

---

**THE POLICY ON CONFLICT OF INTEREST<sup>6</sup> CONTAINS THE FOLLOWING SECTIONS:**

- A. General Principles**
- B. Arrangements Requiring Review by the Committee on Outside Interests**
- C. Mechanisms for Required Reporting to the Committee on Outside Interests**
- D. Review and Management of Conflicts of Interest**
- E. Special Considerations for Review and Management of Conflicts of Interest in Human Subjects Research**
- F. Legal Obligations**
- G. Appeals**
- H. Sanctions for Failure to Comply**
- I. Definitions**

**A. GENERAL PRINCIPLES**

- 1. All financial and fiduciary interests that might appear to present a conflict of interest related to research activities must be reported to and reviewed by the Committee on Outside Interests (Committee).**
- 2. There is no “de minimus” level below which a financial interest is exempt from reporting.**
3. The Committee may recommend either prohibition of the proposed research activity or procedures for management of the conflict of interest.
4. It is presumed that covered parties 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 presumption may not apply to projects that the IRB determines to meet the definition of “no more than minimal risk” to research subjects or which the Committee considers to be low risk, such as conducting studies on tissue samples.) Exceptions may be granted if an investigator provides the Committee with a compelling justification for participating in a specific research project while maintaining certain significant financial interests.
5. Covered parties are additionally responsible for complying with the requirements set forth in the School of Medicine’s policy on conflict of commitment. This policy on conflict of interest is to be interpreted in a manner consistent with the policy on conflict of commitment.

---

<sup>6</sup> Terms used in this policy are defined in Section I.

## **B. ARRANGEMENTS REQUIRING REVIEW BY THE COMMITTEE ON OUTSIDE INTERESTS**

The arrangements described below must be reviewed by the Committee at the time they are proposed. The Committee will recommend to the Dean whether the Dean should approve or disapprove the proposed arrangements. If the Committee recommends approval, it will also recommend conditions for management of the conflict of interest. For additional procedures related to human subjects research proposals, see Section E. Review is required regardless of the value of the financial interest in question; there is no “de minimus” level below which review is not required. Financial interests of one’s spouse, domestic partner, and dependents must be reported as though they were 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 are not expected to inquire into the detailed personal matters of others.

### **1. Royalty**

- a) Proposals to conduct research (regardless of the source of external research support, if any) when the research will be performed by a covered party who receives, or is entitled to receive, royalty from the sale of products, the value of which may reasonably appear to be materially affected by the research. 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.<sup>7</sup>
  
- b) University proposals to license inventions to outside entities.

---

<sup>7</sup> Royalty interests arising from post-marketing sales of approved products are an example of a financial interest that promotes translational research and may be amenable to successful management. To encourage the development of new products, 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. This public policy objective of the Act and the eventual recognition of value of the innovation to the public may, in the judgment of the Committee, constitute compelling justification to permit a potential future financial interest concurrent with human subjects research, subject to appropriate and extensive management conditions. The foregoing may not be interpreted so as to eliminate reporting obligations, limit the Committee’s ability to restrict or prohibit these arrangements, or to determine what constitutes a compelling justification. See Section E for Special Considerations for Review and Management of Conflicts of Interest in Human Subjects Research.

---

## 2. Equity<sup>8,9</sup>

- a) Any proposal for licensing a covered party's invention when the covered party, either directly or through the School of Medicine, 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, if any) involving a covered party who, either directly or through the School of Medicine, holds equity (e.g., stock, options) or will hold equity in: a) a company supporting the research, or b) 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 School of Medicine-based or personal licensing agreement, through inheritance, or as the result of an arms-length purchase;
- c) Any proposal by a covered party 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.
- d) Diversified financial holdings that are not controlled, influenced, or managed by a covered party (e.g., mutual funds) are not considered a relevant financial interest and need not be reported.

## 3. Income/Payments

Any proposal to conduct research that may affect the value of a company or entity from which one receives or is entitled to receive income. 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 institution to support the cost of specific research projects (e.g., grants or contracts).

## 4. Other

- a) Any proposal by a covered party to have a management position, board of directors seat, or other fiduciary role in any organization (non-profit or for profit) whose activities could reasonably be interpreted as related to the University role or activities of the covered party.

---

<sup>8</sup> The term equity also applies to equity instruments such as stock options and warrants, as well as to ownership interests.

<sup>9</sup> The term equity does not include ownership of diversified mutual funds.

- 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.

## C. MECHANISMS FOR REQUIRED REPORTING TO THE COMMITTEE ON OUTSIDE INTERESTS

Covered parties have an affirmative duty to report annually all relevant financial interests, as described in Section B above, to the appropriate institutional officials. Updated reports must be submitted as financial interests change. Reports of the arrangements also are required in connection with specific activities described below.

