Belmont University Policy for Managing the PHS/NIH Revised Conflict of Interest Rule
That Went into Effect 8/24/2012
(Grants sponsored by Public Health Service Agencies/National Institutes of Health and
the National Science Foundation are covered under the new rule and revised policy)

EFFECTIVE BELMONT UNIVERSITY POLICY DATE: July 12, 2013

Promoting objectivity in research is a Belmont University priority. We understand that it is critical to
preserve the public’s trust that research is conducted without bias and with the highest scientific and
ethical standards. To that end, we support this objective through compliance with the Department of
Health and Human Services’ revised Public Health Service\(^1\) (PHS) rule, affecting PHS entities including the
National Institutes of Health (NIH), and the rules of the National Science Foundation\(^2\) (NSF) regarding the
disclosure of Significant Financial Interests (SFI) and the management of Financial Conflicts of Interest
(FCOI) affecting covered research activities.

Belmont University has implemented this policy and the following corresponding procedures that
establish standards intended to provide a reasonable expectation that the design, conduct and reporting
of research\(^3\) funded by the PHS/NIH and NSF will be free from bias resulting from Financial Conflicts of
Interest as defined hereunder. Compliance with these requirements is a condition for submitting a
proposal and accepting an award of Federal financial support from the PHS/NIH or NSF for all activities
conducted by Belmont University. This policy and the associated procedures are intended to supplement
existing Belmont University policies on conflict of interest and conflict of commitment. This policy and
these procedures apply to all individuals who meet the definition of Investigator as defined hereunder
and, as such, may include faculty, Belmont University staff, postdocs, students, external collaborators
and co-investigators from other educational institutions or organizations.

PROCEDURES TABLE OF CONTENTS
The following pages describe the procedures for compliance with Belmont University’s Policy for
Managing Conflict of Interest Requirements Imposed by Federal Sponsors. As with all procedures, these
may change from time to time to ensure the most efficient processes and effective compliance. To help
navigate the complexity of these requirements, we have organized the document as follows:

A. Definitions
   Research
   Investigator
   Institutional Responsibilities
   Significant Financial Interest
   Disclosure
   Financial Conflict of Interest
   Manage

\(^1\) Objectivity in Research-DHHS-Federal Register, Vol. 76, August 25, 2011, pp. 53256 to 53293.


\(^3\) The new FCOI rule and this policy do not apply to non-research grants such as student traineeships or scholarships. The
Federal government’s definition of research is provided in the definitions in this policy and at (42 CFR 50.603 Subpart F).

Last updated 7/12/2013
**Senior/Key Personnel**

**Institutional Official**

B. Required Disclosures
C. Disclosure Review and Management of Financial Conflicts of Interest
D. Reporting
E. Training
F. Recordkeeping
G. Subrecipient Requirements
H. Public Accessibility of Financial Conflicts of Interest
I. Principal Investigator Responsibilities
J. Posting of The Policy and These Procedures
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A. DEFINITIONS

*Research* is defined by the Federal government as: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. The new rule and this Belmont policy do **not** apply to non-research activities such as student traineeships or scholarships.

*Investigator* is the project director or principal investigator, co-investigators, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of the research funded by PHS/NIH or NSF, or proposed for such funding, which may include faculty, Belmont University staff, post-doctoral scholars, students, external collaborators and co-investigators from other institutions or organizations.

*Institutional Responsibilities* includes an Investigator’s professional responsibilities on behalf of Belmont University, including activities such as teaching, research, committee or board membership and services and other administrative duties.

*Significant Financial Interest (SFI)*

The term Significant Financial Interest is defined differently for PHS/NIH and NSF agencies. Please review the following carefully to understand the differences and to ensure accurate application of the rules and reporting:

**SFI for PHS/NIH funding agencies:**

i. Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to relate to the Investigator’s Institutional Responsibilities:

   1) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when
aggregated, exceeds $5,000. Remuneration includes salary and other payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships or honoraria); equity interests includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

2) With regard to any non-publicly traded entity, a significant financial interest exists if the aggregated value of any remuneration received from the entity, in the twelve months preceding the disclosure, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g. stock, stock option or other ownership interest);

3) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income by the Investigator related to such rights and interests;

4) Included in the definition of SFI is the occurrence of any travel related to the Investigator’s institutional responsibilities that is reimbursed or sponsored by an external entity (not Belmont University). “Sponsored travel” is travel that is paid on behalf of the Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available.

ii. The term SFI for PHS/NIH agencies does not include the following:

1) For Belmont University employees, salary, royalties, or other remuneration from Belmont University, including intellectual property rights assigned to Belmont University and agreements to share in royalties related to such rights;

2) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

3) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute;

4) Travel reimbursements by Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute;

5) Income from service or advisory committees or review panels for Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute.

**SFI for NSF funding:**
NSF defines Significant Financial Interest as anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term SFI for NSF does not include:

1) salary, royalties or other remuneration from the applicant institution;

2) any ownership interests in the business, if the business is an applicant under a Phase I Small Business Innovation Research Program or Small Business Technology Transfer Program;

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4 Honoraria is considered in determining whether there is a significant financial interest for purposes of PHS and NSF funding disclosures even though they are not under the University’s general conflict of interest disclosure requirements.
3) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
4) income from service on advisory committees or review panels for public or non-profit entities;
5) an equity interest that, when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets both of the following tests: does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
6) salary, royalties or other payments that, when aggregated for the Investigator and the Investigator’s spouse and dependent children, are not expected to exceed $10,000 during the twelve month period.

Disclosure is the submission of the Belmont University’s SFI and FCOI Entity Statement Disclosure form that may be accessed at the Office of Grants and Scholarship Web site by each Belmont University individual who meets the definition of Investigator. The Disclosure should include the details of the nature of any Significant Financial Interest as defined by the applicable Federal agency which is held by the Investigator, his/her spouse and/or dependent children. For PHS/NIH and NSF proposals or awards involving an external collaborator who meets the definition of Investigator and who has a Significant Financial Interest, Disclosure must happen in one of two ways:

1) If the collaboration is with an Investigator whose institution complies with PHS/NIH or NSF policies, an annual certification from the institution asserting that it complies with PHS/NIH or NSF policy will suffice.
2) If the collaboration is with an Investigator acting as an individual or through an organization that does not comply with PHS/NIH or NSF policies, the collaborator Investigator(s) must file a Disclosure with Belmont through the Office of Grants and Scholarship.

Financial Conflict of Interest
A Significant Financial Interest (SFI) held by an Investigator that could directly and significantly affect the design, conduct, or reporting of his/her PHS/NIH or NSF funded research. The determination as to whether a SFI constitutes a Financial Conflict of Interest (FCOI) is made by the Institutional Official or the Provost’s designee. For purposes of PHS/NIH and NSF, any ownership interests (whether SFI or not) in a business will not constitute an FCOI if the business is an applicant under a Phase I Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer (STTR) Program.

Manage
This means taking action to address a financial conflict of interest, which may include reducing or eliminating the financial conflict of interest, to ensure to the extent possible, that the design, conduct and reporting of the research will be free from bias.

Senior/Key Personnel
The project director or principal investigator and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to PHS by Belmont University.

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5 SFI as defined by the applicable Federal agency.
Institutional Official
Belmont University’s Provost or Associate Provost for Academic Affairs serves as the Institutional Official.

B. REQUIRED DISCLOSURES
Investigators are required to identify and disclose, or identify and re-verify, if previously disclosed, Significant Financial Interests before an application is submitted to either PHS/NIH or NSF, and thereafter within 30 days of discovering or acquiring a new Significant Financial Interest. SFI Disclosures must also be updated at least annually for investigators engaged in PHS/NIH or NSF sponsored research. At the time a proposal is being prepared, the individual serving as principal investigator should alert any other individuals who may meet the definition of Investigator of the need to comply with these procedures. All individuals who are considered to be Investigators (including the principal investigator) are to determine if they have any Significant Financial Interests and, if so, each must file a SFI Disclosure of the nature and magnitude of the financial interest. According to Federal requirements, all such Disclosures must be submitted with the Institutional Official before Belmont University can apply for funds from the covered Federal funding agency (e.g., NIH or NSF). The principal investigator will certify on the proposal routing form, under Principal Investigator Responsibilities that his or her SFI Disclosure form has been submitted to the Institutional Official, and that all eligible senior and key personnel have been asked to submit Disclosures. The proposal cannot be forwarded to the appropriate federal agency until all key personnel have filed Disclosures. Before any expenditure of funds can occur, the Institutional Official must review the Disclosures and address any conflicts of interest. Proposals will only be processed by the Office of Grants and Scholarship if the appropriate certifications have been made on the proposal routing form and the Disclosures are on file.

