

Curadel, LLC Financial Conflicts of Interest Policy

Additional conflicts of interest policies apply when investigators are responsible for the design, conduct or reporting of PHS funded research. Please refer to the conflicts of interest policy under the Administration of Federal Awards section of this policy manual.

In order to maintain compliance with federal laws and regulations governing financial conflicts of interest for publically funded research, CURADEL, LLC has established the following policy. Any investigator responsible for the design, conduct or reporting of research on behalf of CURADEL, LLC shall not participate in any PHS-funded research if he or she has a significant financial interest that could influence the design, conduct or reporting of such research activity. CURADEL, LLC will take immediate action under this policy to manage, reduce or eliminate any such FCOI that is brought to its attention.

The Department of Health and Human Services (“HHS”) published new FCOI Regulations that took effect on August 24, 2012. All PHS-funded research undertaken at CURADEL, LLC shall be conducted in full compliance with this policy and under all applicable federal and state laws to promote transparency as to any FCOI in research, including, without limitation, TITLE 42 CODE OF FEDERAL REGULATIONS (CFR) PART 50 SUBPART F pertaining to grants and cooperative agreements and TITLE 45 CFR PART 94 pertaining to research contracts (collectively, “FCOI Regulations”). The required information will be collected pursuant to the FCOI Regulations and recorded on the CURADEL, LLC FCOI Disclosure form. Investigators failing to comply with all FCOI Regulations shall be subject to corrective counseling and possible corrective action.

CURADEL, LLC employees and scientists may collaborate with companies, universities, research groups or government institutions to develop scientific and medical breakthroughs or to provide expertise. To assure professional and commercial integrity in such matters, CURADEL, LLC reviews these collaborations and, when appropriate, puts measures in place to eliminate, minimize, and manage any FCOI that may arise.

Definition of Terms of FCOI Policy:

Designated Official(s): means a person designated by CURADEL, LLC to determine whether an Investigator’s Significant Financial Interest is related to PHS-funded research, and if related, whether the Significant Financial Interest is a Financial Conflict of Interest.

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.

Financial Interest: means any interest of economic value in or relationship with an entity, whether private or public, including, but not limited to, ownership of stocks, bonds, stock options, partnership or other equity interests, rights to patent or royalty payments, receipt of consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, reimbursed or sponsored travel expenses related to Investigator’s Company Responsibilities, or other remuneration.

Immediate Family or Dependents: means a (i) spouse; (ii) child; or (iii) any other person residing in the same household as the Investigator who is a dependent of the Investigator or of whom the Investigator is a dependent.

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 under PHS grants, cooperative agreements, or contracts, including Investigators working for sub-awardees.

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.

Management Plan: means a written plan for the management, reduction or elimination of a FCOI relating to PHS-funded Research.

CURADEL, LLC's Responsibilities: means an Investigator's professional responsibilities on behalf of CURADEL, LLC, including, but not limited to, activities such as research, research consultation.

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.

PHS Awarding Component: means the organizational unit of the Public Health Service (PHS) that funds the research that is subject to the FCOI Regulations.

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. This term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, grant, or cooperative agreement.

Senior or Key Personnel: means the Project Director or Principal Investigator and any other person identified as Senior or Key Personnel in a CURADEL, LLC grant application, grant proposal, progress report, contract proposal, contract, or other report submitted to the PHS.

Significant Financial Interest: means an Investigator's Financial Interest consisting of one or more of the following interests of the Investigator (and those of his or her Immediate Family or Dependents) that reasonably appears to be related to CURADEL, LLC Responsibilities including:

- Remuneration received from a publicly traded 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 that, when aggregated, exceeds \$5,000. For the 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 a fair market value.
- Remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000 or any equity interest in such entity.
- Intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests.
- Any reimbursed or sponsored travel expenses.

A Significant Financial Interest *does not* include any of the following:

- Salary or other remuneration from CURADEL, LLC.

- Any ownership interests in CURADEL, LLC.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as Investigator does not directly control the investment decisions made in such 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.
- Reimbursed or sponsored travel expenses 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.

Subrecipient: means an individual or entity receiving federal funds that have come from or through CURADEL, LLC to conduct a substantive portion of the PHS-funded research and is accountable to CURADEL, LLC for programmatic outcomes and compliance matters.

