Appendix C

Hospital for Special Surgery

Policies on Conflicts of Interest

Policy on Conflicts of Interest in Research Activities

A. Introduction

Hospital for Special Surgery (HSS) is committed to the highest standards of conduct in research in support of HSS' core mission. Relationships with the commercial sector can play an important role in supporting HSS' research mission, and Institutional and individual Financial Interests, such as gifts, payments, royalty income, and equity, may arise in the normal course of research operations at HSS. However, these Financial Interests should not be permitted to compromise HSS' standards or integrity or unduly influence decisions in any activity at HSS, including research, and circumstances in which the existence of such financial interests might create the appearance of a conflict of interest should be identified and addressed.

To support and promote integrity and advance HSS' mission, HSS recognizes that potential conflicts of interest between HSS' primary objectives and the Financial Interests of HSS and individuals at HSS must be identified and properly managed with appropriate policies and procedures. In order to do this, HSS has established a system of disclosure requirements for all financial interests. Disclosure of relevant Financial Interests is critical to the integrity of the proposed research. It enables HSS to determine whether a potential conflict of interest exists and if so, how that conflict (whether actual or perceived) may be managed and monitored to assure that the research is conducted with objectivity and integrity, and that the results of the research are perceived as objective and reliable.

This Policy on Conflicts of Interest in Research Activities sets forth policies and procedures pertaining to the management of potential conflicts of interest in all research activities at HSS. This Policy applies to all research at HSS, whether or not supported by government or private sponsors.

With respect to research funded by the Public Health Service of the U.S. Department of Health and Human Services (PHS) and any component of the PHS to which the authority involved may be delegated, including the National Institutes of Health, this Policy addresses the requirements of the PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50,

Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) (collectively, the "PHS FCOI Rule"); and Grants and Agreements Conflict of Interest (2 C.F.R. Subpart B Section 200.112) .

This Policy on Conflicts of Interest in Research Activities is part of the following set of policies that together comprise HSS' Policies on Conflicts of Interest:

Guiding Principles and Index to Underlying Policies
Appendix A Policy on Conflicts of Interest in Day-to-Day Operations
Appendix B Policy on Conflicts of Interest in Patient Care
Appendix C Policy on Conflicts of Interest in Research Activities
Appendix D Policy on Conflicts of Interest in Education & Academic Affairs Activities
Appendix E Policy on Outside Consulting by HSS Employees
Appendix F Conflicts of Interest Glossary of Terms

HSS employees and members of the HSS Research Institute Staff, Medical Staff, and Allied Health Professional Staff who are engaged in research activities are also required to comply with HSS' other Policies on Conflicts of Interest, including making the annual disclosure of Financial Interests, and updating that disclosure from time to time as necessary to reflect changes in those interests, in accordance with the Policy on Conflicts of Interest in Day-to-Day Operations.

B. Investigator Relationships with Sponsors of Research

1. **Mandatory Disclosures of Potential Conflicts of Interest (COI): Investigators who have any Financial Interest that might present an actual or perceived COI related to research activities or Institutional Responsibilities must report the potential COI to the Conflict of Interest Committee for Research ("COIC-Research"). All disclosures shall be made electronically to HSS via the electronic reporting system as** designated by HSS. The COIC-Research will use reasonable efforts to limit access to information about disclosed, potential COI to those on a "need to know" basis, subject to any disclosures necessary to effectuate this Policy or to comply with applicable law (including the PHS FCOI Rule). If deemed necessary to evaluate the relationship with industry, Investigators may be required to provide relevant information, including, but not limited to, compensation, projected future compensation, and the contract between the Investigator and the Company.

   Note that existing PHS conflict of interest regulations are applicable to payments that may be received from foreign universities, research organizations, and government agencies. While it is expected that investigators may be invited to speak at or participate in activities with a foreign institution, it is necessary to disclose all financial interests, payments, or support, including stipends and honoraria, that are received directly from foreign universities and government

agencies.

