

Financial Conflict of Interest Policy

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 Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Definitions

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to DNASTAR and PHS.

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 DNASTAR's report of a financial conflict of interest to a PHS Awarding Component.

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

Significant financial interest means:

(1) 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 responsibilities with DNASTAR:

(i) 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. 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;

(ii) 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); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their DNASTAR responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. The disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the DNASTAR's FCOI policy, the Corporate Controller and/or General Manager of DNASTAR 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.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the DNASTAR to the Investigator if the Investigator is currently employed or otherwise appointed by the DNASTAR, including intellectual property rights assigned to DNASTAR and agreements to share in royalties related to such rights; any ownership interest in DNASTAR held by the Investigator, 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.

Responsibilities of DNASTAR regarding Investigator financial conflicts of interest

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this policy, and make such policy available via DNASTAR web site.

(b) Inform each Investigator of DNASTAR's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and each Investigator will complete training of the policy prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

(1) DNASTAR revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to DNASTAR; or

(3) DNASTAR finds that an Investigator is not in compliance with DNASTAR's financial conflict of interest policy.



(c) If DNASTAR carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), DNASTAR investigator and the Corporate Controller will take reasonable steps to ensure that any subrecipient Investigator complies with this policy by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of DNASTAR or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR Part 50 Subpart F. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of DNASTAR for disclosing significant financial interests that are directly related to the subrecipient's work for DNASTAR;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to DNASTAR. Such time period(s) shall be sufficient to enable DNASTAR to provide timely FCOI reports, as necessary, to the PHS;

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

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this policy, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d) The Corporate Controller and/or General Manager of DNASTAR will review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to DNASTAR the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

(2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by DNASTAR, during the period of the award. Such disclosure shall include any information that was not disclosed initially to DNASTAR, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

(f) The Corporate Controller and/or General Manager of DNASTAR will review and determine whether an Investigator's significant financial interest is related to PHS-funded 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 PHS-funded research when the Corporate Controller and/or General Manager of DNASTAR reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. DNASTAR may involve the Investigator in the determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Corporate Controller and/or General Manager of DNASTAR reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient 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.

(h) The Corporate Controller of DNASTAR will provide initial and ongoing FCOI reports to the PHS.

(i) The Corporate Controller of DNASTAR maintain records relating to all Investigator disclosures of financial interests and the Corporate Controller or General Manager DNASTAR's review of, and response to, such disclosures (whether or not a disclosure resulted in DNASTAR's determination of a financial conflict of interest) and all actions under DNASTAR's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS.

Management and reporting of financial conflicts of interest

(a) Management of financial conflicts of interest.

(1) Prior to the DNASTAR's expenditure of any funds under a PHS-funded research project, the Corporate Controller and/or General Manager of DNASTAR shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded 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. Conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);



(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) 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;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing PHS-funded 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 DNASTAR, the Corporate Controller and/or General Manager of DNASTAR shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-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, DNASTAR may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of DNASTAR's review.

(3) Whenever DNASTAR identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by DNASTAR during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Corporate Controller and/or General Manager of DNASTAR shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) 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;

(ii)(A) 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 DNASTAR to constitute a financial conflict of interest; failure by DNASTAR 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 Corporate Controller and/or General Manager of DNASTAR shall, within 120 days of DNASTAR's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.



(B) The Corporate Controller of DNASTAR will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

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

(iii) Based on the results of the retrospective review, if appropriate, the Corporate Controller of DNASTAR shall 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 Corporate Controller of DNASTAR 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 DNASTAR'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, DNASTAR will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, DNASTAR 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 DNASTAR's retrospective review.

(4) Whenever DNASTAR implements a management plan pursuant to this policy, DNASTAR shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

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

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



(B) DNASTAR management determines that the significant financial interest is related to the PHS-funded research; and

(C) DNASTAR management determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the DNASTAR makes available via written response to any requestor within five business days of a request, will include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$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.

(iii) DNASTAR responds to written requests for this purpose, DNASTAR 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 DNASTAR's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) 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.

(6) In addition to the types of financial conflicts of interest as defined in this policy that must be managed, DNASTAR may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as DNASTAR deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to DNASTAR's expenditure of any funds under a PHS-funded research project, DNASTAR shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the DNASTAR to be conflicting and ensure that DNASTAR has implemented a management plan in accordance with this policy. In cases in which DNASTAR identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, DNASTAR will not submit an FCOI report to the PHS Awarding Component.

(2) For any significant financial interest that DNASTAR identifies as conflicting subsequent to DNASTAR's 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), DNASTAR shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that DNASTAR has implemented a management plan. When such 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 DNASTAR (e.g., was not timely reviewed or reported by a subrecipient), DNASTAR also will 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 Corporate Controller of DNASTAR will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section 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 DNASTAR's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

(i) Project number;

(ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;

(iii) Name of the Investigator with the financial conflict of interest;

(iv) Name of the entity with which the Investigator has a financial conflict of interest;

(v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

(vi) Value of the financial interest (dollar ranges are permissible: \$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;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for DNASTAR's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of DNASTAR's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the research project;

(B) Conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

(4) For any financial conflict of interest previously reported by DNASTAR with regard to an ongoing PHS-funded research project, DNASTAR shall 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 shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. DNASTAR shall 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.

(5) In addition to the types of financial conflicts of interest as defined in this subpart that must be reported pursuant to this section, DNASTAR may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as DNASTAR deems appropriate.

Remedies

(a) If the failure of an Investigator to comply with DNASTAR's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Corporate Controller of DNASTAR will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

(c) In any case in which the HHS determines that a PHS-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 DNASTAR, DNASTAR will 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.