must only be made when the aggregate value of any travel sponsored or reimbursed by the entity over the preceding 12 months reaches or exceeds \$5,000.