2. Composition of the COIC-Research: The COIC-Research will be composed of the following individuals: (1) the Vice President, Research Administration, (2) the Medical Director of Clinical Research, and (3) the Chief Scientific Officer; provided, however, that only the Medical Director of Clinical Research will participate in COIC-Research deliberations and determinations regarding Human Subjects Research, and only the Chief Scientific Officer will participate in COIC-Research deliberations and determinations regarding Non-Human Subjects Research. The HSS Chief Legal Officer ("CLO"), or an attorney from the HSS Office of Legal Affairs designated by the CLO, will serve as counsel to the COIC-Research. In order to assure appropriate consideration of the conflict, additional *ad hoc* members, including individuals not affiliated with HSS, may be appointed to the COIC-Research by the CSO or Medical Director of Clinical Research, as appropriate. Likewise, some or all of the standing members of the COIC-Research may be asked to recuse themselves if doing so would better ensure the integrity of the process of considering the disclosed institutional conflict.

   HSS' designated official for purposes of the PHS FCOI Rule is the Vice President, Research Administration.

   a. COIC-Research Review; Management Plans: The COIC-Research will promptly convene to review any disclosures of potential COIs. The COIC-Research will review the potential COI and recommend a management plan consistent with the Conflict Management Matrix attached hereto as Exhibit C-2 and as set forth below:

      The COIC-Research may recommend either prohibiting the proposed research or implementing procedures for management of the COI.

      A management plan may include any or all of the following:

      1. Detailed public disclosure of the COI on the Investigator's HSS web page profile and, if applicable, the proposed informed consent document for the clinical research study.
      2. Monitoring of research, either internally or by an external group or person
      3. Limiting the role of the Investigator with the potential COI ("Conflicted Investigator") in the research
      4. Disqualification of the Conflicted Investigator from participation in the research
      5. Divesture of, or restriction on, the Financial Interest creating the potential COI before the Conflicted Investigator may participate in the

research

6. Other measures or remedies to minimize the impact that a potential COI may have on the validity or perception of validity of the research

See Section E. of this Policy for additional standards applicable to Human Subjects Research.

A COIC-Research determination will be binding when approved by at least a majority of the members of the COIC-Research who are authorized by this Policy to participate in such determination.

b. The Conflicted Investigator may either (1) approve the management plan (by signing it and returning it to the COIC-Research) or (2) appeal the COIC-Research's determination to the Conflict of Interest Committee for Research Appeals Committee (the "COIC-Research Appeals Committee").

C. Research Institute Leadership Relationships with Sponsors of Research

1. Research Institute Leadership: This Section C applies to the following members of the leadership of HSS's Research Institute: (i) the Chief Scientific Officer, (ii) the Medical Director of Clinical Research, and (iii) the Vice President of Research Administration (each, individually, a "Research Institute Leader" and, collectively, "Research Institute Leaders").

2. **Prohibition on Direct Personal Compensation: Just as relationships with the commercial sector can play an important role in supporting HSS' mission generally, so too can relationships between Research Institute Leaders and outside organizations play an important role in supporting HSS' research mission. However, in order to ensure that (i) HSS' standards or integrity are not compromised, (ii) decisions are not unduly influenced by personal financial considerations, and (iii) the appearance of any conflict of interest is minimized, Research Institute Leaders may not accept any direct personal compensation from any organization that has a relationship – direct or indirect – with HSS. HSS may, however, accept compensation from such a "relationship" organization as a result of the work of a Research Institute Leader; provided that (1) such compensatory relationship has first been reviewed and approved by the Chief Scientific Officer (unless the Chief Scientific Officer is to receive such funds, in which case review and approval must be by the HSS Chief Executive Officer), and (2) HSS makes no payment to the Research Institute Leader as a result of such** Institute Leader's work for that "relationship" organization. This prohibition is not intended to apply to interactions of substantive scientific or educational merit, such as participating in research or educational conferences, participating in multi-

institution, multi-disciplinary review panels, serving as an investigator, or serving as an inventor, in which circumstances, the Research Institute Leader is permitted to receive compensation, provided it is at no more than fair market value (FMV) for the services provided by such Research Institute Leader.

