



## **Conflict of Interest in Research**

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### **Introduction**

As an institution dedicated to excellence in education and looking to establish research excellence, Regis College (the College) places a high value on integrity and academic freedom. Objectivity in the conduct of research, the freedom to disseminate ideas through publication of research results, the protection of the rights and interests of research subjects, maintenance of public trust, and the ability to insure that our responsibility to our students and trainees is not compromised are critical to these institutional values. Relationships with industry and other outside entities, while important to the support and advancement of research, can present special challenges in protecting these institutional values.

In the context of conducting research, the primary interest of a researcher should be the objective conduct of the research. Coupled with this, the researcher, the College, and the public share an interest in the complete, objective and timely communication of research results. While the College expects that all of its faculty and other research staff should carry out their professional responsibilities with the highest standards of personal integrity, it is necessary to acknowledge and to avoid or manage situations where a secondary interest could reasonably be expected by others to influence decision-making.

To say that one has a conflict of interest does not necessarily mean that the individual involved acted or is expected to act inappropriately. It is the existence of the competing interests that creates the initial conflict of interest concern.

Conflict of interest can be defined as a situation in which an investigator's external interests undermine, appear to undermine, or have the potential to undermine the investigator's ability to perform his or her ethical, legal, or professional duties. The potential for personal gain or the existence of competing interests must not jeopardize or appear to jeopardize the integrity of the research, its design, or the interpretation or reporting of research results.

The College Policy on Conflict of Interest in Research for grants and proposals requires the disclosure of financial interests or associations with other organizations including reimbursed or sponsored travel that could directly and significantly affect the design, conduct, or reporting of the funded research.

This policy has been adapted from the Conflict of Interest in Research Policy at Tufts University.

## The Policy

The policy is organized into six major sections. The sections are the Preamble, Disclosure, Review, Management, and Reporting of Financial Conflicts of Interest and Other Policy Considerations.

- **The Preamble:**  
The Preamble lays out the authority, applicability and purpose for promoting objectivity in research. Definitions are listed to clarify the meanings of conflict of interest terms and provide examples of reportable activities.
- **Disclosing Significant Financial Interests (SFI) and Conflict of Interests:**  
This section explains the process investigators follow to make their disclosures including sub-recipient investigators as it relates to the project sponsor, that is, whether it's a federal or non-federal sponsor. The section also explains the policy for failure to make a disclosure.
- **Review of Conflict of Interests:**  
The third section, explains the review process taken by the IRB Chair and/or his/her designee when determining whether a disclosure relates to the research and if so, whether there is a conflict of interest. It describes the involvement of the Department Chairs, Program Directors, Associate Deans and Deans in eliminating, reducing or managing a conflict of interest.
- **Management of Financial Conflict of Interests:**  
This section provides examples of when a plan would be imposed and what a plan would entail. It also clarifies the PHS policy on public access to FCOIs that were reported to the PHS.
- **Reporting of Financial Conflict of Interests:**  
Reporting FCOIs is specific to Public Health Service (PHS) sponsors where reporting FCOIs is a federal requirement. This section explains the process and reporting requirements.
- **Other Policy Considerations:**  
The last section addresses various items related to the policy. It touches on Regis' intended review process, Record Retention, Publication, Students/Trainees, Human Subjects, and Special Considerations for Faculty Start-up Companies.

## Preamble

**Authority** – Public Health Service (PHS) regulation at 42 CFR 50, Subpart F is designed to promote objectivity in PHS-funded research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grant awards is not biased by any conflicting financial interests of an Investigator. PHS issued a final rule in the Federal Register, August 2011, that amended 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).

**Authority:** 42 U.S.C. 216, 289b–1, 299c–4; Sec. 219, Tit. II, Div. D, Pub. L. 111–117, 123 Stat. 3034.

**Source:** 76 FR 53283, August 25, 2011, unless otherwise noted.

NIH financial conflict of interest policy: <http://grants.nih.gov/grants/policy/coi/>

National Science Foundation (NSF) encourages the increased involvement of academic researchers and educators with industry and private entrepreneurial ventures, but recognizes that such interactions carry with them an increased risk of conflict of interests. The [NSF Awards and Administration Guide](#), AAG Chapter IV.A contains NSF's policy on conflict of interest.