C. DISCLOSURE REVIEW AND MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST
When an Investigator(s) submits a SFI Disclosure form, Belmont University’s Institutional Official will review the disclosure of Significant Financial Interests in accordance with these procedures to determine whether an actual or potential Financial Conflict of Interest exists. Compliance with Belmont University’s governing policies and these procedures is an ongoing requirement that Belmont University must fulfill in order to be eligible to receive funding from PHS/NIH and NSF. The Institutional Official is designated by Belmont University as responsible for reviewing disclosures of Significant Financial Interests and determining whether a Financial Conflict of Interest exists for purposes of covered Federal funding. When a Financial Conflict of Interest is identified, these individuals also are responsible for determining what steps need to be taken to manage the conflict prior to the expenditure of covered funding. The Institutional Official receiving a Disclosure will review the disclosure to determine if the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest for purposes of the award. If the Institutional Official reviewing the disclosure form believes there is no Financial Conflict of Interest, then the Investigator(s) will be notified of the finding in writing. If the Institutional Official determines a Financial Conflict of Interest exists, the Official will work with the Investigator(s) to develop a management plan for any.
such conflicts before awarded funds are expended. The Institutional Official will work with the Investigator to determine the steps that should be taken to manage the conflict and will prepare a proposed written management plan. The plan should contain a statement between the Institutional Official and the Investigator indicating that both parties participated in the development of the management plan and agree on its provisions. The plan must also contain the investigator’s consent if the plan includes any divestitures, severances, or modifications to any financial interests, personal property, or personal or professional relationships. The proposed management plan will be forwarded to Office of the Vice President for Administration and University Counsel along with the original copy of the Disclosure. The University Counsel will review the Disclosure in the context of the proposed activity along with the management plan proposed by the Investigator and Institutional Official. Before permitting any expenditure of funds from the Federal sponsor, the Institutional Official in collaboration with University Counsel, must approve the management plan describing the conditions and possible restrictions that Belmont University believes are necessary to manage the actual or potential Financial Conflict of Interest. The following are examples of conditions or restrictions that may be included in a management plan:

- public disclosure of significant financial interests;
- monitoring of research by independent reviewers;
- modifications to the research plan;
- disqualification from participation in all or a portion of the activity funded by the Federal agency that would impact the significant financial interest;
- divestiture of significant financial interests;
- severance of relationships that create potential or actual conflicts; or
- require placing of shares or other forms of equity ownership documents in a blind trust.

Copies of the approved management plan will made available to the Investigator and the plan must be implemented before the expenditure of funds. If the Federal Sponsor or University Counsel rejects the management plan, the Institutional Official and Investigator(s) will identify the deficiencies and modify the plan based on the recommendations of the Federal Sponsor or University Counsel. Any modifications to the management plan must adhere to the procedures detailed above.

For PHS/NIH funded activities, all SFI must be reviewed by the Institutional Official and all potential FCOI completely addressed prior to expenditure of funds. Should an SFI arise during the term of the award, the Investigator must file a Disclosure within 30 days and the SFI must be reviewed by the Institutional Official and all potential FCOI completely addressed within 60 days of the Disclosure. If an Investigator does not file his/her Disclosure in a timely manner, additional compliance action by the Institutional Official and the University will be required pursuant to 42 CFR 50.605.

D. REPORTING

The Office of Grants and Scholarship will make any required reports to PHS/NIH and NSF. In the case of PHS/NIH, the PHS agency will review the reported Financial Conflict of Interests to determine if
additional information is needed. The PHS agency may decide that further action is needed to ensure the objectivity of the research or that the Financial Conflict of Interest has not been appropriately managed, reduced or eliminated. The PHS agency may also require suspension of funding until the matter is resolved.

