1. INTRODUCTION

This Policy is intended to establish compliance with the rules adopted by the United States Public Health Service (PHS) set forth at 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, which require that awardee institutions adopt, maintain and enforce written policies pertaining to Financial Conflicts of Interest (or FCOIs) that promote objectivity in the design, conduct and reporting of federally funded research. If the Research at issue is federally funded, but not by a PHS agency (*e.g.*, National Science Foundation), then Celldex's Office of Compliance will consult the conflict of interest in research policies and requirements of that funding agency, and will implement this Policy in a manner that complies with and conforms to any related and applicable legal requirements.

2. SCOPE

This Policy affirms Celldex's commitment to investigating, monitoring, managing and reporting Financial Conflicts of Interest. This Policy applies only to FCOIs of Investigators who participate in, or apply for, Research funded by agencies or offices of the United States government that require disclosure and management of any Investigator conflicting financial interests, and does not supersede any other policies or procedures of Celldex that control or monitor conflicts of interest among Celldex employees and contractors. All Celldex board members, executives, employees, agents and contractors who are acting as Investigators or Senior/Key Personnel and are engaged in Research activities and, as applicable and according to Section 3.3, subrecipients' Investigators or Senior/Key Personnel who are engaged in Research activities are subject to and must follow this Policy. Celldex's Office of Compliance is responsible for implementing this Policy.

3. POLICY

This Policy sets forth the governing processes for investigating, monitoring, managing and reporting Financial Conflicts of Interest.

3.1. Disclosure and Review of Significant Financial Interests (SFI) of Investigators.

3.1.1. Role of the Designated Official. The Designated Official will administer and enforce this Policy, including taking steps to:

(i) Solicit and review SFI disclosures pursuant to this Policy;

(ii) Make determinations as to FCOIs;

(iii) Develop and implement conflict management plans;

(iv) Conduct any required retrospective FCOI reviews, including issuing reports of findings and conclusions;

(v) Communicate with federal sponsors on matters pertaining to this Policy;

(vi) Make recommendations to Celldex with respect to matters covered by this Policy;

(vii) Develop and implement reasonable and appropriate summary procedures for the disposition of matters involving compliance with this Policy; and

(viii) Suspend, for good cause, an ongoing Research project to prevent any probable or continued violations of this Policy.

3.1.2. Investigators Responsibility to Make Disclosures. Investigators are responsible personally for ensuring that their SFI disclosures (and those of their spouse and dependent children) required under this Policy are submitted in a complete and timely manner in accordance with procedures and guidelines established by the Designated Official.

3.1.3. Disclosure of SFIs.

3.1.3.1. Investigators must submit a disclosure of all SFIs to the Designated Official, in a form and manner to be determined by the Designated Official, at any of the following times:

(i) No later than at the time of application for funding of the Research;

(ii) At least annually during the period of the Research award;

(iii) Within thirty (30) days after discovering or acquiring a new or changed SFI;

(iv) Within thirty (30) days after Celldex's joining an ongoing Research project; or

(v) When acting as Investigators, when submitting research protocols to an institutional review board or other designated ethics review committee.

3.1.3.2. In addition to Section 3.1.3.1, for disclosures of SFIs involving travel (which would include only travel expenses that are paid for, provided by or reimbursed by entities external to Celldex), Investigators must submit (at a minimum) the following information to the Designated Official in a form and manner determined by the Designated Official:

(i) The purpose of the trip;

(ii) The identity of the sponsor/organizer;

(iii) The destination;

(iv) The duration;

(v) Whether the Investigator's spouse or dependent children went on the trip and whether all or part of that trip was funded; and

(vi) An estimate of the approximate monetary value of travel.

All travel expenses must abide by all other Celldex policies and policies governing travel by Celldex personnel.

3.1.4. Review of Disclosures.

3.1.4.1. The Designated Official will establish procedures to ensure timely review of Investigators' disclosures of SFI(s) pursuant to Section 3.1.3.1 of this Policy.

3.1.4.2. After a disclosure has been made, the Designated Official will determine whether the SFI is related to Research and, if so related, whether the SFI is an FCOI. An Investigator's SFI is "related" to Research when the Designated

Official determines that the SFI (i) could be affected by the Research; or (ii) is in any entity whose financial interest could be affected by the Research.

3.1.4.3. The Designated Official may involve the affected Investigator in its determination of whether an SFI is related to the Research.