Although the PHS/National Institutes of Health (NIH) and NSF have formal policies, it is Regis's policy to apply these standards to all sponsors, except where there are specific PHS requirements that cannot be applied to a non-PHS sponsor. Examples of some requirements are specific PHS reporting requirements and the definition of significant financial interest.

### **Conflict of Commitment**

A conflict of commitment occurs when the commitment to an individual's external activities may adversely affect his or her capacity to meet College responsibilities. This form of conflict involves a perceptible reduction of the individual's time and energy devoted to College activities. The College recognizes, however, that the contributions and activities of an individual to the College may extend beyond the work done directly for the College. The College also understands the desire of an individual, within the constraints set forth below, to earn and accept outside income for activities that do not create a conflict of interest.

According to the Faculty Handbook, a full-time faculty member may not work for compensation except during the summer. If work is contemplated at any time written permission must be obtained from the School Dean. Tutoring for pay is allowed with the formal permission of the School Dean and the Chair of the faculty member's department. This permission is never given to an instructor to tutor for pay for a member of his/her own class.

According to the Employee Handbook full time Administrative Council Members, Directors and Managers may not accept part-time employment in any other institution or agency without the authorization of the President. Such authorization may be given if it is determined that the service to the College will not be impaired through such non-College employment. Employees are permitted to engage in outside employment (including self-employment) as long as it does not interfere with the effectiveness or ability to fulfill the duties or responsibilities of the position at Regis College. It is the decision of the supervisor as to whether or not this additional employment conflicts with the interests of the College or with the employee's ability to perform their job. If at any future time a supervisor believes an outside job is interfering with an employee's performance, approval may be withdrawn.

It is important to recognize that each individual's obligations move beyond the letter of these requirements to their spirit. The College requires that its faculty meet their teaching, administrative and clinical obligations, and remain productively involved in their research and other scholarly pursuits. External activities that compromise or diminish an individual's capacity to meet these obligations represent a conflict of commitment, regardless of how much time an individual devotes to these activities.

## **Applicability**

This Policy applies to all Regis College faculty members and other individuals — such as researchers, students, and visiting researchers — who are responsible for the design, conduct or reporting of research at Regis on federally funded grants and cooperative agreements, to include proposals. “Investigator” in this Policy refers to such faculty members and other individuals.

Additionally, this policy applies to Investigators participating in federal research, as defined by the PHS regulation, **including** sub-grantee/contractor/collaborating Investigators, but **excluding** applications for Phase I support under the SBIR and Small Business Technology Transfer (STTR) programs.

## **Purpose**

This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under federal grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

## **Definitions**

In describing the requirements, the regulations use a number of definitions. Accurate understanding of the requirements depends upon an accurate understanding of each term’s meaning.

**Disclosure of Significant Financial Interests** means an Investigator’s disclosure of significant financial interests to the College.

**Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**FCOI Report** means the College’s report of a financial conflict of interest to a PHS Awarding Component.

**Federally Funded** means any funding i.e., grant, cooperative grant, contract, received from any United States government agency, department or entity.

**Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

**HHS** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

**Institutional Responsibilities** means an Investigator’s professional responsibilities on behalf of Regis College. That is, all activities that derive or descend from the investigator’s standing or expertise and are tied to those responsibilities and activities the investigator was hired to perform and for which the investigator is paid by the College. Some examples are, research, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards and Faculty Standing Committees.

**Investigator** means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

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

**PD/PI** means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this policy.

**PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to this policy.

**Public Health Service Act** or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

**Research** means 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). As used in this subpart, the term includes any such activity for which research funding is available from a federal 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.

**Senior/key personnel** means the PD/PI and any other person identified as senior/key personnel by Regis in the grant application, progress report, or any other report submitted to the federal sponsor by Regis under this policy.

#### **Significant Financial Interest (SFI)**

Depending on whether the sponsor is federal or non-federal apply the following definitions:

**For federal sponsors SFI 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 **be related to the Investigator's institutional responsibilities:**

**For non-federal sponsors SFI 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 **be related to the Investigator's research project:**

The following applies to both federal and non-federal SFIs:

- 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 disclosure, **when aggregated, exceeds \$5,000.**
- With regard to any non-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, **when aggregated, 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).