E. TRAINING
For PHS/NIH funded or proposing Investigators, Belmont University will provide Investigators with training regarding the requirements of these procedures and the governing policy and any changes thereto: 1) prior to an Investigator’s engagement in research related to any PHS funded project; 2) every four years; and 3) whenever an Investigator is found to be out of compliance with these procedures, their governing policy, or an applicable management plan. The principal investigator will be responsible for certifying that all investigators have undergone the required training prior to their engagement in the covered research. NSF funded or proposing Investigators should familiarize themselves with the University’s Conflict of Interest Policy and these procedures and the governing policy relative to obligations required by NSF.

F. RECORDKEEPING
The University will maintain required records of all Disclosures and of all actions taken to manage actual or potential conflicts of interest for at least three (3) years from the date the final expenditure or project report is submitted to PHS/NIH or NSF or until the resolution of any legal or government action involving these records, whichever is later.

G. SUBRECIPIENT REQUIREMENTS
Belmont University will include provisions in all covered subawards requiring subrecipients to comply with PHS/NIH and NSF rules related to the disclosure of Significant Financial Interests and management of Financial Conflict of Interests consistent with Federal requirements for covered awards.

H. PUBLIC ACCESSIBILITY OF FINANCIAL CONFLICTS OF INTEREST
Upon written request to the Office of Grants and Scholarship, Belmont University is required to provide, within 5 business days, a written disclosure of Financial Conflicts of Interest held by Senior and Key Personnel proposing for funding or funded by PHS/NIH, including: 1) the Investigator’s name; 2) the Investigator’s title and role with respect to the research project; 3) the name of the entity in which the Significant Financial Interest is held; 4) the nature of the Significant Financial Interest; 5) the approximate dollar amount of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

I. PRINCIPAL INVESTIGATOR RESPONSIBILITIES
Belmont University requires that the designated principal investigator for an activity that is proposed to be, or actually is, funded by a covered Federal sponsor is required to:
1) Become familiar with these procedures and the governing policy for Managing Conflict of Interest Requirements Imposed by Federal Sponsors.

2) Distribute copies of this document to any individual who either meets or can reasonably be expected to meet the definition of Investigator and who will participate on any covered activity that is proposed to be, or is, Federally funded by PHS/NIH or NSF.

3) Assure the Institutional Official and the Office of Grants and Scholarship, through certification on the proposal routing form accompanying all proposals, they, themselves, and to the best of their knowledge, all individuals who satisfy the definition of Investigator:
   (a) have reviewed their responsibilities with respect to this document and the Belmont University Policy on Conflicts of Interest,
   (b) have determined whether they have any Significant Financial Interests as defined in this document,
   (c) have submitted SFI Disclosure form(s) to Belmont University or their own Institution, as required; and
   (d) have completed all required FCOI training. The principal investigator must also indicate whether he or she knows of any potential Financial Conflicts of Interest between any Investigator, including him/herself, arising from a Significant Financial Interest and the proposed work.

4) Notify the Office of Grants and Scholarship of those external collaborators on PHS/NIH or NSF proposals that would fulfill the role of Investigator so that institutional certifications can be obtained, where appropriate.

J. POSTING OF THE POLICY AND PROCEDURES
Belmont University will post these procedures and the governing policy for Managing Conflict of Interest Requirements Imposed by Federal Sponsors on its public Office of Grants and Scholarship Web site. All current and future personnel receiving or proposing to receive funds from the covered federal sponsors are required to become familiar with these procedures and the governing policy.

K. SANCTIONS
Failure to timely comply with Disclosure requirements for PHS/NIH and NSF funded awards may result in delays in accessing funds or suspension of expenditures on funded activities. Individuals who fail to adhere to these procedures and the governing policy may be subject to suspension of funds, to removal from participation on the covered award and disciplinary action up to and including termination of employment.

L. ASSISTANCE
The Provost's Office, Office of Grants and Scholarship, and University Counsel are available to provide advice and assistance to any individual on the interpretation of these requirements and the applicability to a specific situation.

Last updated 7/12/2013