### 1. Proposals for Outside Support

Information Sheets are required by the Office of Research Administration in conjunction with applications for outside funding. Those forms include questions concerning relevant financial interests. If a covered party has a relevant financial interest, as described in Section B, above, the appropriate questions on the Information Sheet must be answered in the affirmative. All proposals with affirmative answers will be referred to the Committee for review.

### 2. Human Subjects Research

- a) Local IRBs: Protocol applications submitted to the Johns Hopkins Medicine Institutional Review Boards ("JHM IRBs") include a question concerning relevant financial interests. If a covered party has a relevant financial interest, as described in Section B, above, the question on the application must be answered in the affirmative. All protocol applications containing an affirmative answer to the question concerning relevant financial interests will be referred to the Committee for review.
- b) 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 Committee review by submitting the proposed protocol directly to the Committee. The Committee review must be completed before the principal investigator submits the protocol to the outside IRB. Procedural questions should be directed to the Office of Policy Coordination.

---

### **3. Written Agreements with Outside Entities**

As outlined in the Policy on Conflict of Commitment, all proposed written agreements with outside entities must be submitted to the Office of Policy Coordination. All written agreements must be reviewed, regardless of the level of compensation to the covered party. If a covered party serving as a consultant or scientific advisor proposes to participate in research that is sponsored by the consulting client or involves a product of the consulting client, the proposed consulting activity requires Committee review.

### **4. Technology Transfer**

When a covered party proposes to participate in a license agreement between the School of Medicine and an outside entity, Johns Hopkins Technology Transfer (JHTT) office will report the proposed financial interests of the covered parties to the Office of Policy Coordination for review by the Committee. Institutional financial interests in licensed technology are subject to review by the Committee.

### **5. Appointment Letters**

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

If a covered party has a financial interest that is potentially a source of bias or perceived bias in research and has not reported that interest through one of the mechanisms listed above, the covered party must make a report to the Dean through the Office of Policy Coordination.

## **D. REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST**

### **1. Review**

The Committee reviews information related to all financial and/or fiduciary arrangements in light of related research activity. In its review, the Committee considers the following factors:

- a) impact on the integrity of research data;
- b) risks to the rights and safety of human research subjects (see Section E, “Review and Management of Conflicts of Interest in Human Subjects Research”);

- c) risks to the rights and obligations of students and trainees participating in research;
- d) impact on the availability of research results to the scientific community for use in the public interest;
- e) appearance of a conflict of interest.<sup>10</sup>

## 2. Determination/Management

Upon completing its review, the Committee will recommend to the Dean that the proposed arrangements be either a) prohibited, or b) permitted, subject to specific management conditions. After reviewing the recommendation of the Committee, the Dean will render a final decision and will communicate that decision, with a description of any specific management conditions, to the involved covered party in writing. The Dean shall report his decision in each case to the Committee.

For proposed arrangements involving human subjects research, the Committee will make a recommendation to the Dean and to the IRB. This procedure is described more fully in Section E.

If the Committee determines that a conflict of interest may be permitted, it will recommend that management of the conflict of interest be implemented using, for example, one or more of the following:

- a) Disclosure - Disclosure is required in every case approved by the Dean, including: i) public disclosure of the financial interests of the investigator and of the School of Medicine, if applicable, in all relevant publications, presentations (whether or not academic presentations), including presentations at the level of the covered party's primary department or higher, and 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;
- b) Restriction on Equity - i) placement of stock in escrow until a trigger date specified by the Committee, as outlined in The Johns Hopkins University School of Medicine Intellectual Property Guidelines and associated policies, or ii) requirement that options, warrants, and similar instruments not be exercised without the prior permission of the Committee;<sup>11</sup>

---

<sup>10</sup> In agreements and contracts related to the arrangements under review by the Committee, the Institution will require terms that ensure the freedom of timely academic publication, uphold the rights and responsibilities of students and trainees, and ensure appropriate reporting of inventions and assignment of intellectual property rights.

<sup>11</sup> Covered parties should be aware that separate Securities and Exchange Commission and other state and federal regulations may apply to their ownership of such equity. Obtaining the necessary information and complying with such regulations is the responsibility of the covered party.

- 
- c) 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 i) serve as principal investigator, ii) analyze data, iii) determine whether potential subjects are eligible for enrollment, iv) solicit consent, or v) determine whether an adverse event report is required;
  - d) Oversight - appointment of a disinterested individual or group to monitor the relevant research activity. An oversight committee might 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 other cases, an oversight committee might meet quarterly and review protocols, subject accrual, complications, and other issues as appropriate;
  - e) Divestiture - allow arrangements to go forward contingent upon the sale or disposal of specified financial interests to eliminate or reduce the financial conflict of interest by a certain date;
  - f) 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 Committee may recommend other conditions or restrictions on the proposed arrangements if, in its view, such conditions or restrictions will contribute to the elimination, reduction, or management of the conflict of interest.