For purposes of this definition, remuneration includes:

- salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
- equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Disclosure of travel applies only to federal sponsors  
For federal sponsors; Investigators also **must disclose** the occurrence of **any reimbursed or sponsored travel related to their institutional responsibilities.** For example, costs that were paid on your behalf and not reimbursed to you, so that the exact monetary value may not be readily available, provided however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by:
  - Federal, state, or local government agency;
  - Institution of higher education as defined at 20 U.S.C. 1001(a); and
  - Academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- The details of this disclosure will include, at a minimum:
  - dollar amount or value,
  - purpose of the trip,
  - identity of the sponsor/organizer,
  - destination, and
  - duration.

- The Chair of the IRB and/or his/her designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- The term **“significant financial interest”** **does not include** the following types of financial interests:
  - Salary, royalties, or other remuneration paid by Regis to the Investigator if the Investigator is currently employed or otherwise appointed by Regis, including intellectual property rights assigned to Regis and agreements to share in royalties related to such rights;
  - Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization i.e., for STIR and SBIR (both defined below);
  - 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;
  - Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
  - Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. The term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

### **Other Reportable Activities**

Activities of the types described in the following examples must be disclosed, and in most circumstances will be subject to oversight as a potential conflict of interest:

- An individual participates in clinical research on a technology that was developed by the individual or his or her spouse or dependent child, but which is owned by or licensed to a business in which neither the individual, nor the spouse or dependent child, has a consulting relationship, a management position or a significant financial interest.
- An individual or his or her spouse or dependent child serves on the board of directors or scientific advisory board of a business from which the individual receives sponsored research support or with which Regis has a contractual relationship known to the individual.

- An individual publishes the results of research which could have an impact on a significant financial interest of his or hers, provided that the individual discloses his or her significant financial interest in the publication.

The following examples represent types of activities presumed to constitute major conflicts of interest. Such activities must be disclosed, are not permitted without express authorization of the College, and usually will be prohibited, or permitted only with continuing oversight:

- An individual receives sponsored research support (whether in dollars or in kind) for research from a business in which he or she or his or her spouse or dependent child holds a significant financial interest.
- An individual participates in clinical research on a technology owned by or licensed to a business in which the individual, and/or his/her spouse or dependent child, has a significant financial interest.
- An individual makes patient referrals to a diagnostic company in which he or she or his or her spouse or dependent child has a significant financial interest.
- An individual directs the purchase of supplies for Regis to a business in which he or she or his or her spouse or dependent child has a significant financial interest.
- An individual conducts research externally that could be conducted within the College.
- An individual assigns a student, fellow or other trainee to a project in which the individual has a significant financial interest.
- An individual assumes an executive position in an outside entity engaged in commercial or research activities related to the individual's field.

#### **Training Requirement: Applies Only to Federal Sponsors**

For federal sponsors each Investigator is required to complete training regarding financial conflicts of interest prior to engaging in research related to any federally funded grant and at least every four years, and immediately when any of the following circumstances apply:

- The College revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- An Investigator is new to Regis; or
- The College finds that an Investigator is not in compliance with this financial conflict of interest policy or management plan.

Opportunities for taking a Conflict of Interest course are available through the Collaborative Institute Training Initiative found at <http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm>

#### **Disclosing Significant Financial Interests (SFI) and Conflicts of Interest**



## **Introduction**

The College designates the Chair of the Institutional Review Board and/or his/her designee, as the institutional official to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, sponsored research.

This policy requires each Investigator who is planning to participate in sponsored research disclose to The Chair of the Institutional Review Board via the Financial Interest Disclosure Form, of the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application.

The College is responsible for maintaining an up-to-date, written, enforced policy on conflicts of interest (including financial) that complies with the regulation, and makes such policy available through the staff and faculty handbooks.

## **Disclosing Significant Financial Interests and Conflicts of Interest**

At any time an individual has a potential conflict of interest related to his or her research he or she must disclose it to the Chair of the Institutional Review Board and/or his/her designee. In addition, with each application for funding (and with each submission of a protocol for human subject research to the Institutional Review Board (IRB)), each Investigator involved in the research must complete and submit a Financial Conflict of Interest Disclosure Form for the specific project. It is the responsibility of each Investigator to update this information at any time that it changes. It is the responsibility of the principal investigator (PI) to ensure that each Investigator working under his or her direction on a research project or receiving support from his or her grant or contract receives a copy of this Policy and submits disclosure forms as required by this Policy.

