Financial Conflict of Interest Policy
for Research Supported by The National Institutes of Health

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of Clarigent Health research funded by the National Institutes of Health.

A. Persons covered by this policy

This policy applies to all Investigators and key personnel, including all full-time, part-time, temporary, and contract employees, of Clarigent Health who are planning to participate in, or are participating in, National Institutes of Health ("NIH") funded research by means of a grant or cooperative agreement.

B. Preamble

1. The primary goal of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest and to prevent an employee's activities from adversely influencing Clarigent operations.
2. It is recognized that research related conflicts of interest can arise from legitimate and appropriate activities including economic development, public-private interactions, and employee's and their family's personal business relationships.
3. This policy is implemented in accordance with 42 CFR Part 50 Subpart F - "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" and 45 CFR Part 94 "Responsible Prospective Contractors" as well as all other relevant policies of federal funding and oversight agencies.

C. Statement of general policy

1. The design, conduct, and reporting of Research funded under NIH grants or cooperative agreements should be free from bias resulting from Investigator financial conflicts of interest.
2. To provide a reasonable expectation of achieving the goal of this policy,
    a) Investigators shall
        (i) complete appropriate training as required under this policy; and
        (ii) disclose perceived and real financial conflicts of interest annually and provide new or updated disclosures in a timely manner.
    b) Clarigent shall
        (i) provide for the elimination or management of Financial Conflicts of Interest; and
        (ii) make disclosures to both the NIH and to the public as required under this policy.
3. Nothing in this policy shall be construed to permit, even with disclosure, any activity that is prohibited by law.
4. Nothing in this policy shall be construed to limit or abridge the authority of Clarigent Associates to take such action as they deem appropriate regardless of any action or inaction by an Officer of Clarigent.

D. Definitions

1. *Associate* means any full-time, part-time, temporary, and contract employees of Clarigent.
2. *Disclosure* means an Investigator's disclosure of significant financial interests to Clarigent.
3. *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.
4. *FCOI Report* means Clarigent's report of a Financial Conflict of Interest to a PHS Awarding Component.
5. *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.
6. *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.
7. *Clarigent* means Clarigent Corporation D/B/A Clarigent Health.
8. *Clarigent Responsibilities* means an Investigator's professional responsibilities on behalf of Clarigent, and as defined by Clarigent in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, training, professional practice, and service on panels.
9. *Investigator* means the project director (PD) or Principal Investigator (PI) 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, subcontractors, or consultants.
10. *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.
11. *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 subpart.
12. *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).
13. *President* means the President of Clarigent.
14. *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS/NIH through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Clarigent training grant, program project, or research resources award.
15. *Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by Clarigent in the grant application, progress report, or any other report submitted to the PHS by Clarigent and any other personnel considered to be essential to work performance in accordance with HHSAR subpart 352.242–70.
16. *Significant Financial Interest means:*

    a) 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 Clarigent responsibilities:

(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 a management or governance position; or

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

b) Travel:

(i) 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 Clarigent responsibilities;

(ii) 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 Institute 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 Institute of higher education.

(iii) Disclosure for travel shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Clarigent 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/NIH-funded research.

c) Exclusions: The term Significant Financial Interest does not include the following types of financial interests:

(i) Salary, royalties, or other remuneration (including equity) from Clarigent if the Investigator is currently employed or otherwise appointed by Clarigent, including intellectual property rights assigned to Clarigent and agreements to share in royalties related to such rights;

(ii) any ownership interest in Clarigent held by the Investigator, if Clarigent is a commercial or for-profit organization;

(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 intuition 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 Clarigent of higher education;

(v) Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Clarigent 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 Clarigent of higher education; and

(vi) An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest. "Potential" means an opportunity with a reasonable likelihood of occurring.

E. Policy Implementation

1. Training Required: Investigators shall complete FCOI training provided by Clarigent on or before their becoming subject to this policy and then every four years thereafter. Training will include information on Clarigent's policy, Investigator's disclosure responsibilities, and the Federal regulation (45 CFR Subtitle A, subchapter A, part 94). Immediate training will be required if Clarigent revises this policy in a manner that affects the Investigator, when an Investigator is new to Clarigent, or as a result of a finding of noncompliance with this policy or a management plan, or other related misconduct.

2. Disclosure Requirement:

   a) An Investigator shall disclose any situation in which the Investigator has, or may have, a real or potential Significant Financial Interest as defined and provided for herein. Research should not be undertaken where a Significant Financial Interest is present until a determination and approval has been made pursuant to this policy.

   b) Investigators shall keep their supervisors informed of the Investigator's Significant Financial Interest. If a supervisor becomes aware of a conflict of interest that an employee has not disclosed, the supervisor shall discuss the situation with the employee, require that a written disclosure be made as provided in this policy, and inform the President to anticipate the receipt of a new Disclosure.

