

**Krieger School of Arts and Sciences
The Johns Hopkins University
Policy on Conflict of Commitment and Conflict of Interest**

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1. Preamble

The mission of the Krieger School of Arts and Sciences (KSAS) is both to create new knowledge related to the arts and sciences, and to propagate this knowledge through publications, patents, and educational programs. Essential to fulfilling this mission is the active participation of Academic Staff in research, which often involves interactions with government, industry, business, and other institutions. Hence, KSAS encourages its 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 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 KSAS, the University, and all its Academic Staff. The 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. The KSAS 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 KSAS Policy builds upon and implements the Johns Hopkins University Policy on Conflict of Interest and Conflict of Commitment and was developed in accord with the recently revised Johns Hopkins School of Medicine Policy on Conflict of Commitment and Conflict of Interest. Both the KSAS Policy and the School of Medicine Policy abide by federal regulations designed to protect research integrity and the safety of human subjects. The KSAS Policy will be reviewed regularly and, when necessary, revised to ensure that it remains in compliance with the University's policy and relevant federal regulations.¹

¹ Portions of this Policy also are drawn from Northwestern University's "Policy on Faculty Conflict of Commitment and Conflict of Interest." Permission granted by the Office of the Vice President for Research at Northwestern.

2. Summary

- This Policy applies to Academic Staff of the Krieger School, including faculty, researchers, postdoctoral fellows, research associates and assistants (including graduate students), teaching assistants, undergraduates working in research laboratories, as well as other professional and senior staff who are compensated for their services or otherwise supported by 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 financial interests, or that of their family or others, to the detriment of students, colleagues, funding agencies, or the University. Most conflicts arise when Academic Staff propose to do research within the University that may provide direct financial benefit to themselves or family members by virtue of ownership interest in a company.
- Conflicts are common and practically unavoidable in a research university. Hence, it is KSAS policy that conflicts be managed, supervised, or monitored whenever practical. However, some conflicts carry significant risks and therefore may not be manageable.
- Activities subject to review are divided into two categories. Category I activities have a moderate potential for conflict and are likely to be manageable. Category II activities have a high potential for conflict and are not likely to be manageable.
- Academic Staff must submit for review any agreement or arrangement that might pose a conflict before that activity is undertaken. The faculty annual report also requires reporting of external activities.
- Reports of potential conflicts of commitment or interest are reviewed by the KSAS Conflict Review Committee (CRC), comprised of senior KSAS faculty members. The CRC makes recommendations for conflict management or elimination to the Dean of Research. Issues solely related to employment status are forwarded directly to the Vice Dean for Faculty and Academic Programs.
- Academic Staff may appeal recommendations of the KSAS Conflict Review Committee or decisions of the Dean of Research to the Dean. 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 KSAS. ***“Academic Staff” includes tenured and tenure track faculty, members of the research staff (professors, scholars, scientists, and engineers with research titles), postdoctoral fellows, research associates and assistants (including full-time graduate students), teaching assistants, undergraduates working in research laboratories, as well as other professional and senior staff who are compensated or otherwise supported by KSAS for their services or who appear to act as agents of KSAS in using, controlling, or assigning to others the use of KSAS facilities and resources in the conduct of research. The immediate family of an Academic Staff member includes her or his spouse, domestic partner, and/or dependent children.***²

While the immediate family of Academic Staff are not covered by this Policy, according to federal regulations their financial and fiduciary interests must be reported.

The Policy on Conflict of Interest also applies to KSAS itself, insofar as specific financial or fiduciary interests of 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.

This Policy acknowledges that potential conflicts of interest 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 KSAS Conflict Review Committee (CRC), the Dean or his/her designee may request that the CRC review and provide advice concerning financial interests related to other activities.

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 culture of research 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

² Definitions appear in bold italics and pertain to capitalized terms used throughout this policy.

