Orphagen Pharmaceuticals, Inc.

FINANCIAL CONFLICT OF INTEREST POLICY

Version A: May 24, 2021

Policy Overview: The performance of research in an objective and fair manner is a core value of Orphagen Pharmaceuticals, Inc. ("Orphagen"). It is expected that members of the Orphagen research team ("Investigators"), its subgrantees, clinical research partners, and vendors related to research, uphold to this standard in order to ensure public trust and meet scientific, program, and ethical goals of our National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by biomedical and behavioral researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (DHHS) have published their final rules. The management and research team at Orphagen believe we have fully addressed the requirements (including those of our defined sub-level vendors) of this ruling. We will continue to review and update our Financial Conflict of Interest (FCOI) policy as needed, particularly in regards to any relevant changes in management or research personnel, or upon further NIH, PHS, and/or DHHS guidance.

Policy Effective Date: Orphagen FCOI Policy Rev A, is effective as of May 24, 2021.

Policy Intended Personnel: This FCOI Requires that each investigator, subrecipient(s), subgrantee(s), and collaborator(s) affiliated with Orphagen by NIH or any other applicable grant or contract, be in compliance with the following federal regulations:

- 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements
- 45 CFR Part 94 for contracts

This legislation spells out NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. Orphagen intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

Policy Access and Training: This FCOI policy and related guidance, are incorporated into the Orphagen Employee Handbook and employee on-boarding process, and will also be publicly available on the Orphagen web site to enable access by all interested parties (42 CFR 50.604(a), also see NIH GPS 4.1.10, 42 CFR 50.605(a)(5)(i-iv)).

Policy Definitions and Requirements: The following key terms referred to in this FCOI policy guidance for principal or program investigators, subrecipients, subgrantees, and collaborators affiliated with Orphagen are defined below:

Investigator: An Investigator is any person (including subrecipients, subgrantees, and collaborators) who is responsible for the design, conduct, or reporting of research funded by PHS.

Training Requirement (42 CFR 50.604(b)): All Investigators are required to complete training related to FCOI. Training is required:

1. Prior to engaging in research related to any PHS-funded grant or contract,
2. No less than every 4 years, or as designated based on grant or role circumstances,
3. Immediately if,

a). Orphagen revises the FCOI policy that affects requirements of Investigators,

b). An Investigator is new to Orphagen,

c). An Investigator is not in compliance with the policy or management plan.

Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site at grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm.

Significant Financial Interest (SFI, 42 CFR 50.604(f)): Significant Financial Interest is defined by the regulations as:

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 institutional responsibilities:

1.1. 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 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 in stock, stock options, or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;

1.2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations 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 interests (e.g. stock, stock options, or other ownership interest) or

1.3. 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 institutional 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, medical center, or research institute that is affiliated with an institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which 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 Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

3. The term Significant Financial Interest does not include the following types of financial interests: salaries, royalties, or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirements 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, or an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or 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, or 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.

Financial Conflict of Interest (FCOI): A Financial Conflict of Interest exists when Orphagen reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of NIH-funded research. If any conflicts of interest are found or known, they must be disclosed.

Disclosure, Review, and Monitoring Process for FCOI (42 CFR 50.603, 42 CFR 50.604(e)(1)-(3)): Each Investigator (new or existing) is required to disclose all SFI(s) related to Investigator's institutional responsibilities to Orphagen that meet(s) or exceed(s) the above-stated definition of SFI within the following timeframes:

1. No later than at the time of application for PHS-funded research,
2. Not less than annually during the award,
3. Within 30 days of discovering or acquiring a new SFI.

Designated official(s) (see Point of Contact below, 42 CFR 50.604(d)) of Orphagen will review (42CFR 50.604(g), 42 CFR 50.605(a)(1)(2)(3)(i-iii)(4)) all "disclosures," within sixty (60) days of submission of the disclosure, or prior to expenditure of PHS funds, to:

1. evaluate whether they contain any SFIs related to PHS-funded research,
2. determine if an FCOI(s) exists including SFI(s) that could directly or significantly affect the design, conduct, or reporting of the NIH-funded research,
3. develop and implement management plans (immediate interim and continual), as needed to manage FCOI(s) until completion of the project.

Upon review of the disclosure form by the Designated official(s), the findings of FCOI(s) will be reported (42 CFR 50.604(h), 42 CFR 50.605(b),(a)(3)(iii), 42 CFR 50.606(a)). If:

1. no FCOI is found then the reviewed "disclosure form" will be filed in the Orphagen SFI database,
2. a FCOI is identified then it will be included in the FCOI report through the eRA Commons FCOI module (or appropriate PHS prior to expending any funds) within sixty (60) days,
3. any FCOI(s) are identified subsequent to the initial report they must be reported to Orphagen within thirty (30) days,
4. a PHS-funded project is conducted by an Investigator or Signing Official with a FCOI that was not disclosed or managed, Orphagen is required to disclose the conflict in each public presentation related to the results of the research.

The reporting of initial, annual (i.e. ongoing), and revised FCOI reports, including reporting elements required by regulation, will be made to the NIH if applicable, as required by regulation:

1. prior to the expenditure of funds
2. within sixty (60) days of identification for an Investigator who is newly participating in the project,
3. within sixty (60) days for new, newly identified, FCOI(s) for existing Investigator(s),
4. no later than annually, at the same time that Orphagen is required to submit the annual progress report, multi-year report, if applicable, or at time of extension, to provide the status of FCOI and any changes to the management plan, if applicable, until the completion of the project,
5. following a retrospective review to update a previously submitted report, if appropriate.

Management of a FCOI: Means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

If bias is found with the design, conduct, or reporting of NIH-funded research, caused by an Investigator failing to comply with the FCOI or FCOI management plan, then Orphagen is required to submit a Mitigation Report to notify the NIH.

Subrecipient Requirements (42 CFR 50.604(c)(1)(i-iii), also see NIH Grants Policy Statement 15.2.1): To ensure that non-Orphagen Investigators who participate in PHS-funded research comply with federally-compliant FCOI policy, they will either be required to comply with this FCOI or will be required to attest to comply with the subrecipient's federally-compliant FCOI, which will be establish as part of the subaward/subcontract agreement signed by appropriate institutional officials.

PHS Awarding Component: The PHS awarding component is any sub-agency of the Public Health Service (PHS) / Dept. of Health and Human Services (DHHS).

Records Management (42 CFR 50.604(i)): The records of all financial disclosures and all actions taken by Orphagen will be maintained for at least three years from the date of submission of the final expenditures report.

Research: PHS research is any project governed by PHS regulation, but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STIR) programs.

Compliance Enforcement and Penalties for Non-Performance (42 CFR 50.604(j), 42 CFR 50.605(a)(3), 42 CFR 50.606(c)): If an investigator fails to comply with Orphagen's FCOI policy, within 120 days, Orphagen shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, Orphagen shall submit a mitigation report to NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. Orphagen will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, Orphagen is required to mandate the Investigator disclose the FCOI in each public presentation with research results if it was not reported up front, and if needed, to request an addendum to

previously published presentations. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Point of Contact (Designated Official): If you have a conflict of interest or if you have a question to discuss, contact the Orphagen Institutional Official / Signing Official, Scott Thacher, PhD. Any potential CFOI of the Signing Official's will be reviewed by the Orphagen Board of Directors. Dr. Thacher, as member of the Board, will recuse himself from this review.