



Manual of Procedures (MOP)
Section 2. Policies and Procedures
Appendix 1. Conflict of Interest Policy

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1. OVERVIEW

This Conflict of Interest policy establishes standards to ensure there is no reasonable expectation of bias in the scientific design, conduct, or reporting of research related to the vitamin D and type 2 diabetes (D2d) study that might arise from conflicting interests of an investigator or other study personnel (collectively referred to as “Covered Individuals,” see below for definition). D2d Conflict of Interest policy: (1) sets forth principles for disclosing potential conflicts of interest and (2) describes the procedures for the implementation of the policy, (i.e. review and management of real or apparent conflicts of interest). In developing the D2d Conflict of Interest policy, the planning committee followed the latest guidelines described in the PHS Final Rule, posted in the NIH Guide NOT-OD-11-109, and also reviewed and adopted several components of policies from other multicenter trials, supported by the study’s primary sponsor, NIDDK. It is important to recognize that this policy shall be adhered to *in addition* to any obligations required by Federal or State law and local institutional policies.

2. CONFLICT OF INTEREST POLICY

2.1 Description of Disclosure Policy

Definition of Covered Individual: Any research team member who has direct contact with participants, contributes to the research in a substantive way, has contact with participants’ identifiable data or biological samples (e.g., tissue, blood, urine, saliva), or uses participants’ personal information. Research members without direct contact with participants, but with substantive contributions (e.g. study design, management of coordinating center) are also considered Covered Individuals. The D2d Conflict of Interest Subcommittee (CIS) makes the final decision of which research team members are considered a Covered Individual and is therefore subject to disclosing potential conflicts of interest.

Conflicts of interest largely arise because a Covered Individual may be in a position to influence study-related decisions or outcomes in ways productive of personal gain. Because of the potential that a real or apparent conflict of interest could bias multiple phases of the D2d study (design, conduct, data analysis and interpretation and reporting of results) and because even the perception of a conflict of interest could compromise the study’s credibility, Covered Individuals should make reasonable efforts to avoid the occurrence of such conflicts and disclose all potential conflicts of interest.

It is the policy of the D2d study that:

- A. All Covered Individuals have an obligation to *avoid* ethical, legal, financial, or other conflicts of interest that reasonable peers, the informed public, or both might construe to conflict with the investigators’ unbiased contributions to the study or its welfare.
- B. Relationships between Covered Individuals and outside entities (e.g. private or publicly-held companies, institutions, foundations) must not impede the unbiased design and conduct of the study or influence data analyses and open communication of research results.
- C. All Covered Individuals engaging in an outside activity, have a personal interest or both that could lead to a conflict of interest must fully disclose ties to these entities by completing a *D2d Conflict of Interest & Financial Disclosures (D2d COI)* form prior to the start of the study and update the form

annually. If a real, apparent or potential conflict should arise during the study, interim reporting should occur within 30 days from the date of onset of the new potential conflict of interest.

- D. Verbal disclosure will also occur during committee meetings when study issues that relate to the specific use of commercial products or entities are discussed and voted upon, as described below. At the start of the meeting, the Committee Chair will remind committee members of the need to disclose real or potential conflicts that may be relevant to the committee's tasks. Committee Chairs will be informed of any relevant action taken by the CIS on any committee member's real or apparent conflict of interest.
- E. Disclosure applies to remuneration received by Covered Individuals, their spouses, domestic partners, and/or dependent children.
- F. This policy will apply (and completed D2d-COI forms will be collected) from the onset of involvement in the D2d study and will continue (as long as the Covered Individual is still involved in the study) for 12 months past the publication date of the primary study results manuscript and one month past the publication of any other manuscript with D2d study data in which the investigator is an author. This is binding for all Covered Individuals including those who might leave the study, for any reason, prior to its completion, if they still wish to be considered as co-authors.
- G. The Covered Individual must disclose all potential conflicts of interest related to the D2d study. To guide individuals in making decisions on what types of activities to declare, the D2d-COI form includes the following general types of commercial interests, related to for-profit and non-for-profit organizations. In general, if there is doubt as to what constitutes potential conflict of interest, it is advised that Covered Individuals err on reporting all relationships.
 - Stock ownership where the Covered Individual directly controls investment decisions. Investment vehicles (such as retirement accounts, blind trusts, mutual funds including sector funds e.g. Fidelity Select Pharmaceuticals) are excluded from disclosure if the Covered Individual does not directly control the investment decisions made in these vehicles.
 - Intellectual property rights (patents, royalties, licensing fees etc.).
 - Personal compensation.
 - a. Fees for presentations (if received directly from industry or a company acting on behalf of an industrial sponsor).
 - b. Consulting fees.
 - c. Other honoraria (paid directly or donated on behalf of the Covered Individual).
 - d. Salary support if paid directly. In general, salary support for a research project provided through one's institution does not qualify as a conflict.
 - Payments received for travel or other meeting expenses (if received directly from industry).
 - Other forms of direct compensation (e.g. salary, equipment, property).
 - Federal or non-federal research contracts or grants.
 - Arrangements for future employment.
 - Debts or liabilities in connection with a commercial entity.
 - Memberships on Boards of Directors or Advisory Committees.
 - Serving as Director or Officer.