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 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, KSAS has experienced growth in entrepreneurial endeavors among Academic Staff and students. While KSAS encourages 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 their 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 are not 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 KSAS Policy is the reporting and review of activities that may pose a conflict. Conflict of Commitment and Conflict of Interest issues are reported to the KSAS Conflict Review Committee (CRC) for review and its recommendations are implemented by the Dean of Research. Conflict of Commitment cases relating solely to employment status are negotiated with the Vice Dean for Faculty and Academic

Programs. 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

Determination of whether a Conflict of Commitment or Conflict of Interest exists in a particular instance always will be a matter of judgment. While informal discussion with the Dean, Associate Dean, Department Chair, Center Director, and/or other KSAS or University representatives may provide guidance, Academic Staff must report in writing any activity that may conflict, or appear to conflict, with their primary commitment to the University. For this purpose, one should use the KSAS “Academic Staff Conflict of Commitment and Conflict of Interest Initial Report Form.” The responsibility for reporting potential Conflicts of Commitment or Conflicts of Interest rests with the individual. 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 the management, reduction, or elimination of the conflict. Consistent with Johns Hopkins’ research culture, the activities of Academic Staff must be governed by thoughtful and shared consideration of individual circumstances, rather than rigid rules. Consequently, Academic Staff are encouraged to provide the CRC with their own suggestions for conflict management. Nonetheless, a conflict may be so profound that the CRC recommends that the Academic Staff member not be allowed to participate in a particular transaction and/or activity.

5. Activities Exempt from Review

KSAS encourages its Academic Staff to engage in external professional activities that enhance their teaching, research, and service to the University. These activities should be reported following established KSAS procedures for annual reporting, but need *not* be reviewed before being undertaken unless the activity otherwise represents a conflict as detailed below. These external professional activities include, but are not limited to, service to public institutions, educational organizations, and professional societies. Specific examples include:

- Occasional lectures, colloquia, and seminars given at colleges, universities, meetings of professional societies, and organizations with which the Academic Staff member has no research relationship.
- Preparation of books, monographs and chapters.
- Preparation of textbooks and other pedagogical materials.
- Providing editorial services for educational or professional organizations.
- Peer review of articles and grant proposals.

- Membership on editorial boards.
- Service on advisory committees or evaluation panels for government funding agencies (e.g., NSF, NIH), nonprofit foundations, and educational organizations.

Such activities are desirable and bring honor and credit to the Academic Staff member and to the University, but excessive time devoted to these activities can compromise the Academic Staff member's ability to meet his/her obligations to Johns Hopkins. Hence, Academic Staff should be judicious in their acceptance of such activities, and in any event, the time should not exceed the limits given for consulting in Section 6.2. In addition, Academic Staff at ranks below full professor must consider the impact of secondary commitments on their ability to fulfill the criteria for promotion.

6. Conflict of Commitment

6.1 Definition

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 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 School.

Acceptance of a full-time appointment 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, KSAS expects 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.***

6.2 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 encouraged. 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. In this Policy, consulting includes a fee-for-service or equivalent relationship with a third party as well as entrepreneurial activities. 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 directly 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 KSAS 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 one day per week during the academic year and at times they are receiving their full-time salary.³ 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.

6.3 Activities Requiring Review

As noted above, Johns Hopkins has a tradition of excellence in both teaching and research. It also has a tradition of academic freedom with minimal rules and regulations. Maintaining this freedom requires that Academic Staff conduct themselves with the highest levels of integrity and recognize that they owe their primary intellectual and professional efforts to the University. Any relationship (or combination of relationships) that could potentially violate this principle is subject to review and requires approval of the Dean. Examples include:

- Faculty members who receive their full-time salary are allowed to consult or engage in entrepreneurial activity one day (ten hours) per week. 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 Research.

³ The one-day per week limit was approved by the Homewood Schools Academic Council on October 26, 1994.

- Academic Staff may not hold a substantive appointment at another academic institution without approval of the Vice Dean for Faculty and Academic Programs.
- Significant management roles (e.g., those that involve supervision of the work of others and/or day-to-day responsibility for operating decisions in another organization) often are demanding in terms of both time and energy. Accordingly, Academic Staff who wish to accept significant managerial responsibilities in another organization must negotiate an appropriate reduction in University responsibilities and compensation with the Vice Dean.