3. Disclosure Frequency:

   a) Disclosure must be made no later than at the time of application for NIH-funded research.

   b) Disclosure must be made annually to Clarigent, and such disclosure shall include any information that was not disclosed initially. If no Significant Financial Interest is present a Disclosure must still be submitted that states "none". The date such annual Disclosure is due shall be set by the Associates and disseminated Clarigent wide.

   c) In addition to the annual Disclosure, a new or updated Disclosure must be completed in a timely manner whenever a new or potential Significant Financial Interest arises or when a significant change occurs concerning an existing Disclosure.

   d) In any event, Disclosure must be made within thirty (30) days of discovery or acquiring a new Significant Financial Interest.

   e) Newly hired Investigators should make a Disclosure as part of their new hire employment process.

4. Review and Management:

   a) The Associates shall solicit and review SFI Disclosures and determine if they are a FCOI. The criterion for Associates to apply when considering if an FCOI exists is whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS funded research.

(i) Associates shall review SFI Disclosures and determine if they are a FCOI when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI.

(ii) Associates shall review SFI Disclosures and determine if they are a FCOI and implement a management plan within 60 days whenever Clarigent identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by Clarigent.

b) If a determination is made that a FCOI exists, then the Associates shall seek input from the Investigator and recommend to the President a suitable action plan ("Management Plan") to eliminate or manage the FCOI consistent with the objectives of this policy. The Management Plan shall provide for its periodic review and updating at least annually. In the event that there is no reasonable way to manage a FCOI, then the Investigator may be prohibited from participating in the related Research until such a time as the FCOI is eliminated.

c) Examples of 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.

d) The President shall review the proposed Management Plan and can approve, modify and approve, or return to the Associates for additional work. Final review and determination must be completed prior to the expenditure of any PHS funds for the applicable Research.

F. Violations and Sanctions

1. Sanctions: Violations of Clarigent policies, including the failure to avoid a prohibited activity or disclose a Significant Financial Interest in a timely manner, will be dealt with in accordance with applicable policies and procedures that may include disciplinary actions up to and including termination of employment.

2. Clinical Research: In any case in which the HHS determines that a NIH-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 FCOI that was not managed or reported by Clarigent as required by this policy, the Associates shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

G. Clarigent Reporting

1. Clarigent, through its Associates shall provide annual and revised reports of FCOI to National Institutes of Health (NIH) per the applicable regulations:
    a) Prior to the expenditure of funds;
    b) within sixty days of identification for an Investigator who is newly participating in the project;
    c) within sixty days for new or newly identified FCOIs for existing investigators;
    d) at least annually (at the same time as when Clarigent is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
    e) following retrospective review to update a previously submitted report, if appropriate.
2. Clarigent, through its Associates, shall notify NIH of bias found in the design, conduct, or reporting of NIH funded Research including whether Investigator failure to comply with this FCOI policy or management plan appears to have caused such bias. In the event bias is found, Clarigent will submit a Mitigation report in accordance with the regulation. The mitigation report must include, at a minimum, a description of the impact of the bias on the research project and Clarigent'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).
3. FCOI records shall be maintained for at least three (3) years from the submission of the final expenditure reports for the pertinent NIH funding or longer as required by other policy or regulation.

H. Subrecipients

1. Clarigent, through its Associates, shall require sub-recipient compliance with pertinent FCOI requirements as mandated by PHS regulation:
    a. If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
    b. If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows Clarigent to report identified FCOIs to NIH as required by the regulation.
    c. Alternatively, if applicable, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable Clarigent to identify, manage, and report identified FCOIs to NIH.
2. Clarigent shall provide applicable FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators consistent with this Policy.

I. Public Accessibility Requirement

1. Clarigent shall maintain, update and post this FCOI policy on Clarigent public website, as required by the regulation.
2. FCOI Informational requests by the public concerning identified FCOIs held by senior/key personnel should be made to the President. The President shall respond to requests for FCOI information within five (5) business days with minimum reporting elements as provided for under applicable regulations.

J. Certifications and General Obligations of Clarigent under this Policy:

1. Clarigent shall certify, in each contract proposal to which this Policy applies, that Clarigent:
   a) Has in effect at that Clarigent an up to date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;
   b) Shall promote and enforce Investigator compliance with this Policy's requirements including those pertaining to disclosure of significant financial interests;
   c) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this Policy;
   d) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and Clarigent's review of, and response to, such disclosure, whether or not the disclosure resulted in Clarigent's determination of a financial conflict of interest; and
   e) Shall fully comply with the requirements of this Policy.