Investigators submit a Financial Interest Disclosure Form (FIDF) with each proposal submitted for funding. Once the forms are received by the Institutional Review Board, they are reviewed by the Chair of the Institutional Review Board and/or his/her designee. If there is an indication on the form that a conflict of interest is being disclosed, the forms are forwarded to the Department Chair/Program Director/Associate Dean for review. By signing the FIDF, investigators acknowledge, among other things, the College's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of 42 CFR 50, subpart F, Promoting Objectivity in Research.

## **Department Chair**

All Principal and other Investigators proposing to participate in research must complete this form and first return it to the Chair of the Regis College Institutional Review Board (IRB) and/or his/her designee prior to or when submitting a funding proposal. Information disclosed in this form is confidential- and will be released only on a need-to-know basis. If there are any responses indicating the presence of a financial interest, the IRB Chairperson and/or his/her designee must submit this form for review and signature to the Investigator's Department Chairperson/Program Director/Associate Dean. If the Department Chairperson/Program Director/Associate Dean is or will be directly involved in the proposed research, the Dean must sign in the space designated for the Department Chairperson/Program Director/Associate Dean. It is the responsibility of the Investigator to update this information promptly if it should change prior to completion of the proposed research. It is the responsibility

of the Principal Investigator (PI) to ensure that each Investigator working under his or her supervision on the proposed research project submits this disclosure form when required by the Regis College Policy on Conflict of Interest in Research. The IRB Chair and/or his/her designee will inform the Grant Officer that this paperwork has been filed.

In addition to the need to disclose conflicts of interest to the College, it is also important that such conflicts be disclosed to others who might be affected by the research. This includes, for example, human subjects, other researchers who might rely on the research results, and the public. It is expected that all researchers will disclose conflicts of interest related to specific research projects at any time that the results of that research are presented or published.

At the time of the application/proposal submission, Regis must certify, in each application for funding that it has an up-to-date written, and enforced administrative process to identify and manage, reduce, or eliminate conflicting interests with respect to all research projects for which funding is sought or received. Regis additionally certifies that it will:

- promote and enforce Investigator compliance with this policy's requirements including those pertaining to disclosure of significant financial interests;
- manage financial conflicts of interest and provide initial and ongoing FCOI reports to the Awarding Component (required for all PHS/NIH projects);
- make information available, promptly upon request, to the Awarding Component relating to any Investigator disclosure of financial interests and Regis's review of, and response to, such disclosure, whether or not the disclosure resulted in the College's determination of a financial conflict of interest; and
- fully comply with the requirements of 42 CFR 50.f, Promoting Objectivity in Research.

### **Disclosing Financial Interests**

There are different criteria for making disclosures; it depends on whether the sponsor is federal or non-federal.

- **For federal sponsors:** Investigators are required to disclose to the Chair of the IRB and/or his/her designee, a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appears to **be related to the Investigator's institutional responsibilities**. Investigators also must disclose the occurrence of **any reimbursed or sponsored travel** related to their institutional responsibilities. For example, costs that were paid on your behalf and not reimbursed to you so that the exact monetary value may not be readily available. However there are exceptions for travel disclosures, see the definition of SFI.
- **For non-federal sponsors:** Investigators are required to disclose to the Chair of the IRB and/or his/her designee, a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appears to **be related to the Investigator's research project**.

- **An “Investigator” for this purpose:** An “Investigator” is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. The definition of Investigator’s financial interests includes the interests of the Investigator’s spouse and dependent children.

**Regulations Apply to Sub-grantees, Collaborators of Grantees (e.g. consortia) or Subcontractors**

If an Investigator through the College carries out sponsored research through a sub-recipient (e.g., subcontractors or consortium members), the College as the awardee Institution will take reasonable steps to ensure that any sub-recipient Investigator complies with this policy:

For federal sponsors, Regis will incorporate as part of a written agreement with the sub-recipient, terms that certify the sub-recipient has a financial conflicts of interest policy that meets the PHS (or other federal sponsors such as NSF) requirements for disclosure and reporting of FCOI. If not, the sub-recipient should follow Regis Financial Conflict of Interest Policy. Such assurance enables Regis to comply with the sponsors requirements. Sub-recipient will report to Regis all significant financial conflict of interest as defined by the federal sponsor and will provide assurance that the interest has been managed, reduced or eliminated in accordance with the sponsor requirements.