## **E. SPECIAL CONSIDERATIONS FOR REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH<sup>12</sup>**

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

Covered parties are required to report all financial interests in human subjects research. It is presumed that individuals (faculty, staff, trainees, students, administrators, and researchers) may not participate in research projects involving human subjects while they have a significant financial interest in the research

---

<sup>12</sup> In preparing this Section of the Policy, 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.

project or in a financially interested company. (This principle may not apply when the proposed research activity involves “no more than minimal risk” to research subjects.) Exceptions may be made in specific cases when, in the judgment of the Committee, individuals holding significant conflicting financial interests provide the Committee with a *compelling justification* - consistent with the rights and welfare of human research subjects - for being permitted to simultaneously hold the financial interest and participate in the human subjects research project. If a covered party 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 covered party has a significant financial interest, as defined below, the research project will be not presumed to be prohibited. Such a determination by the IRB may be judged by the Committee a “*compelling justification*” for permitting participation in a human subjects research project by covered parties with significant financial interests. Although the arrangements will not be presumptively prohibited, the research project will still be subject to review by the Committee.

## 1. Significant Financial Interests

Although all financial interests are subject to reporting and review, only significant financial interests are presumed to be prohibited. (N.B.: financial interests below the thresholds listed below are not exempt from reporting.) Significant financial interests include:

- a) 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 in a given twelve month period, excluding reimbursement of expenses such as travel expenses incurred as a direct result of performing consulting services;
- b) An equity interest of any amount, including stock options or warrants, in a non-publicly-traded financially interested company (or entitlement to the same);
- c) An equity interest, including stock options or warrants, (or entitlement to the same) in a publicly-traded financially interested company that exceeds \$25,000<sup>13</sup> 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 covered party must notify the IRB.) This does not apply to diversified mutual funds or similar instruments in which the shareholder has no control over the equities held

---

<sup>13</sup> 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.

---

by the fund. Equity holdings worth less than \$25,000 and rights to acquire additional equity will nevertheless be subject to restrictions;

- d) 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 Institution;<sup>14</sup>
- e) 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 Section E above) to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested company or from the Institution;
- f) 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.<sup>15</sup>
- g) 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.

## **2. Review and Determination/Management**

As described in Section E, the Committee will review reports of proposed financial interests in human subjects research projects. Recommendations concerning the covered party’s relationship to the outside entity will be communicated in writing to the Dean and to the appropriate IRB. The Dean will communicate his decision concerning the covered party’s relationship with the outside entity to the covered party

---

<sup>14</sup> 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. To encourage the development of new products, 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. This public policy objective of the Act and the eventual recognition of value of the innovation to the public may, in the judgment of the Committee, constitute compelling justification to permit a potential future financial interest concurrent with human subjects research, subject to appropriate and extensive management conditions. The foregoing may not be interpreted so as to eliminate reporting obligations, limit the Committee’s ability to restrict or prohibit these arrangements, or determine what constitutes a compelling justification.

<sup>15</sup> 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 in Footnote 14.

in writing. Never-theless, 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 covered party in the human subjects research protocol. Accordingly, the IRB will communicate its decision concerning participation in the human subjects research protocol to the covered party and will provide a copy of that communication to the Committee.

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 Committee review and the Committee may review the project as if it were “human subjects research” for the purposes of this Section.

The Committee’s recommendation may involve either prohibition or management. These options are described below.

- a) **Prohibition:** If, upon reviewing specific evidence provided by the covered party with the relevant financial interest, the Committee believes that a conflict of interest is incompatible with human subjects research, it will recommend to the appropriate IRB that the involved covered party be required to eliminate the relevant financial interest before beginning the project or be barred from participation in the research.
- b) **Management:** In cases involving non-significant financial interests, the Committee will generally recommend that the covered party 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 Committee concludes that the justification provided by the covered party 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 covered party 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 covered party may not be allowed to i) serve as principal investigator, ii) analyze data, 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, as detailed in Section D, may also be recommended.

---

The Committee'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 Committee 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 will then communicate its determination to the covered party in writing. Upon concluding its evaluation, the IRB will inform the Dean and the Committee of its determination, but the IRB's decision will be final.

## **F. LEGAL OBLIGATIONS**

Covered parties should be aware that as a result of their financial interest or fiduciary role in a company they might 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 institution 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.<sup>16</sup> For a copy of the complete regulations, contact the Office of Policy Coordination.

### **2. U.S. Food and Drug Administration (FDA)<sup>17</sup>**

The FDA requires applicants, under various regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), to submit to 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. For a copy of the complete policy, contact the Office of Policy Coordination. Individuals holding Investigational New Drug applications (IND) applications and Investigational Device Exemptions should consult FDA concerning applicable rules and regulations.