Training on CURADEL, LLC's FCOI Policy

Each Investigator who is a CURADEL, LLC employee, or consultant engaged by CURADEL, LLC who will be responsible for the design, conduct or reporting of PHS funded research will be trained prior to engaging in any PHS-funded Research and then periodically, but no less than once every four years. Each such Investigator is required to provide documentation that they have completed the NIH FCOI tutorial available at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

- CURADEL, LLC's Financial Conflict of Interest policy changes in a manner that affects Investigator requirements.
- An Investigator is found to be non-compliant with CURADEL, LLC's FCOI policy or Management Plan.

Disclosure of Investigator's Financial Interests

It is each Investigator's responsibility to disclose all of his or her (including Immediate Family and Dependents) Financial Interests as set forth herein. All such Significant Financial Interests can be submitted on Curadel, LLC FCOI Disclosure form.

Reporting Prior to Making a Research Submission

Prior to the submission of an application or proposal for PHS-funded Research, each Investigator must submit any Significant Financial Interest over the previous twelve-month period as well as Immediate Family and Dependents, that reasonably appear to be related to the Investigator's institutional responsibilities. Such Significant Financial Interest may include remuneration from any publicly traded or non-publicly traded company, and any reimbursed or sponsored travel in the preceding twelve (12) months. CURADEL, LLC will not expend any funds under a PHS-funded research project in the event an Investigator reports a Significant Financial Interest, without first providing a FCOI report to the PHS Awarding Component outlining CURADEL, LLC's implementation of a Management Plan for the Investigator with a Significant Financial Interest. However, if CURADEL, LLC eliminates the conflict of interest prior to the expenditure of PHS-awarded funds, a FCOI report will not be submitted.

Reporting an After-Acquired Financial Interest

CURADEL, LLC shall submit a CURADEL, LLC Disclosure Form identifying any new or increased Significant Financial Interest within sixty (60) days of acquiring such Financial Interest. These reports shall be submitted to CURADEL, LLC's Designated Official in accordance with the reporting instructions set forth below.

Reporting Annually on Financial Interests

CURADEL, LLC shall submit annually a CURADEL, LLC Disclosure Form during the period of the applicable PHS-funded Research program. Annual reporting shall include submission of any new significant financial interests. These reports shall be submitted to CURADEL, LLC's Designated Official via email as instructed on the form.

Designated Official(s) Review of Disclosure Forms

If any Financial Interests are disclosed on the CURADEL, LLC FCOI Disclosure form, CURADEL, LLC's Designated Official will work with appropriate support to design a COI management plan and make appropriate disclosures to the Federal Government as required by TITLE 42 CODE OF FEDERAL REGULATIONS (CFR) PART 50 SUBPART F pertaining to grants and cooperative agreements and TITLE 45 CFR PART 94.

Standards for Approval for Financial Disclosures

Proposed Research will only be approved if the Designated Official(s) determines that 1) no FCOI exists or that 2) an adequate Management Plan can be implemented to manage or eliminate a Financial Conflict of Interest.

Management Plan for Financial Conflicts of Interest

The Designated Official shall determine the terms, conditions and restrictions, if any, that are required as part of a Management Plan. The Designated Official will convey the Management Plan in writing to the persons deemed appropriate.

The Management Plan will address, at a minimum:

- The role and principal duties of the conflicted Investigator in the research project
- Conditions of the Management Plan
- How the Management Plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the Management Plan.
- Monitoring compliance with the Management Plan

The Management Plan may require that one or more of the following actions are taken in order to manage, reduce, or eliminate a potential FCOI that was not managed or prior disclosed by CURADEL, LLC:

- Disclosure of the Financial Conflict of Interest, in each public presentation of the results of the Research and to request an addendum to previously published presentations;
- Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals or committees;
- Disqualification from participation in all or a portion of the PHS-funded Research;

- Requiring that Significant Financial Interests be divested, restructured, or placed in blind trust;
- Modification or severance of relationships that create a potential FCOI;
- Changing terms of agreement relating to the PHS-funded Research;
- Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted;
- Requiring additional disclosures or actions; or
- Requiring non-participation in any business transactions between CURADEL, LLC and parties to agreements involving sponsored PHS-funded Research.

Retrospective Review

When CURADEL, LLC identifies a Significant Financial Interest that was not timely disclosed by an Investigator or otherwise was not previously reviewed during a PHS-funded Research project, the Designated Official will review the Financial Interest and determine whether it is related to the PHS-funded Research, and whether it is a Significant Financial Interest within sixty (60) days. The Designated Official will implement a Management Plan specifying actions that have been or will be taken to manage the Significant Financial Interest.