**FOR PHS/NIH FUNDED PROJECTS ONLY** (Under the regulation, Regis does not have the authority to apply the following requirements to non-PHS federally funded projects.). As part of a written agreement:

- Requiring a Non-Regis Investigator Financial Disclosure Form to be filled out at the proposal stage, which will provide certification that the potential sub-recipient has a FCOI policy in place that meets the PHS requirements. Alternatively, this requirement can be met by checking the [Federal Demonstration Partnership’s \(FDP\) Institutional Clearinghouse website](#) to see whether the sub-recipient is listed as being in compliance. If so, then a notation should be made on the internal coordination form when the proposal is submitted.
- If the sub-recipient’s Investigators must comply with the sub-recipient’s financial conflicts of interest policy, the sub-recipient shall certify as part of the agreement that its policy complies with 42 CFR 50 Subpart F. If the sub-recipient cannot provide such certification, the agreement shall state that sub-recipient Investigators are subject to the financial conflicts of interest policy of Regis College for disclosing significant financial interests that are directly related to the sub-recipient’s work for the College;
  - Additionally, if the sub-recipient’s Investigators must comply with the sub-recipient’s financial conflicts of interest policy, the agreement shall specify time period(s) for the sub-recipient to report all identified financial conflicts of interest to the College. Such time period(s) shall be sufficient to enable the College to provide timely FCOI reports, as necessary, to the PHS as required by Regis’s policy;

- Alternatively, if the sub-recipient's Investigators must comply with the Regis College's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the sub-recipient to submit all Investigator disclosures of significant financial interests to the College. Such time period(s) shall be sufficient to enable the College to comply timely with its review, management, and reporting obligations under the College's policy.

### **Affiliations**

When a person employed by Regis accepts a position as an officer or a board member of another company or organization, he or she may be taking on a fiduciary duty to act in the best interests of that organization. In situations where that company or organization is doing business with, sponsoring research at, or licensing intellectual property from Regis, a conflict of interest exists. Such a conflict of interest must be disclosed and either managed or eliminated.

### **New Investigators and New Disclosures by Existing Investigators**

Whenever, in the course of an ongoing sponsored research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the College, the designated official(s) of the College will, within sixty days:

- review the disclosure of the significant financial interest;
- determine whether it is related to federally-funded research;
- determine whether a financial conflict of interest exists; and, if so:
- Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, the College may determine that additional interim measures are necessary with regard to the Investigator's participation in the federally-funded research project between the date of disclosure and the completion of the College's review.

### **Untimely Disclosures**

Whenever Regis identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the College during an ongoing sponsored research project (e.g., was not timely reviewed or reported by a sub-recipient), the designated official(s) shall, within sixty days:

- review the significant financial interest;
- determine whether it is related to federally-funded research; determine whether a financial conflict of interest exists; and, if so:
- Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

- In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the College to constitute a financial conflict of interest; failure by the College to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the College will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the sponsored research project to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

### **Failure to Disclose a Conflict of Interest**

The College has established adequate enforcement mechanisms and provides for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

Failure to disclose the existence of a financial conflict of interest can result in disciplinary action or sanctions at the institutional level and involve restitution, criminal prosecution, or corrective action by the funding agency or the College. Allowing a conflict of interest to influence one's judgment in the context of research may also constitute or lead to scientific misconduct, which may result in disciplinary action under the College Policy on Misconduct in Research.

In the event that an Investigator's failure to comply with this policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the sponsored research, Regis will promptly notify the sponsor of the corrective action taken or to be taken. The sponsor will consider the situation and, as necessary, take appropriate action, or refer the matter back to Regis for further action, which may include directions on how to maintain appropriate objectivity in the funded research project. The sponsor may for example, require employing such an Investigator to enforce any applicable corrective actions prior to an award or when the transfer of a grant(s) involves such an Investigator.