3.1.4.4. An FCOI exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of the Research.

3.1.5. Timing of Review.

3.1.5.1. Prior to the expenditure of any funds under a Research project, the Designated Official will review all disclosures of SFIs to (i) determine whether any SFI relates to the Research and whether any SFI constitutes an FCOI; and (ii) if so, develop and implement a management plan that specifies the actions that have been and will be taken to manage such FCOI.

3.1.5.2. Whenever, in the course of an ongoing Research project, Investigators who are new to participating in the Research project disclose an SFI or Investigators who already are participating in the Research project disclose a new SFI, the Designated Official will, within sixty (60) days, review the SFI disclosure to (i) determine whether the SFI relates to the Research and whether an FCOI exists; and (ii) if so, develop and implement, on at least an interim basis, a management plan that specifies the actions that have been and will be taken to manage such FCOI.

3.1.5.3. Whenever an SFI is identified that was not disclosed timely by an Investigator or, for whatever reason, was not reviewed previously by the Designated Official during an ongoing Research project, the Designated Official will, within sixty (60) days, review the SFI disclosure to (i) determine whether the SFI related to the Research and whether an FCOI exists; and (ii) if so, develop and implement, on at least an interim basis, a management plan that specifies the actions that have been and will be taken to manage such FCOI going forward. See Section 3.2.3 (Retrospective Reviews) for further requirements that apply when an FCOI has not been identified or managed in a timely manner.

3.2. <u>Management of Financial Conflicts of Interest</u>.

3.2.1. Management Plan. If the Designated Official determines that an FCOI exists, a conflict management plan will be developed and implemented in consultation with the affected Investigator, project manager for the Research project, or others as deemed appropriate by the Designated Official.

3.2.1.1. The conflict management plan will consist of measures that in the reasonable judgment of the Designated Official will reduce, eliminate or manage the effects of the FCOI, and will be designed to safeguard objectivity in the Research project.

3.2.1.2. In developing a conflict management plan, the Designated Official may conduct factual inquiries (in conjunction with the outside counsel) and consult with and

receive recommendations from such persons as the Designated Official deems necessary and appropriate.

3.2.1.3. The terms of a conflict management plan will be consistent with legal and regulatory requirements and the requirements of this Policy, and may include one or more of the following elements designed to manage the FCOI:

(i) Public disclosure of the FCOI (*e.g.*, if presenting or publishing the research, including addenda to previously published presentations);

(ii) For research projects involving Research with human subjects, disclosure of FCOIs directly to such subjects;

(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 FCOI;

(iv) Modification of the Research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or part of the Research;

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

(vii) Severance of relationships that create financial conflicts.

3.2.2. Ongoing Monitoring.

3.2.2.1. Celldex will monitor Investigator compliance with each management plan on an ongoing basis until completion of the Research project.

3.2.2.2. All Investigators who are subject to a conflict management plan will provide annual update reports in a form and manner specified by the Designated Official.

3.2.2.3. In general, annual update reports will require each Investigator to confirm that there has been no material change in the nature or amount of any SFIs or report any such change, and confirm that s/he is complying with the terms of any conflict management plan.

3.2.2.4. Investigators will be restricted from submitting funding applications, expending funds and conducting Research on projects until annual update reports are current.

3.2.3. Retrospective Reviews.

3.2.3.1. A retrospective review will be conducted whenever an FCOI is not identified or managed in a timely manner, including due to a failure by:

(i) Investigators to disclose an SFI that is determined by the Designated Official to constitute an FCOI;

(ii) The Designated Official to review or manage such FCOI in a timely manner; or

(iii) Investigators to comply materially with an FCOI management plan.

3.2.3.2. Within one-hundred twenty (120) days after Celldex's determination of noncompliance, Celldex will complete a retrospective review of the Investigator's activities and the Research project to determine whether the Research project, or a portion thereof, conducted during the time of noncompliance was biased in the design, conduct or reporting of such Research.

3.2.3.3. The Designated Official will document all retrospective reviews, including (but not limited to) the following key elements: (i) project number; (ii) project title; (iii) principal investigator/project director or, if there are multiple, the contact principal investigator/project director; (iv) name of the Investigator with the FCOI; (v) name of the entity in which the Investigator has an FCOI; (vi) the reason(s) for the retrospective review; (vii) a detailed description of the methodology used for the retrospective review (*e.g.*, composition of the review panel, documents reviewed); and (viii) the findings and conclusions of the review.

3.2.4. Mitigation Report Based on Retrospective Reviews.

3.2.4.1. Based on the results of the retrospective review, the Designated Official will update the any previously submitted FCOI report in accordance with Section 3.4 below, specifying the actions that will be taken to manage the FCOI going forward.