In addition, written agreements *must* be reviewed by the Dean of Research whenever the wording of the document creates a question about potential conflicts with university policies. Written agreements must be reviewed whenever:

- The Academic Staff member's relationship to the outside party might appear to influence the conduct of research within the University;
- The Academic Staff member's relationship to the outside party might appear to influence the conduct of University business with the outside party;
- The agreement provides for intellectual property rights to an organization other than the University;
- The agreement restricts the Academic Staff member's public reporting of information developed by the Academic Staff member under the agreement or of the existence of the agreement itself;
- The agreement involves the use of University facilities or resources; or
- The name, symbols, or logo of The Johns Hopkins University or the Krieger School of Arts and Sciences might be used by another party.

Academic Staff also have a responsibility to report their outside activities as part of their annual report. Academic Staff also may be requested by the Dean, Department Chair, or Center Director to report all outside activities in special circumstances such as appointment, promotions, administrative assignments, institutional clearance, certification of research, application of support for academic endeavors, purchases of equipment, or research proposals. Academic Staff are referred to the University's Policy on Conflict of Interest and Conflict of Commitment for additional information on these issues.

6.4 Recommended Review

In addition to the activities listed above which require review, KSAS recommends that Academic Staff review any agreement for professional services (including consulting) with the Dean of Research before the agreement is signed. This review is not meant to interfere with an Academic Staff member's legitimate outside activities or to invade his/her privacy. Rather, review of written agreements with outside entities will provide Academic Staff assurance that they are in compliance with University policies. Given the increasing complexity of such agreements, this recommended review also may assist Academic Staff in protecting their intellectual property rights and in identifying potential

legal liabilities. However, this review is not a substitute for legal counsel. Therefore, Academic Staff should not assume that their rights are being protected by this review and should consult with outside legal counsel if there are clauses in an agreement that are not understood fully.

7. Conflict of Interest

7.1 Definition

KSAS seeks to foster creativity and facilitate the translation of discoveries into technologies 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 investors. 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. Such conflicts also may place human research subjects at additional risk as well as reduce public confidence in research programs at KSAS.

This Policy is designed to maintain the trust of the public and the scientific community in KSAS’s research enterprise and to support University compliance with applicable government regulations.⁴ 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.

7.2 Review of Activities

In keeping with Johns Hopkins’ tradition of faculty governance, all potential Conflicts of Interest are reviewed by the KSAS Conflict Review Committee (hereafter CRC), which is a standing body consisting of senior faculty of KSAS. The CRC is charged with maintaining the integrity of the research process by management, whenever feasible, or elimination of conflicts that might compromise, or appear to compromise, the conduct of research. The CRC will recommend to the Dean of Research whether the proposed arrangements should be allowed or not. The CRC may recommend either procedures for

⁴ This Policy on Conflict of Interest is to be interpreted in a manner consistent with the Conflict of Commitment principles presented earlier.

management of the Conflict of Interest or, when the circumstances are such that the conflict cannot be managed effectively, may recommend not allowing the proposed research activity.

Review is required regardless of the value of the financial interest in question; there is no "de minimis" level below which review is not required. Financial interests of one's spouse, domestic partner, and dependents must be reported as though they are one's own. Individuals who are aware of significant relevant financial interests of other family members (e.g., parents, adult children, or siblings) that might present the appearance of a Conflict of Interest should report such interests, but Academic Staff are not required to inquire into the detailed personal matters of others.

All of the arrangements described below must be reviewed by the CRC before any grants, contracts, licenses, or any other agreements are negotiated. For ease of reference, activities are divided into two categories.⁵ ***Category I activities generally have a moderate potential for conflict and are likely to be manageable. Category II activities have a high potential for conflict and are not likely to be manageable.*** These categories and the activities listed below are intended for use only as guidelines and do not indicate whether a particular activity will be allowed. The CRC reviews cases on an individual basis and makes recommendations based on the particulars of each situation. Hence, depending on the circumstances, certain Category I activities may not be allowed, while some Category II activities may be allowed in exceptional circumstances or in the presence of compelling justification.

7.3 Category I: Activities with a Moderate Potential for Conflict

7.3.1 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, a Conflict of Interest arises because the Academic Staff member might participate in and benefit from both sides of the negotiation. In such situations, the Office of Licensing and Technology Development will forward the proposed licensing agreement and financial details to the CRC for review. Experience has shown that such situations usually can be managed if the Academic Staff member is willing to 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.)

