

## A.7 Financial Disclosure Policy for All Senior Personnel Conducting Research Funded by Federal Grants

The federal government requires Trinity College to establish and administer a financial disclosure policy and training program for investigators conducting federally funded research. This requirement is designed to ensure appropriate management of actual or potential conflicts of interest. Trinity College's Financial Disclosure Policy (the "Policy") fulfills the requirements of grantee institutions as set forth in the National Institutes of Health's guidelines (see <http://grants.nih.gov/grants/policy/coi/index.htm>) and the National Science Foundation's conflict of interest policies (see [http://www.nsf.gov/pubs/policydocs/pappguide/nsf08\\_1/aag\\_4.jsp#IVA](http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/aag_4.jsp#IVA)).

**A. Disclosure of Significant Financial Interests.** All personnel responsible for the design, conduct or reporting of research under the terms of a federal grant or contract (each, an "Investigator") are required to disclose to the College's Dean of Faculty or her designee (collectively "DOF"), who will act as a research integrity officer for purposes of this Policy, all "Significant Financial Interests" of the Investigator and/or the Investigator's spouse, partner, and dependent children.

### **B. Nature of "Significant Financial Interests".**

- 1) Definition. A Significant Financial Interest means one or more of the following interests that reasonably appear to be related to the Investigator's institutional responsibilities, including all research, teaching and/or service to the College:
  - a) 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, exceed \$5,000. Remuneration includes any 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.
  - b) 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 spouse, partner, or dependent children) owns any equity interest in the entity, regardless of dollar value.
  - c) Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests. This does not include any income received from Trinity College for intellectual property rights assigned to the College based on agreements to share in the royalties related to such rights in conformity with the College's Patent and Invention Policy.
  - d) Any reimbursed or sponsored travel related to your institutional responsibilities must also be disclosed, including in connection with instruction, research or service to Trinity College, with the exception of any travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research center affiliated with an institution of higher education. Travel that is reimbursed by Trinity College from a sponsored fund account whose sponsor is an entity that is not one of those exempt entities shall be treated as a Significant Financial Interest. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be requested by the DOF and must be furnished upon request.
- 2) Exclusions. The term "Significant Financial Interest" does *not* include: a) salary, royalties, or other remuneration from Trinity College; b) income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; c) income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education; d) income from service on advisory committees or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

**C. Timing of Required Disclosures.**

- 1) Investigators must provide all required financial disclosures *at the time a proposal is submitted*.
- 2) In addition, Investigators must *update* those financial disclosures:
  - a) Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest; and
  - b) Annually within the period of the grant, beginning with the anniversary date of the original disclosure.
- 3) An Investigator who is new to an existing research project must provide all required financial disclosures before being permitted to participate in the project.

**D. Review of Financial Disclosures.** The following process shall apply to financial disclosures submitted by Investigators.

- 1) Determination of Financial Conflicts of Interest. Prior to the expenditure of federal research funds, the DOF shall review each disclosed Significant Financial Interest and determine whether it relates to the federally funded research. A Significant Financial Interest is related to federally funded research if the DOF reasonably determines that the interest could be affected by the research or involves an entity whose financial interest could be affected by the research. If the Significant Financial Interest is so related, the DOF shall determine whether a Financial Conflict of Interest (as defined below) exists and, if so, determine what conditions or restrictions, if any, should be imposed by the College to manage, reduce, or eliminate such conflict of interest. The DOF may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an ad hoc review committee to assist in a timely review. When evaluating FCOIs, the DOF shall use policies and procedures in place at Trinity College for investigating allegations of unethical research practices, as set forth in the *Faculty Manual*.
- 2) “Financial Conflict of Interest”. A “Financial Conflict of Interest” exists when the DOF reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally funded research or educational activities.
- 3) Management of Financial Conflicts of Interest. If the DOF determines that a Significant Financial Interest constitutes a Financial Conflict of Interest, the DOF will convene a committee consisting of faculty, senior staff and/or outside experts as detailed in the procedures relating to unethical research practices set forth in the *Faculty Manual* (the “COI Committee”). The COI Committee will review the research, the financial interests in question, and the areas of conflict, and devise a plan for the management of the Financial Conflict of Interest (a “Management Plan”) with a combination of elements it deems most conducive to the continued objective pursuit of research. The Management Plan may include conditions or restrictions to manage, reduce, or eliminate Financial Conflicts of Interest, which may include (but are not limited to): a) monitoring of research by independent reviewers; b) modification of the research plan; c) disqualification from participation in the portion of the federally funded research that would be affected by the Significant Financial Interest; d) divestiture of Significant Financial Interests; e) severance of relationships that create conflicts; or f) public disclosure of Financial Conflicts of Interest. The Investigator will be consulted as to the implementation of the Management Plan; the Investigator must agree to the plan before the research can proceed. If the COI Committee and the Investigator cannot agree upon a management plan, the relevant regulatory bodies and sponsoring agencies will be notified.