D. Institutional Relationships with Sponsors of Research

1. Institutional Relationships with Sponsors of Research: HSS may not participate in *any research* when HSS has an Institutional Financial Interest (see Glossary), unless the research is reviewed and receives the approval of the COIC-Research (which, in the instance of research involving a potential Institutional COI, will include at least one individual with appropriate expertise who is independent to, and not on, the Medical Staff, Allied Health Professional Staff or Research Institute Staff of HSS, as appointed by the CSO or Medical Director of Clinical Research, as appropriate) and then only on the conditions approved by the COIC-Research, which may include a plan to manage and monitor the COI. A management plan may include any or all of the following:

i. Detailed public disclosure of the COI;
ii. Monitoring of research, either internally or by an external group or person;
iii. Divesture of, or restriction on, the Institutional Financial Interest creating the potential COI; and
iv. Other measures or remedies to minimize the impact that a potential COI may have on the validity or perception of validity of the research.

If, following review and approval as set forth above, HSS participates in research when HSS has an Institutional Financial Interest, then the following conditions shall also apply: (i) in the case of Human Subjects Research, the Institutional Financial Interest is disclosed to the patient prior to the patient's consenting to participate in such research, and in the case of Non-Human Subjects Research, HSS discloses such Institutional Financial Interest to the entities, if any, sponsoring such research, and in all publications and reports pertaining to such research, and (ii) once the drug, biologic, or device or other product (a "Product") is approved by the appropriate regulatory body for sale and use in patients, HSS agrees not to accept royalty payments arising from the sale of such Product to HSS for use on patients at HSS. Similar provisions may be applied before an individual with a potential COI is permitted to conduct research at HSS.

E. Human Subjects Research

1. If the research is Human Subjects Research, the COIC-Research may permit the

research to proceed at HSS, notwithstanding a COI, *only* (i) if there are compelling reasons that justify conducting the research at HSS; (ii) when Conflicted Investigator has a potential COI; if there are compelling reasons that justify involvement of the Conflicted Investigator, and (iii) if not participating would seriously jeopardize the science. These decisions will take into considerations the factors outlined in Section E.2. below. If the COIC-Research determines that compelling reasons exist or that science would be seriously jeopardized if the research were not to be permitted as proposed, a management plan will be prepared in accordance with section B.2. above.

2. Factors to be considered in making a determination as to whether to permit Human Subjects Research where a COI may exist include but are not limited to:

i. Whether the research is to be conducted at multiple sites and, if so, whether HSS' role is relatively passive or will be the site responsible for gathering and/or monitoring the data from all other sites;
ii. Whether HSS' resources are fundamentally important to the progress of the science or the investigator is uniquely qualified or necessary to administer the research or conduct the trial;
iii. Whether the interests of the human subjects will be adversely affected by use or non-use of HSS as a site; and/or
iv. The proportion of the total subjects in the study that are under the supervision of HSS.

F. Appeal and Monitoring of Management Plans

1. COIC-Research Appeals Committee: The COIC-Research Appeals Committee will be constituted on an *ad hoc* basis and will be composed of the following individuals: (1) the Chief Scientific Officer or Medical Director of Clinical Research, as applicable, (2) the Chief of Research from the Conflicted Investigator's Service, and (3) an individual with expertise in bioethics who is not on the Allied Health Professional Staff, Medical Staff or Research Institute Staff of HSS. The COIC-Research Appeals Committee shall, on a timely basis, communicate its decision to the Conflicted Investigator.