3.2.4.2. If the Designated Official determines during its review that the FCOI introduced bias into the Research, Celldex must determine promptly whether notification and reporting is necessary to the awarding agency.

(i) If a mitigation report is required to be submitted to a PHS awarding component (*e.g.*, National Institutes of Health), such report must include, at a minimum, the key elements documented in the retrospective review (above), a description of any impact of the bias on the Research, and Celldex's plan of action(s) taken to eliminate or mitigate the effect of the bias (*e.g.*, extent of harm done, including any qualitative or quantitative support).

(ii) The Designated Official will submit annual FCOI reports addressing the status of the identified FCOI and any changes to the conflict management plan for the duration of the Research in accordance with Section 3.4 below.

3.2.5. Confidentiality.

3.2.5.1. Due to the sensitive information contained in them, except as required by applicable law, disclosure forms and follow-up information may only be reviewed by the Designated Official; where needed, such information may be shared with outside counsel to assist in making an FCOI determination.

3.2.5.2. The forms and information cannot be shared with any other employees or third parties (except as authorized by the Law Department in writing).

3.3. **Subrecipient Compliance.** If Celldex carries out Research through a subrecipient (*e.g.*, a subcontractor):

3.3.1. Celldex will include as part of the written agreement with the subrecipient terms that establish whether the subrecipient's or Celldex's FCOI policy will apply to personnel of the subrecipient who are engaged in Research activities;

3.3.2. If the subrecipient's personnel will comply with the subrecipient's FCOI policy, Celldex will obtain written certification from the subrecipient that its policy complies with all applicable laws and regulations. Alternatively, if the subrecipient cannot provide such certification, the agreement will state that subrecipient personnel will comply with this Policy.

3.3.3. If the subrecipient's FCOI policy will be followed, the agreement will specify a time period for the subrecipient to report all identified FCOIs of subrecipient to Celldex, which period must be sufficient to enable Celldex to provide timely reports to the PHS agency (or other awarding agency, as applicable); and

3.3.4. Alternatively, if subrecipient personnel will be subject to this Policy, the agreement will specify a time period for the subrecipient to submit SFI disclosures to Celldex, which period must be sufficient to enable Celldex to comply timely with its review, management and reporting obligations under this Policy.

3.4. **Reporting to the PHS Awarding Component**.

3.4.1. Prior to expending any Research funds, if the Research is funded by a PHS agency, Celldex will provide the PHS awarding component (*e.g.*, the National Institutes of Health) with an FCOI report regarding any Investigator's SFI found by Celldex to be conflicting and ensure that Celldex has implemented a management plan. No report is necessary if the FCOI has been identified and eliminated prior to the expenditure of Research funds.

3.4.2. For any SFI that Celldex identifies as conflicting subsequent to its initial FCOI report during an ongoing Research project, Celldex will provide the PHS awarding component, within sixty (60) days after identification, an FCOI report regarding the FCOI and ensure that Celldex has implemented a management plan. Pursuant to Section 3.2.3, when such FCOI report involves an SFI that was not disclosed timely or was not previously reviewed or managed by the Designated Official, Celldex also must complete a retrospective review to determine whether any Research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct or reporting of such Research. Also, pursuant to Section 3.2.4, if bias is found, Celldex promptly must notify, and submit a mitigation report to, the PHS awarding component.

3.4.3. Any reports submitted under Sections 3.4.1 or 3.4.2 must contain sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI, and to assess the appropriateness of Celldex's management plan. Elements of the FCOI report must include, but are not limited to, the following:

(i) Project number;

(ii) Principal investigator/project director or, if multiple, the contact principal investigator/project director;

(iii) Name of the Investigator with the FCOI;

(iv) Name of the entity with which the Investigator has a FCOI;

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

(vi) Value of the financial interest;

(vii) A description of how the financial interest relates to the Research and the basis for Celldex's determination that the FCOI conflicts with the Research; and

(viii) A description of the key elements of the 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 the Investigator's compliance; and

(f) Other information as needed.

3.4.4. For any FCOI previously reported by Celldex with respect to an ongoing Research project, Celldex must provide the PHS awarding component with an annual FCOI report that addresses the status of the FCOI and any changes in the management plan, including an explanation of whether it is still being managed or why it no longer exists. These annual reports will be provided for the duration of the award period.