---

<sup>16</sup> "Objectivity in Research." NIH. <http://grants.nih.gov/grants/guide/notice-files/not95-179.html>. (July 14, 1995)

<sup>17</sup> "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 covered parties who hold equity in a financially interested company. For additional information, covered parties should seek advice from personal counsel. It is the obligation of the financially interested individual to ensure compliance 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 the Office of Research Administration.

## **G. APPEALS**

If a covered party believes that a determination made by the Committee in a specific case and adopted by the Dean or an IRB is not appropriate or is based on erroneous information, the covered party may request additional Committee review by submitting a written request to the Vice Dean for Research. If, after a second review by the Committee and second determination by the Dean, the covered party still wishes to appeal, the covered party may appeal to the University Provost. The decision of the Provost shall be final.

In the event the Dean decides not to adopt a Committee recommendation and the Committee wishes to appeal that decision, it may appeal to the University Provost. The decision of the Provost shall be final.

Covered parties 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.

## **H. SANCTIONS FOR FAILURE TO COMPLY**

Failure to comply with the policies on conflict of commitment and conflict of interest and with Committee recommendations adopted by the Dean and IRBs is subject to review under the School of Medicine's Procedures for Dealing with Issues of Professional Misconduct and the Procedures for Dealing with Issues of 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.

---

## **I. DEFINITIONS**

### **1. Committee on Outside Interests (the Committee)**

The Committee is a standing body consisting of senior faculty members of the School of Medicine and the University as well as senior members of the University administration, serving ex officio. The Committee includes at least one member who also is a member of a School of Medicine institutional review board (IRB) or has served on a School of Medicine IRB. In addition, the Committee includes at least one senior faculty member from outside the School of Medicine.

### **2. Covered Party**

Those covered by the Policy on Conflict of Interest include faculty, staff, trainees, students, administrators and researchers who are compensated or otherwise supported by The Johns Hopkins University School of Medicine for their services or who appear to act as agents of the School of Medicine in using, controlling, or assigning to others the use of School of Medicine facilities and resources in the conduct of research. Johns Hopkins Health System staff who are participating in research under the auspices of the School of Medicine also are considered covered parties. While the spouse, domestic partner, and minor dependents of those listed above are not considered covered parties, their financial and fiduciary interests must be reported in accordance with this policy.

This policy on conflict of interest also applies to the Institution itself, insofar as specific financial or fiduciary interests of the 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, income from royalty or equity interests obtained as a result of licensing technology to outside entities and income or other financial interests obtained through outside consulting. This policy will be interpreted in a manner consistent with The Johns Hopkins University's Intellectual Property Guidelines and the policies encompassed by those Guidelines.)

This policy acknowledges that potential conflicts of interest may exist, for both covered parties and the Institution, with respect to activities that, in the determination of the Committee, do not involve research. An example of such activity would be procurement. Accordingly, although conflict of interest in research is the focus of the Committee, the Dean may request that the Committee review and advise him concerning financial interests related to other activities.

The policy shall be interpreted in a manner consistent with applicable federal and state statutes and implementing regulations.

### 3. Fiduciary Role

A fiduciary role refers to a legal and/or ethical obligation on the part of a covered party to act in the best interests (i.e., the financial success) of another. Examples of fiduciary roles include, but are not limited to:

- Membership on a board of directors
- Management role in a company or partnership

### 4. Financially Interested Company

Financially interested company means a commercial entity whose financial interests would reasonably appear to be affected by the conduct or outcome of the research. Examples include, but are not limited to, companies that hold patent rights for discoveries, drugs or devices being studied in research protocols or companies that provide financial or in-kind support for research projects. This term includes companies that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered party knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).

### 5. Research/Conducting Research

“Research” shall mean any organized program of scientific inquiry. “Conducting Research” includes designing research, directing or serving as an investigator, performing laboratory experiments, having a role in soliciting consent from research subjects or making decisions related to eligibility of patients to participate in research, analyzing or reporting research data, or submitting manuscripts or abstracts concerning the research for publication. Examples include, but are not limited to, projects for which outside support is requested and projects for which approval of an IRB is required. For purposes of this policy, the determination of what constitutes research and what constitutes the conduct of research shall be made by the Committee, although such determinations shall be consistent with Section 6, below.

### 6. Human Subjects Research

Human subjects research includes all research meeting the definition of “research” performed with “human subjects” as defined in the Federal Common Rule (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. In the event that the Common Rule definitions of “human subject” or “research” are modified through rulemaking,

---

any such revisions shall apply for the purposes of this policy. See Section E for special considerations related to human subjects research.

**7. Institution**

Institution means The Johns Hopkins University School of Medicine.