2. The Conflicted Investigator may either (1) approve the COIC-Research Appeals Committee decision or (2) appeal the determination to the Chief Compliance Officer

3. Appeal to Chief Compliance Officer: The COIC-Research Appeals committee will provide its report and recommendations to the Chief Compliance Officer. The report and recommendation will be reviewed with the HSS President & CEO and the HSS Surgeon-in-Chief, who will make the final determination as to whether the research will proceed and, if so, the

conditions that will be required to manage the potential COI. This may include a monitoring committee, including members external to HSS, to formulate, adopt and oversee compliance with an institutional conflict of interest management plan, in order to further protect human subjects and the integrity of the research. Members of the COIC-Research Appeals Committee will be available for comments and questions, as needed.

4. Monitoring of Management Plans. HSS Research Administration and/or Corporate Compliance will monitor compliance with the management plan on an ongoing basis until the completion of the research project.

G. Timing of Disclosures of Financial Interests by Investigators

1. Investigators must disclose their Financial Interests as follows:

- **a.** To Corporate Compliance on an annual basis (as required by HSS' Policy on Conflicts of Interest in Day-to-Day Operations);
- **b.** To the COIC-Research prior to or upon submission of any research proposal (whether submitted to the HSS IRB, an outside IRB, or to the PHS);
- **c.** Electronic submissions to the Institutional Review Board (IRB) will prompt investigators to update their disclosures profile at the time of initial submission, continuing review and amendments to add investigators to approved studies
- **d.** To Corporate Compliance and to the COIC-Research within thirty (30) days of acquiring any new Financial Interest;
- **e.** To Corporate Compliance and to the COIC-Research at the time of submission to the HSS committees reviewing proposals for new biologics or implants for use in a human subjects research study; and
- **f.** To the publisher upon submission for publication of any manuscript, article, report or other material.

H. Violations of this Policy

If there is reasonable cause to believe an Investigator has failed to disclose a potential COI, a Financial Interest, or otherwise has violated this Policy on Conflicts of Interest in Research Activities (including the failure to adhere to any decision under this Policy with respect to management of a particular COI), the Chief Compliance Officer (or his/her designee) may take appropriate steps to determine whether there has been inappropriate non-disclosure or another violation of this Policy, and if so, whether, under the circumstances, necessary disciplinary and corrective action should be recommended in accordance with HSS' policies and procedures.

I. Reporting Requirements for PHS-Funded Research

When the COIC-Research determines that a "Financial Conflict of Interest" (as such term is defined in the PHS FCOI Rule; each an "FCOI") exists with respect to an Investigator, HSS' Research Administration will report the FCOI to the PHS Awarding Component by submitting a "Financial Conflict of Interest" report to the PHS Awarding Component through the electronic Research Administration (eRA) Commons FCOI Module. In addition, in compliance with Grants and Agreements Conflict of Interest (2 C.F.R. Subpart B Section 200.112), any potential conflict of interest will be disclosed in writing to the Federal awarding agency or pass-through entity in accordance with that agency's applicable Federal awarding policy.

FCOI reports will include all of the information required by the PHS FCOI Rule and will be submitted:

- Prior to the expenditure of any funds under a PHS-funded research project. An initial FCOI report will be submitted when (i) an Investigator's Financial Interest is found by the COIC-Research to be an FCOI in accordance with the PHS FCOI Rule, or (ii) a subrecipient reports an FCOI to HSS in accordance with Section J below.

- Within sixty (60) days after (i) the COIC-Research determination that an FCOI exists for (A) an Investigator who is newly participating in the project or (B) an existing Investigator who discloses a new Financial Interest to HSS during the period of award, or (ii) a subrecipient reports an FCOI to HSS in accordance with Section J. below.

- Annually during the duration of the project period at the same time as when HSS is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable). The annual FCOI report will include HSS Investigators as well as any subrecipient Investigators.