3.5. **Training for Investigators.** Prior to engaging in Research, and no less often than every four (4) years thereafter, all Investigators engaged in Research activities must complete training with respect to this Policy and the then-current PHS conflict of interest rules and regulations. In addition, the Designated Official will establish a process to ensure that Investigators receive training when any of the following occur:

3.5.1. Celldex revises this Policy in any manner that materially affects the obligations and responsibilities of Investigators;

3.5.2. Investigators who will participate in Research activities first become associated with Celldex; and

3.5.3. The Designated Official determines that a particular individual to whom this Policy apply is not in compliance with this Policy or any applicable conflict management plan.

3.6. **Public Accessibility**.

3.6.1. This Policy will be made available via Celldex's publicly accessible Web site.

3.6.2. If Senior/Key Personnel disclose an SFI that Celldex determines is related to a Research project and is an FCOI, information concerning such FCOI will be posted on Celldex's publicly accessible Web site, which posting will contain at least the following information:

(i) The name of Senior/Key Personnel;

(ii) The title and role of the Senior/Key Personnel with respect to the Research project;

(iii) The name of the entity in which the SFI is held;

(iv) The nature of the SFI; and

(v) The approximate dollar value of the SFI set forth in range amounts, or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value.

3.6.3. The information made available under Section 3.6.2 must be updated at least annually, and must remain posted for a period of three (3) years after the date on which the information was most recently updated. In addition, Celldex must update the Web site within sixty (60) days after its receipt or identification of information concerning any additional SFI of the Senior/Key Personnel for the Research project that was not disclosed previously, or upon disclosure of an SFI of Senior/Key Personnel new to the Research project, if Celldex determines that the SFI is related to the Research project and is an FCOI.

3.7. **Maintenance of Records.** Celldex will maintain records relating to all disclosures of SFIs and the Designated Official's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of an FCOI) and all actions under this Policy or retrospective review, if applicable, for at least three (3) years after the date the final expenditures report is submitted to the PHS agency (or later dates specified in 45 C.F.R. § 75.361 (Retention Requirements for Records) for different situations, as applicable).

4. DEFINITIONS

"**Conflict of Interest**" or "**COI**" may occur when professional obligations or interests could be undermined or jeopardized by personal interests (*e.g.*, a financial or fiduciary interest in a non-Celldex entity or a personal relationship or interest that may benefit from Research results) such that an independent observer might reasonably question whether an individual's professional actions or decisions are determined by considerations of personal gain. The existence of a COI will depend on the particular facts and circumstances of a given situation.

"**Designated Official**" means the individual(s) designated by the Celldex Office of Compliance to solicit and review disclosures of significant financial interests from each Investigator (and those of his/her spouse and dependent children) related to his/her Research activities.

"**Financial Conflict of Interest**" or "**FCOI**" means a Significant Financial Interest related to Research that could directly and significantly affect the design, conduct or reporting of the Research.

"**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 a federal agency, or proposed for such funding, which may include, for example, collaborators or consultants.

"**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 or drug). As used in this Policy, Research is limited to any such activity for which funding is made available by a federal agency or office, or proposed for funding by a federal agency or office, by means of a grant, cooperative agreement or contract.

"**Senior/Key Personnel**" means the Investigator and any other person identified as senior or key personnel by Celldex (or applicant in the case it is an entity other than Celldex) in a grant application, award or contract, or in any progress report or any other report submitted to the funding agency.

"**Significant Financial Interest**" or "**SFI**" means:

(i) A financial interest consisting of one or more of the following interests of an Investigator (and those of his/her spouse and dependent children) that reasonably appears to be related to his/her institutional responsibilities:

  (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 (12) 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. 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;

  (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 (12) months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or his/her spouse or dependent children) holds any equity interest (*e.g.*, stock, stock option or other ownership interest); or

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

(ii) 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 available readily), related to his/her institutional responsibilities; provided, however, that this does not apply to travel that is reimbursed or sponsored by Celldex, a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

SFI does not include the following types of financial interests:

(i) Salary, royalties or other remuneration paid by Celldex to the Investigator if s/he currently is employed or otherwise appointed by Celldex, including intellectual property rights assigned to Celldex and agreements to share in royalties related to such rights;

(ii) Any ownership interest in Celldex held by the Investigator;

(iii) 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;

(iv) Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or

(v) Income from service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

5. ROLES AND RESPONSIBILITIES

- Designated Official: Celldex Senior Vice-President and General Counsel

6. CONSEQUENCES OF NON-COMPLIANCE

Violations of this Policy may result in disciplinary action up to and including termination.