If, during the course of an ongoing project, an Investigator who is new to a research project discloses a Significant Financial Interest, an existing Investigator discloses a new Significant Financial Interest, or an existing Significant Financial Interest is discovered that was not previously identified, the DOF will, within 60 days, review that Significant Financial Interest and determine whether a Financial Conflict of Interest exists. If so, the DOF will implement, on at least an interim basis, a Management Plan that will specify the actions that have been and will be taken to manage the Financial Conflict of Interest.

- 4) Retrospective Reviews. If a Financial Conflict of Interest is not identified or managed in a timely manner, the College will, within 120 days of its determination of noncompliance, complete a retrospective review to determine whether any of the research conducted during the period of non-compliance was biased in design,

conduct or reporting. The College shall document this review as required by the sponsoring agency and shall update the previously submitted FCOI report to specify additional actions to manage the FCOI going forward. If bias is found, the College shall notify the sponsoring agency promptly and submit a mitigation report that will include the key elements of the retrospective review, a description of the impact of the bias on the research project, and the College's plan of action to eliminate or mitigate the effect of the bias.

5) Reporting of Financial Conflicts of Interest.

- a) *Sponsoring agency.* A Significant Financial Interest that is determined by the DOF to be a Financial Conflict of Interest will be reported to the sponsoring agency in accordance with its requirements prior to the expenditure of federal funds or, if related to an ongoing research project or a new Investigator, within 60 days of identification of the FCOI. Retrospective reviews and Mitigation Reports will also be submitted to the extent required by the sponsoring agency.
- b) *Public request.* To the extent required by the sponsoring agency, information on the nature of a Financial Conflict of Interest will be made available to members of the public by the DOF in response to inquiries specifying the investigator name and the research project in question within 5 business days of receipt of such requests.
- c) *College reporting.* The DOF will also compile regular reports of conflicts and, where appropriate or necessary, a report shall be delivered to the Board of Trustees.

E. **Enforcement.** The College shall establish appropriate mechanisms, in accordance with sponsoring agency requirements, for enforcement of this Policy, which shall provide for sanctions where appropriate.<sup>7</sup> Disciplinary proceedings initiated in connection with this Policy shall be conducted in accordance with the Trinity College *Faculty Manual*, the Trinity College *Employee Manual* or the Student Code of Conduct. All relevant regulatory bodies and sponsoring agencies will be promptly informed of disciplinary sanctions.

F. **Records.** The College shall maintain records of all financial disclosures and of the College's review of and response to such disclosures, whether or not the disclosure involved a Financial Conflict of Interest, for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records, whichever is longer.