H. Remuneration from entities with commercial interests related to specific components of the D2d study must be declared. These include, but are not limited, to the following:

- Companies that develop, manufacture, market or sell vitamin D supplements. In general, remuneration from companies that do not specialize in supplements (e.g. CVS) does not constitute a conflict of interest but needs to be disclosed.
- Companies that develop, manufacture, market or sell technology that results in raising vitamin D concentration (e.g. tanning beds).
- Companies that develop, manufacture, market or sell technology that measures vitamin D concentration in the blood.

2.2 Failure of Disclosure

- Failure to submit and update the D2d-COI form, despite multiple requests by the CC, may result in terminating the Covered Individual's participation in the study.
- Failure to disclose the existence of a financial conflict of interest may result in terminating the Covered Individual's participation in the study.
- Failure to disclose the existence of a financial conflict of interest may also result in disciplinary action or sanctions at the Covered Individual's institutional level and involve restitution, criminal prosecution, or corrective action by the funding agency or the Institution.
- 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 D2d, the Executive Committee will promptly notify the primary sponsor (NIDDK) 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 the Executive Committee for further action, which may include directions on how to maintain appropriate objectivity in the funded research project.

2.3 Publication of the Policy

- The D2d Conflict of Interest policy is available on the study's public website and will be included in publications that arise from the D2d study, according to the specific journal's requirements.

3. IMPLEMENTATION OF THE CONFLICT OF INTEREST POLICY

3.1 Submission of D2d-COI Forms

The requested disclosure and the process of implementing the policy attempt to balance the D2d study's need to prevent conflicts of interest with the Covered Individuals' reasonable expectation of privacy in their personal affairs.

- At the start of the D2d study, or at the initiation of their involvement in the D2d study, all Covered Individuals must abide by this policy by completing the *D2d COI* form (see Appendix).
- The form needs to be updated annually on a calendar year basis (due at the end of each year, disclosing all potential conflicts of interest during the prior year). Covered Individuals need to update the form more frequently than annually, if there are any changes suggesting development of a possible, apparent or real conflict of interest. Such interim reporting should occur within 30

days from the date of onset of the new relationship that may constitute a potential conflict of interest.

- ⇒ The site (or core unit) Principal Investigator and the D2d Executive Committee *share responsibility* for ensuring that all Covered Individuals involved in the conduct of the D2d study abide by this policy by completing and updating the form, as required.
- The site Principal Investigator and each research team member (i.e. Covered Individuals) are to complete the form.
- The PI is to submit his completed form to the D2d Coordinating Center (CC).
- The PI will review all forms from all other Covered Individuals at their site and any form(s) with “yes” responses are also to be submitted to the CC. The PI will retain in the local study files the completed Form(s) for Covered Individuals who answer “no” to all questions.
- Covered Individuals that are not affiliated with a site or core units (e.g., consultants, Clinical Outcome Committee members) will submit their forms to the CC.
- Completed forms are submitted via electronic mail to the CC at D2d@TuftsMedicalCenter.org or using a web-based submission.
- Completed and signed forms are tracked and stored securely in the D2d study management database. Forms will be destroyed after the close of the study on a date determined by the D2d Executive Committee.
- The D2d Project Manager or designee will conduct an initial review of all forms submitted to the CC. Forms with a disclosure reported will be forwarded to the CIS.

3.2 Review and Management of D2d-COI Forms

- Forms with a disclosure will be reviewed by the CIS, which is composed of three members of the EC and two other members from the D2d Study Group.
- The CIS will have oversight of this process for all individuals with the exception of themselves, for whom the process of oversight will devolve to the NIDDK Program Official.
- If, after review of the form, a potential conflict of interest is deemed to exist, the CIS will implement, at least on an interim basis, a management plan that will specify the actions that have been and will be taken to eliminate or limit the potential impact of such conflict(s). Such recommendation may include removal of committee chairmanship or removal from discussions / voting on specific issues where a potential conflict of interest may exist. In cases of a conflict of interest that cannot be mitigated effectively, the Covered Individual may need to be removed from the D2d Study Group.
- At its discretion, the CIS may refer cases to the NIDDK Program Official for an additional level of review before making a recommendation.
- The Chair of the CIS will report the conclusion of the review and management plan to the site PI and the subcommittee’s report will be filed at the CC with the disclosure form. The site PI will communicate the subcommittee’s report to the Covered Individual and will provide written acceptance of the report’s recommendations and follow-up on implementation of the subcommittee’s recommendations.

3.2.1 Criteria for Significant Conflict of Interest

A significant financial relationship is considered to exist based on considerable commercial ties based on (1) aggregate dollar amount received over the past one year or anticipated receipts over the next year or (2) percent of equity holdings. The CIS will determine the threshold levels for these criteria.

4. APPENDIX

Appendix 1a. Conflict of Interest Disclosure Form