### **For Federal Sponsors**

The federal sponsor may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the College's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the determination of a financial conflict of interest. Regis will submit, or permit on site review of, all records pertinent to compliance with the regulation. To the extent permitted by law, the federal sponsor will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the federal Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the federally-funded research to such an extent that further corrective action is needed or that the College has not managed the financial conflict of interest in accordance with this policy. The federal sponsor may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

In any case in which the federal sponsor determines that a federally-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the College as required by the US Code of Federal Regulations, the College shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

### **Review of Conflicts of Interest**

The Chair of the Institutional Review Board and/or his/her designee follows the Policy guidelines contained herein to determine whether an Investigator's disclosure of a significant financial interest related to their research project or for federal sponsored projects, institutional responsibilities is related to the sponsored research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to sponsored research when the College, through its designated official(s), reasonably determines that the significant financial interest:

- Could be affected by the sponsored research; or
- Is in an entity whose financial interest could be affected by the research.

The policy encourages the Investigator to be involved with the Chair of the Institutional Review Board or other body as determined by the College in determining whether a significant financial interest is related to the sponsored research. A financial conflict of interest exists when the Chair of the Institutional Review Board and/or his/her designee, or other body as determined by the College, with the involvement of the Investigator, the Department Chair and possibly other knowledgeable third parties, reasonably determines that the significant financial interest **could directly and significantly affect** the design, conduct, or reporting of the sponsored research.

If it is found that a SFI could directly and significantly affect the design, conduct, or reporting of the federally-funded research, the Chair of the Institutional Review Board or other College official will take actions as necessary to reduce, eliminate or manage the financial conflicts of interest, including any financial conflicts of a sub-recipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report.

In instances where the disclosed financial interest is minimal (when aggregated less than \$5,000 per year) and/or only requires a straight-forward and modest plan to reduce, eliminate or manage the potential conflict, the Chair of the of the Institutional Review Board and/or his/her designee may elect to conduct an expedited review and approval. These actions are reported to the entire IRB on a quarterly basis by the Chair so that all disclosures are shared with the membership of the committee.

Where there are questions or the Conflict of Interest is not determined to be minimal, the Chairperson of the IRB and/or his/her designee will contact the PI and Department Chair, Program Director or Associate Dean in order to review the COI and determine the relatedness of the COI to the research, that is how the SFI could directly and significantly affect the design, conduct, or reporting of the PHS funded research. This determination will require the input of the members of the IRB as well as third party faculty who understand the science, the COI and the potential for bias. Once the review is completed, the IRB Chair and Department Chair/Program Director/Associate Dean will prepare an information packet for the Dean's review.

The information packet will be reviewed by the Dean of the involved school. Based on the information provided by the IRB Chairperson and/or his/her designee, the Dean may require the conflict be eliminated, may decline to allow the research to take place, or may recommend a management plan.

If the Dean recommends that the research proceed, a plan for management or elimination of any conflicts shall be prepared by the Dean in collaboration with the IRB Chairperson and/or his/her designee. The plan recommended by the Dean and the review packet are then sent to the IRB for review and recommendation. The IRB's comments and disposition are sent to the Vice President of Finance and Business who will make the final decision on behalf of the College as to whether or not any conflict of interest can be appropriately managed or eliminated.

In cases where the College determines that it cannot manage the conflict, it may require that the conflicted be eliminated or that the research not proceed. Factors in this decision might include such considerations as the involvement of human subjects in the research:

- the level of risk involved,
- the nature and significance of the conflict,
- the potential for having a serious adverse impact on the scientific field or on the reputation of the College, and
- the level of difficulty involved in managing the conflict relative to the benefit of doing the research.

Decisions of the Vice President of Finance and Business may be appealed to the President, whose decision on these matters will be final. Deans must submit their own disclosure forms to the Vice President of Finance and Business which may, if there is a potential conflict, forward them to the President may report the existence of the conflict to funding agencies.

An approved plan for management or elimination of the conflict of interest must be in place before the research begins. Grant applications may be submitted while the College is considering a possible conflict of interest with the understanding that the College will not accept the funds unless the conflict can be managed or eliminated.

### **Retrospective Review**

The College is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

### **Management of Financial Conflicts of Interest**

Whenever the College implements a management plan it will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the federally-funded research project.