J. Subrecipient Institutions/Investigators and Reporting of Identified FCOIs for PHS-Funded Research

HSS' Research Administration is responsible for ensuring that subrecipients comply with the PHS FCOI Rule and for reporting to the PHS Awarding Component identified FCOIs and potential FCOIs, as required for the awarding agency, for

subrecipient Investigators. The HSS Subaward Agreement includes certification by the subrecipient that it complies with the PHS FCOI Rule and has a written and enforced administrative process in place in accordance with PHS FCOI Rule regarding financial conflicts of interest with respect to federally funded research. The Subaward Agreement further provides that the FCOI policy of the subrecipient will apply to the subrecipient and that the subrecipient must report identified FCOIs and potential FCOIs, as required, to HSS in sufficient time to allow HSS to report the FCOI to the PHS Awarding Component.

K. Retrospective Review and Mitigation Report for PHS-Funded Research

Whenever a FCOI is not identified or managed in a timely manner, including:

i. *Failure by an Investigator to disclose a Financial Interest that is determined by the COIC-Research to constitute an FCOI;*

ii. *Failure by the COIC-Research to review or manage such an FCOI; or*

iii. *Failure by an Investigator to comply with an FCOI management plan; within 120 days of becoming aware of such non-compliance, HSS' Research Administration shall complete a "retrospective review" of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance was biased in the design, conduct, or reporting thereof.*

Based on the results of the retrospective review, if appropriate, HSS Research Administration will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, HSS will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component that addresses the following: (i) impact of the bias on the research project and (ii) HSS' plan of action or actions taken to eliminate or mitigate the effect of the bias.

L. Training Requirements for PHS-Funded Research

Each Investigator must complete training prior to engaging in PHS-funded research and at least every four (4) years, and immediately under the following circumstances:

HSS' Financial Conflict of Interest policies change in a manner that affects Investigator requirements;

- An Investigator is new to HSS; or
- HSS finds that any Investigator is not in compliance with this Policy on Conflicts of Interest in Research Activities or an FCOI management plan.
- Training will be provided by HSS' Research Administration and will include

certification that the Investigator has completed the training established by HSS Research Administration. Training materials are available on the Research Institute intranet page.

Definitions
Capitalized terms not otherwise defined herein are defined in Appendix - F Conflict of Interest Glossary of Terms

Index to Exhibits

Exhibit C-1	**Investigator/Staff Conflict of Interest Disclosure Form Exhibit**
C-2	**Investigators/Staff Conflict Management Matrix**

DATE ISSUED:
05/07

DEVELOPED BY:

DATE REVISED/REVIEWED:
09/15
11/19

REVISED/REVIEWED BY:
Compliance/ Legal and Research Dept.
Research Administration

DISTRIBUTION: Policy Medical

EXHIBIT C-1: Investigators/Staff/Institutional Conflict Management Matrix: Research

Relationship

Compensation (prior 12 months or expected in the next	Equity in a Private Company	Equity in a Public Company	Royalty (prior 12 months or expected in the next 12 months)	Leadership
II	I	II	II	I

*Subject to modification as necessary to meet applicable regulatory standards

Management Category I – Participation only with the approval of the COIC-Research

- Full disclosure to
  - Research Institute
  - Potential subject – language in the informed consent document explaining the relationship
- Independent informed consent (i.e., informed consent must be obtained by someone other than the investigator/staff member with the relationship)
- Data collection/entry/editing/analysis
  - Independent (i.e., data collection must be by someone other than the investigator/staff member with the relationship)
  - Oversight (i.e., HSS Clinical Research Administration, the IRB and/or some other group designated by CRA or the IRB oversees/ monitors/audits/checks the data collection process)
  - Reporting back to the COIC-R as requested

Management Category II

- Full disclosure to
  - Research Institute
  - Potential subject – language in the informed consent document explaining the relationship
- Data entry/editing/analysis
  - Oversight (i.e., HSS Clinical Research Administration, the IRB, the Program Director)
  - Reporting back to the COIC-R as requested