G. **Training.**

- 1) *Investigators on NIH/PHS-funded projects.* Each Investigator (including senior/key personnel) on projects funded by or proposed to NIH or other Public Health Service (PHS)-affiliated agencies must complete training in the College's Financial Disclosure Policy. For Investigators of NIH grants existing or pending as of December 31, 2012, this training will consist of a *mandatory* meeting with a representative of the Faculty Grants Office, which meeting will cover institutional policies, Investigator responsibilities under those policies, and the federal regulations that mandate those policies. The College will also require the completion of an online tutorial on FCOI at regular intervals during the life of the grant.
- 2) *New or previously unfunded Investigators.* New and/or previously unfunded Investigators who notify the Office for Faculty Grants of their intent to submit a research proposal to NIH or another PHS-affiliated agency after January 1, 2013 will be required to complete training (and make the disclosures described above) prior to submission of their proposal. This training will consist of a scheduled meeting with an assigned member of Faculty Grants Office staff and completion of an online tutorial.
- 3) *Investigators on non-NIH/PHS projects.* For Investigators sponsored by or seeking funding from NSF and/or other federal agencies, as well as any Investigators initiating research sponsored by a private, for-profit entity, the above training activities are optional but strongly recommended.

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<sup>7</sup>Such sanctions may include, but are not limited to, any one or more of the following: Letter of Admonition; temporary suspension of access to active research funding, either for a fixed term or pending completion of a remediation plan; temporary suspension of rights to apply for internal and external research funding as a PI, either for a fixed term or pending completion of re-training and remediation; investigation and mitigation of possible research bias resulting from improperly disclosed Significant Financial Interests, and reporting of corrective action to the relevant sponsoring agency/ies; inquiry into possible research misconduct in accordance with the College's policies and procedures; non-renewal of appointment, as per the terms and procedures outlined in the *Faculty Manual*; and involuntary termination of employment, as per the terms and procedures outlined in the *Faculty Manual*. This passage shall not be construed to contradict or supersede any disciplinary policies and procedures detailed elsewhere in the *Faculty Manual*.

- 4) *Repeat training.* Group training of active NIH/PHS-funded Investigators, consisting of a mandatory workshop, will be repeated (i) every four years and (ii) on any occasion when the College revises its Financial Conflict of Interest policies and procedures in any manner that affects the requirements of Investigators. Any Investigator who is determined not to be in compliance with this Policy will also be required to immediately undergo repeat training.

H. **Disclosure Statement.** Copies of the College's Financial Disclosure Form are available on the College website, and are distributed by the Office of Faculty Grants together with the College's transmittal form, which must be completed before applying externally. This Disclosure Statement must be completed by all senior personnel who are submitting proposals to a federal funder. The certification page of a proposal cannot be signed until forms for all Investigators are submitted to the DOF. By signing this form the applicant certifies that he/she a) does not have potential Financial Conflicts of Interest ("*I hereby certify that I have read the Financial Disclosure Policy in the Trinity Faculty Manual which is effective for all federal proposals submitted through the College. I certify to the best of my knowledge that neither I nor my spouse, partner, or dependents hold any significant financial interests that would reasonably appear to be related to my research, teaching and service responsibilities to Trinity College*") or b) does have potential conflicts ("*I have the following relationships, affiliations, activities, or interests (financial or otherwise) which constitute potential conflicts under the Trinity College Financial Disclosure Policy*"). In either case, the applicant also declares that he/she will notify the DOF of any change or discovery requiring modification of the above statement.

I. **Subrecipients.** The College is responsible for ensuring that all subrecipients, (e.g., subcontractors or consortium members) comply with applicable federal regulations regarding Financial Conflicts of Interest. To this end, the College shall enter into a written agreement with each subrecipient that shall specify whether this Policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient Investigators. If the subrecipient is to be subject to its own FCOI policy, the subrecipient shall certify as part of the written agreement referenced above that its policy complies with federal regulatory requirements. The written agreement will specify the timing for reporting of FCOIs by subrecipients to Trinity College to enable the timely review and reporting of such FCOIs in compliance with sponsoring agency requirements.

J. **Certifications.** The College shall provide all certifications required by the sponsoring agency, including that it maintains an up-to-date, written and enforced administrative process to identify and manage financial conflicts of interest, promotes and enforces compliance with requirements pertaining to disclosure of Significant Financial Interests, manages financial conflicts of interest, provide required reports, and agrees to make available promptly upon request information relating to disclosure of financial interests.

*(Issued November 2012)*