Prior to the expenditure of any funds for a research project, the Chair of the IRB and/or his/her designee will, as the process above describes, review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to the research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;



- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

An example of a plan could entail the following:

- Disclose the support the Investigator received from the company or other sponsor.
- Disclose the Investigator's financial relationship with company.
- Describe the steps taken to inform current or new students and other trainees of the conflict of interest.
- Determine whether student projects are different in any way from those of other members of the group with respect to the way they interface with company's goals.
- Determine whether a student thesis project has been altered in any direction because of a change in those goals.
- Demonstrate how publications and meeting presentations (within Regis and external) are handled to allow the co-existence of the company's and academic goals.
- State whether students or other trainees were included in patents obtained by the group.
- State whether students were compensated beyond the student stipend for work performed under the sponsoring company.
- Ensure that all COI's are disclosed.
- PI acknowledges Regis FCOI policy and agrees to abide by it and the plan and makes assurances that the PI will disclose any new SFI.

Once a management plan is in place it is reviewed annually, and the Investigator is required to inform the CCIR of any changes in the COI.

### **Public Accessibility to the FCOI Policy and Disclosed Significant Financial Interests on PHS Funded Projects**

Prior to the College's expenditure of any funds under a PHS-funded research project, the College will ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the College that meets the following three criteria:

- The significant financial interest was disclosed and is still held by the senior/key personnel;

- The College determines that the significant financial interest is related to the PHS-funded research; and
- The College determines that the significant financial interest is a financial conflict of interest.

The information that the College makes available via a written response to any requestor within five business days of a request, will include, at a minimum, the following:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- name of the entity in which the significant financial interest is held;
- nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or
- statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The information the College keeps will be updated at least annually. In addition, the College will update its files within sixty days of the receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the College determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. If the College responds to written requests for the purposes of this subsection, the College will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the College's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the significant financial interests of an individual subject to this policy shall remain available, for responses to written requests for at least three years from the date that the information was most recently updated.

Written request should be mailed to:

Institutional Review Board Chair, Office of Graduate Studies  
 Regis College  
 235 Wellesley Street  
 Weston, MA 02493

## **Reporting of Financial Conflicts of Interests**

### **PHS/NIH Specific Reporting Requirements**

Prior to spending any funds under an PHS/NIH award, (only applies to PHS/NIH) Regis must report to the PHS Awarding Component the existence of a conflicting financial interests that is reasonably determined to be a COI that is significant to the point that it could directly and significantly affect the design, conduct and reporting of the funded research. In these cases, Regis will ensure the interest has been managed, reduced, or eliminated in accordance with the regulation. The regulation does not require Regis to report to NIH officials the nature or other details of a reported FCOI; however, Regis is required to make information available, upon request, to the NIH regarding all Financial Conflicts of Interest (FCOI) identified by Regis and how those interests have been managed, reduced, or eliminated to protect the research from bias.

For any significant financial interest that Regis identifies as conflicting subsequent to the its initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the College will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that Regis has implemented a management plan in accordance with the regulation. Where such a FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by Regis (e.g., was not timely reviewed or reported by a sub-recipient), the College is also required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, the College is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

### **The FCOI Conflict of Interest Report Specific to the PHS/NIH**

Any FCOI report required by the regulation shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the College's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by

increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

- A description of how the financial interest relates to the PHS-funded research and the basis for the College's determination that the financial interest conflicts with such research; and
- A description of the key elements of the College's management plan, including:
- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

#### **Annual FCOI Report to the PHS Awarding Component**

For any financial conflict of interest previously reported by the College with regard to an ongoing PHS-funded research project, Regis will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The College will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

#### **PHS/NIH Mitigation Report if Bias is Found During Retrospective Review**

Based on the results of the retrospective review, if appropriate, the College will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the College is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the College's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the College will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, the College may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the College's retrospective review.

Sub-recipient Special Reporting for PHS/NIH Projects: The College is responsible for providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all sub-recipient Investigators consistent with this policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

### **Other Reporting**

In addition to the types of financial conflicts of interest as defined in this policy that must be reported pursuant to the regulation, the College may require the reporting of other financial conflicts of interest in its policy on non-federal financial conflicts of interest, as it deems appropriate.

### **Other Policy Considerations**

The Grant Officer will be informed of conflicts in order to meet reporting requirements to funding agencies.

### **Record Retention**

The Institutional Review Board will retain records of all financial disclosures and all actions taken by the College with respect to conflicts of interest.