In addition, the Designated Official will conduct and document a retrospective review in the case of non-compliance with this policy. This review will be conducted within one hundred and twenty (120) days of the Designated Official's determination of such non-compliance. If bias is identified as a result of the retrospective review, CURADEL, LLC will promptly notify the PHS Awarding Component and submit a mitigation report documenting the retrospective review, describing the impact of the bias on the Research project, and CURADEL, LLC's plan of action to eliminate or mitigate the effect of the bias.

Summary Disposition Procedures

The Designated Official may implement procedures for the disposition of matters involving compliance with this policy that it deems reasonable and appropriate. These procedures may include written approvals for annual reports, renewals, and no-cost extensions where the Designated reasonably determines that the facts and circumstances pertaining to the matter being approved have not materially changed since the date of the original review and approval. All such summary approvals shall be in writing.

Public Disclosure for FCOIs Managed by CURADEL, LLC, related to PHS-Funded Research

Investigator FCOIs managed by CURADEL, LLC will be made available within this section of CURADEL, LLC's publicly accessible Web site to ensure public accessibility of information concerning any Significant Financial Interest disclosed to CURADEL, LLC that meets the following three criteria: 1) the Significant Financial Interest was disclosed and is still held by the Senior or Key Personnel; 2) CURADEL, LLC determines that the Significant Financial Interest is related to the PHS-funded research; and 3) CURADEL, LLC determines that the Significant Financial Interest is a FCOI. Such Significant Interest will remain disclosed on CURADEL, LLC's website for the period during which the research is ongoing, in situations where a conflict exists, but not less than three (3) years from the date that the information was most recently updated.

Sanctions and Remedies for Violation of CURADEL, LLC's FCOI Policy

Whenever an Investigator has violated this policy, including failure to make a required disclosure of Significant Financial Interests or failure to comply with the requirements of any Management Plan, the

Designated Official shall be responsible for enforcing this policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to: 1) suspending expenditures on applicable Research account; 2) administratively suspending approval; and 3) instituting disciplinary measures to include suspension or termination of such Investigator.

Subrecipient Requirements

Each Subrecipient Investigator is subject to conflict of interest rules, and must provide assurances to CURADEL, LLC that Subrecipient has policies and procedures no less stringent than this FCOI policy. CURADEL, LLC takes reasonable steps to confirm that all Investigators who are Sub-awardees participating in PHS-funded Research are in compliance with the FCOI regulation. Such reasonable steps include: 1) incorporating into a written agreement that dictates that Subrecipient will adhere to CURADEL, LLC's FCOI policy if it is determined that the FCOI policy applies to Subrecipient's Investigators; 2) if the Subrecipient Investigator is to comply with Subrecipient's FCOI policy, the Subrecipient shall certify that such policy complies with CURADEL, LLC's FCOI policy, or if certification cannot be obtained, the written agreement must state the subrecipient Investigators are subject to disclosing significant financial interests that are directly related to the subrecipient's work for CURADEL, LLC; 3) subrecipient's Investigators must comply with the subrecipient's FCOI policy and the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to CURADEL, LLC so that CURADEL, LLC can provide timely FCOI reports, as necessary, to the PHS, or alternatively, subrecipient's Investigators must comply with Curadel's FCOI policy and the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to CURADEL, LLC so that CURADEL, LLC can comply timely with its review, management, and reporting obligations; and 4) CURADEL, LLC providing FCOI reports to the PHS Awarding component regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

Reporting to PHS Awarding Component

CURADEL, LLC shall be responsible for reporting to the applicable PHS Awarding Component all Significant Financial Interests in accordance with federal requirements. CURADEL, LLC will promptly notify the applicable PHS Awarding Component in accordance with federal regulations if bias is found with the design, conduct, or reporting of any Research. This report will address the impact of the bias of the Research and the actions CURADEL, LLC has taken, or will take, to eliminate or mitigate the bias.

Record Retention of Financial Conflict of Interest Disclosure Forms

Records of and related to Significant Financial Interest disclosures shall be retained by CURADEL, LLC for no less than six (6) years after the termination or completion of the PHS-funded Research to which they relate or from the date the final expenditure report is submitted to the PHS Awarding Component, whichever is later.