7.3.2 Royalties

⁵ This is not an exhaustive list of activities or arrangements that may require review. Academic Staff who have financial interests not specifically listed in this section that may pose or appear to pose a conflict must report them to the Dean of Research.

A Conflict of Interest arises whenever research is conducted that could affect the value of a product for which an Academic Staff member receives, or is entitled to receive, royalties. Therefore, proposals to conduct research on topics related to intellectual property licensed by the University must be reviewed regardless of the source of financial support for the research. However, a compelling justification may exist that allows such research to occur despite the conflict. For example, the Bayh-Dole Act obligates institutions to attempt to commercialize inventions resulting from federally funded research and to distribute a portion of the royalty income from marketed products to inventors. The public policy objective of this Act and the eventual recognition of the value of an innovation to the public may, in the judgment of the CRC, constitute compelling justification to permit a potential future financial interest concurrent with sponsored research. Other examples where research may be conducted on licensed intellectual property include research on processes or on commodity products that are in competitive markets.

7.3.3 *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. Except for those situations stipulated in Section 7.4, these arrangements usually can be managed.

- A. Any proposal for licensing an Academic Staff member's invention when the Academic Staff member, either directly or through 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 KSAS, holds equity or will hold equity (e.g., stock options) in a company supporting the research, or a company whose technology is a subject of 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.

7.3.4 *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. Hence, any proposal to conduct such research must be

reviewed. This includes, but is not limited to, income for consulting, advisory or lecturing services, honoraria, and in-kind support. This does not include payment to the University to support the cost of specific research projects (e.g., grants or contracts).

7.3.5 Proposals for Outside Support

Information Sheets are required by the Research Projects Administration in conjunction with applications for outside funding, including questions concerning relevant financial interests. If an Academic Staff member has a relevant financial interest, as described above, the appropriate questions on the Information Sheet must be answered in the affirmative. All proposals with affirmative answers will be referred to the CRC for review.

7.3.6 Written Agreements with Outside Entities

As outlined above in section 6 on Conflict of Commitment, all proposed written agreements with outside entities where the relationship of an Academic Staff member to the outside party might appear to influence the conduct of research within the University must be reviewed by the Dean of Research.

7.3.7 Appointment Letters

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

7.3.8 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.

7.4 Category II: Activities with a High Potential for Conflict

Some activities pose a high potential for conflict and are not likely to be manageable; however, in keeping with Johns Hopkins' unique research culture, the CRC considers each situation individually. Hence, situations involving Category II activities may be allowed in exceptional circumstances or in the presence of compelling justification. Such exceptions require that the conflict be managed with particular care on the part of all parties concerned.

7.4.1 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 policy⁵, maintains beneficial ownership of more than ten percent (10%) of the company or one of its affiliates, where beneficial ownership is defined as the aggregate of stock, options, warrants, and other ownership instruments.

7.4.2 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.

7.4.3 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 Dean of Research. 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

⁶ Such ownership interest remains subject to applicable University policies on intellectual property and Conflict of Interest.

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.

7.4.4 Human Subjects Research

Johns Hopkins is committed to protecting the rights and safety of human research subjects. Even the appearance of a conflict in regard to human subjects research is extremely damaging to research integrity and the reputation of Johns Hopkins and its Academic Staff. Therefore, in general, Academic Staff may not participate in research projects involving human subjects while having a significant financial interest in the research project or in a financially interested company. This prohibition may not apply to projects that the Institutional Review Board (hereafter IRB) determines to meet the definition of "no more than minimal risk" to research subjects or which the CRC considers to be low risk, such as conducting studies on tissue samples. In such cases, an exception to the prohibition may be granted if an Academic Staff member provides the CRC with a compelling justification for participating in a specific research project while having a significant financial interest. See Appendix A for details.

7.4.5 Involvement of Students and Support Staff in External Commercial Activities

The integrity of the University as a community of scholars requires the free and open exchange of ideas and research results. Students, postdoctoral scholars, and collaborators must be able to pursue topics of interest, have access to available information and facilities, and be able to communicate the results of their work to other scholars and the public. Therefore, 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, support staff, and collaborators is not exploited. Hence, the involvement of University students or employees in the external compensated or commercial activities of Academic Staff must be reviewed by the CRC.