The College is required to keep all records as follows:

- **For grants or cooperative agreements** – for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) for different situations
- For research contracts – for three years after final payment or, where applicable, for the other time periods specified in 48 CFR part 4, subpart 4.7.

**Publication** The College requires in all its contracts for support of research or education that the researchers be free to objectively analyze and publish all results of their work. The College may accept reasonable delays on publication (normally not to exceed 90 days) that allow for the protection of intellectual property, the deletion of confidential information provided by a research sponsor or for the completion of a multi-site clinical trial.

### **Students/Trainees**

An important part of the training of graduate students and postdoctoral fellows is mentored research. The College and the faculty who oversee student research must insure that the educational interests of these trainees are not compromised by institutional or individual conflicts of interest. Care must be taken to insure that the source of research funding does not cause a change in the training experience. Students and fellows should not be placed in a situation where publication will be unduly restricted or excessively delayed (any delay greater than 90 days will be considered excessive) or where the financial interests of the company or the mentor will influence the direction of the research project. Students must be able to publicly present dissertations and theses and to publish their research.

In a situation where a student is to work on a corporate sponsored research project in which his or her advisor has a financial interest, prior approval from the student's Department Chair/Program Director/Associate Dean is required. The financial interest must be disclosed to both the Department Chair/Program Director/Associate Dean and the student prior to beginning the research project. If the Chair approves of the involvement of the trainee in that research and the trainee is a graduate student, the Chair will inform the student's thesis committee. If the individual is a fellow or a student who does not have a thesis committee, the Department Chair/Program Director/Associate Dean will work with the Chairperson of the IRB and/or his/her designee in developing a management plan that will ensure the PI informs, in writing, students and postdoctoral trainees funded from this source about the conflict of interest, and in doing so inform the trainees that should they have concerns, they should contact their Department Chair/Program Director/Associate Dean in which they are enrolled.

### **Human Subjects**

In situations where research could involve risk to human subjects, the protection of those subjects must be of paramount concern. With each protocol involving human subject research each Investigator must submit to the IRB a conflict of interest disclosure. Forms that indicate a possible conflict of interest will be subject to the review and management procedure described under "Review and Management of Conflicts of Interest" above. IRB approval will not be granted until the conflict of interest oversight or management plan has been set up and approved by the Vice President of Finance and Business. The College may prohibit research that involves a conflict of interest even if the IRB approves the research.

In accordance with federal regulations governing human subject research, a study participant is to be fully informed of research related risks before he or she consents to participate in the research. Informed consent forms and procedures should include the disclosure of any conflict of interest that could reasonably appear to influence an investigator's judgment in conducting the research.

Additionally, No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (45 CFR 46.107(e)).

### **Special Considerations for Faculty Start-up Companies**

In situations where a faculty member obtains or owns equity in a company that relates to his or her research, it is especially important to be mindful of conflicts of interest and conflicts of commitment. Care should be taken to keep sight of what is the property of the College versus what belongs to the company. The faculty member should assure that time invested in the company does not exceed the amount of time allowed for outside activities under the conflict of commitment policy and does not compromise his or her ability to perform his or her regular duties and obligations to the College, to funding agencies or to students. College facilities and resources may not be used for the benefit of the company without a written agreement authorizing the use approved by the Dean. Faculty members and staff who own equity in a company should not personally negotiate or attempt to influence the licensing terms that the College offers to that company. An attorney or executive of the company with no connection to the College should be used for that purpose. The needs and interests of students and fellows must be carefully considered. The Institutional Review Board will work closely with faculty

members who are starting companies and the faculty members' deans. Normally, a special conflict of interest oversight committee may be convened and meet at least annually as long as the faculty member remains involved with the company. This committee will be a subcommittee of the Institutional Review Board and should consist of one member of the Institutional Review Board and two individuals who are familiar with the area of research. The subcommittee will report annually to the Institutional Review Board. Alternatively, in lieu of the subcommittee, the Chair of the Institutional Review Board and/or his/her designee can work with the Investigator and submit the plan to the Institutional Review Board for review. Once the plan is approved and in place, the Chair may ensure annual reports are conducted and submitted to the Institutional Review Board.

Individual Responsible for Implementation and Revision: The Chairperson of the IRB