Students. Part-time involvement of students in the consulting or commercial activities of Academic Staff may, under certain conditions, offer the potential for substantial benefits to the education of the student. (In this context, "involvement" means any substantive activity, whether paid or unpaid.) Student involvement in such activities can provide them with experience and financial support not otherwise available. In considering such arrangements, Academic Staff will be guided by the need to avoid infringement upon the student's academic duties and rights. 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.

Hence, in most cases, 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. Each case is

considered on an individual basis, however, and exceptions may be made in certain circumstances (e.g., cases involving critical sources of financial support for students). When such involvement is allowed, written agreements will be drawn up to protect the rights of all parties. Academic Staff must inform students and collaborators in writing of their personal commercial interests in a research project. Students and collaborators also must sign an agreement with the Academic Staff member indicating they fully understand the circumstances of their work for the Academic Staff member. This agreement also will include details concerning the ownership of intellectual property, consistent with the Johns Hopkins University Intellectual Property Policy. Signed copies of this agreement will be retained by the Academic Staff member, students and/or support staff, and the Dean of Research.

If Academic Staff already are associated with students in commercial activities (e.g., common involvement in a start-up company), they should disqualify themselves from becoming research supervisors, academic program advisors, or examiners for an advanced degree for those students. Within a Johns Hopkins research laboratory or other academic unit, Academic Staff should take care not to give the impression of favoritism to those students with whom they are associated in outside activities.

Support staff. 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 discouraged, but may be allowed in extraordinary circumstances. When no such relationship exists, it may be appropriate for support staff to assist Academic Staff in their external compensated and/or commercial activities, depending upon the nature and extent of the support staff involvement. However, any support staff involvement must be reviewed by the CRC and, if approved, the appropriate parties must sign a written agreement describing this involvement. Academic Staff may not require support staff to perform duties related to their personal and nonprofessional activities.

7.4.6 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 use University resources, including facilities, equipment, computers, or confidential information, for non-University purposes. 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 Dean of Research 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 Reporting and Review

8.1 Reporting

As detailed in Sections 6 and 7, all activities that pose or may appear to pose a Conflict of Commitment or Conflict of Interest must be reported to the office of the Dean of Research (DOR) for review. Academic Staff also are encouraged to review all written agreements with outside entities related to professional activities in their field or discipline with the DOR. Academic Staff should use the KSAS “Academic Staff Conflict of Commitment and Conflict of Interest Initial Report Form” provided by the DOR to prepare their initial report. Copies of all proposed agreements and other relevant documentation must be attached to this report. Reports will be promptly assessed by the DOR’s office to determine if the matter requires review by the CRC. If the matter is deemed inconsequential, the Academic Staff member will receive a letter from the DOR allowing the activity with the condition that any changes be reported.

Any agreements that have the potential to pose or appear to pose a conflict will be forwarded to the CRC for review. The Academic Staff member may be asked to provide additional information and/or materials to assist the Associate Dean or the CRC in their assessment. Academic Staff also are strongly encouraged to provide their own suggestions for mitigating or managing any real or perceived conflict(s).

Conflict of Commitment cases solely concerning the employment status of an Academic Staff member will be reviewed by the Vice Dean for Faculty and Academic Programs in

consultation with the Department Chair or Center Director, when appropriate. In those cases where there are limitations on what activities an Academic Staff member can undertake, a written agreement will be signed and copies retained by the Vice Dean and the Academic Staff member that details an acceptable arrangement. Decisions of the Dean are final. Academic Staff can request a reexamination of the issue, but cannot appeal the resulting decision.

Cases concerning the KSAS Dean and Associate Deans will be reviewed by the CRC. In those cases involving an Associate Dean, the Committee's recommendation and relevant case materials will be forwarded to the Dean. In those cases involving the Dean, the Committee's recommendation and relevant case materials will be forwarded to the Provost.

8.2 Review

In keeping with the University's traditions of academic freedom and faculty governance, the KSAS's Conflict Review Committee (CRC) is a standing body made up of senior Academic Staff of KSAS. The DOR is an ex officio, non-voting member of the CRC. Other members of KSAS or University administration may be asked to attend meetings to provide guidance or to answer questions (e.g., the Associate Dean of Academic Affairs for cases involving students), but do not vote. The CRC reviews information related to all financial and/or fiduciary arrangements in light of related research activity. In its review, the CRC considers the risks the proposed activity poses to the rights and obligations of collaborators and students participating in research; to the rights and safety of human research subjects (see Appendix A); and to the academic, research, and educational missions of the University. The CRC also considers the impact on the availability of research results to the scientific community and on the integrity of research results. The appearance of a Conflict of Commitment or Conflict of Interest also is an important factor in the CRC's review.

The CRC meets as necessary, and all cases will be reviewed in a timely fashion to ensure that the research activities of Academic Staff are not inconvenienced unduly. KSAS understands, however, that some situations arise quickly and the usual review process might cause problematic delays. In such circumstances, Academic Staff may request the DOR to make an interim decision pending the next meeting of the CRC and full review of the case.

In agreements and contracts related to the arrangements under review by the CRC, the University requires terms that ensure the freedom of timely and unhindered publication of results, uphold the rights of students and postdoctoral fellows, and ensure appropriate reporting of inventions and assignment of intellectual property rights.

8.3 Management Recommendations

Upon completing its review, the CRC will recommend to the Dean of Research 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 Dean of Research 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 Dean of Research 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 Dean of Research 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:

8.3.1 *Disclosure* - Disclosure is required in every case approved by the Dean of Research, including: i) public disclosure of the financial interests of the investigator and of 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;

8.3.2 *Restriction on Equity* - i) placement of stock in escrow until a time specified by the CRC; or ii) requirement that options, warrants, and similar instruments not be exercised without the prior permission of the CRC;

8.3.3 *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);

8.3.4 *Oversight* - appointment of a disinterested individual or group to monitor the relevant research activity. An oversight committee will be charged, at a minimum, with reviewing abstracts and manuscripts before they are submitted for publication to ensure 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 Dean or Associate Deans, the individual or group monitoring the activity shall be appointed by and report to the Vice Provost for Research.

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

8.3.6 *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.

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.

8.4 Implementation of Recommendations

The Committee's recommendations will be presented to the Academic Staff member in the form of a written agreement, signed by the Dean of Research. The Academic Staff member will be asked to sign two copies of the agreement thereby indicating his/her acceptance of the CRC's recommendations. One copy of the agreement will be kept on file in the DOR's office and the other may be kept for the Academic Staff member's own records.

8.5 Appeals

If an Academic Staff member believes that a recommendation made by the CRC in a specific case or decision by the Dean of Research is not appropriate or is based on erroneous information, the Academic Staff member may request an additional CRC review by submitting a written request to the Dean of Research. If, after a second review by the CRC and second decision by the Dean of Research, the Academic Staff member still wishes to appeal, then he/she may appeal to the Dean. The decision of the Dean shall be final.

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

9. Sanctions

Failure to comply with the KSAS Policy on Conflict of Commitment and Conflict of Interest and with CRC recommendations adopted by the Dean or Associate Dean and, if warranted, IRBs, is subject to review under KSAS's "Policy on Integrity in Research." Potential sanctions under these policies range from a reprimand by the Dean and placement of a letter in the Academic Staff member's file, to suspension for a specified period of time, to termination.

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

Although all financial interests are subject to reporting and review, only 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);

⁷ This section of the KSAS 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.

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;

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*: Research Project Notification (RPN) forms submitted to the Joint Committees on Clinical Investigation (JCCIs) and Johns Hopkins Bayview Institutional Review Boards (Bayview IRBs) (together, "institutional review boards" or "IRBs") include a question concerning relevant financial interests. If an Academic Staff member has a relevant financial interest, as described above, the question on the RPN form must be answered in the affirmative. All RPNs containing an affirmative answer to the

question concerning relevant financial interests will be referred to the 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 Dean of Research.

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 Associate Dean for Dean and to the appropriate IRB. The Dean of Research 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 Dean of Research 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.

1. 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." (Source: "Objectivity in Research." NIH. <http://grants.nih.gov/grants/guide/notice-files/not95-179.html>. July 14, 1995).

2. 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).

3. 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.

4. 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.