# Origent Data Sciences, Inc.
# Financial Conflict of Interest Policy

*Effective April 1, 2018; Revised November 6, 2026*

**Overview**

Objective research is of paramount importance to Origent Data Sciences, Inc. (Origent), its Investigators, subrecipients, collaborators, consultants, and the public. Origent maintains this Financial Conflict of Interest (FCOI) Policy to promote objectivity in research and to provide a reasonable expectation that the design, conduct, and reporting of research funded by the Public Health Service (PHS), including the National Institutes of Health (NIH), will be free from bias resulting from Investigator financial conflicts of interest.

This Policy implements the requirements of 42 CFR Part 50, Subpart F, Promoting Objectivity in Research, for applicable PHS/NIH grants and cooperative agreements. It applies to all NIH grants and cooperative agreements for which the regulation applies, including applicable Phase II, Direct-to-Phase II, and Fast-Track SBIR/STTR activities. Phase I SBIR/STTR applications and awards are excluded from the requirements of 42 CFR Part 50, Subpart F.

Origent will maintain and enforce this Policy and will revise it as necessary to remain consistent with applicable federal requirements.

**Definitions**

*Funded Research*

Funded Research means research for which PHS/NIH funding is sought or received and to which the FCOI regulation applies. For purposes of this Policy, research includes a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including biomedical, behavioral, translational, product development, and related research activities.

*Investigator*

An Investigator is the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Funded Research or proposed Funded Research. Depending on the individual's role, this may include employees, officers,

founders, consultants, collaborators, scientific advisors, contractors, subrecipient personnel, or others. Investigator status is determined by responsibilities on the project, not solely by job title, employment status, compensation, or designation as Senior/Key Personnel.

*Institutional Responsibilities*

Institutional Responsibilities are an Investigator's professional responsibilities on behalf of Origent, which may include research, research consultation, product or scientific development, professional practice, management or administrative responsibilities related to research, service on committees or panels, and other activities assigned or undertaken for Origent.

*Senior/Key Personnel*

For purposes of the public accessibility provisions of the FCOI regulation, Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by Origent in a grant application, progress report, or other report submitted to NIH under the FCOI regulation.

*Designated Institutional Official*

Origent designates an Institutional Official to administer this Policy and carry out the Institution's responsibilities under the FCOI regulation. The Designated Institutional Official may be contacted at fcoi@origent.com.

*PHS Awarding Component*

The PHS Awarding Component is the organizational unit of PHS, including an NIH Institute or Center, that funds the research subject to this Policy.

*Significant Financial Interest (SFI)*

A Significant Financial Interest is a financial interest of an Investigator, or the Investigator's spouse or dependent children, that reasonably appears to be related to the Investigator's Institutional Responsibilities and meets one or more of the criteria below.

1. For a publicly traded entity, an SFI exists when the value of 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. Remuneration includes salary and payments for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship. Equity includes stock, stock options, or other ownership interests.

2. For a non-publicly traded entity, an SFI exists when remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000,

or when the Investigator, spouse, or dependent children hold any equity interest in the entity.

3. Intellectual property rights and interests, such as patents and copyrights, constitute an SFI when income received related to those rights and interests during the twelve months preceding the disclosure, when aggregated, exceeds $5,000.

4. Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities when the aggregate value of such travel paid or reimbursed by a single outside entity exceeds $5,000 during the preceding twelve (12) months. This $5,000 de minimis threshold is applied per entity. The disclosure requirement does not apply to travel reimbursed or sponsored by a United States federal, state, or local government agency; a United States institution of higher education as defined at 20 U.S.C. 1001(a); a United States academic teaching hospital; a United States medical center; or a research institute affiliated with a United States institution of higher education. Travel paid or reimbursed by Origent is not reportable under this provision. When disclosure is required, it must include, at a minimum, the purpose of the trip, sponsor or organizer, destination, duration, and approximate value. Origent may request additional information as needed to determine whether the travel constitutes an FCOI.

The term SFI does not include: salary, royalties, or other remuneration paid by Origent to an Investigator who is currently employed or otherwise appointed by Origent; intellectual property rights assigned to Origent and agreements to share royalties related to such rights; any ownership interest in Origent held by the Investigator; income from investment vehicles such as mutual funds and retirement accounts when the Investigator does not directly control the investment decisions; or income from seminars, lectures, teaching engagements, advisory committees, or review panels sponsored by a United States federal, state, or local government agency, a United States institution of higher education as defined at 20 U.S.C. 1001(a), a United States academic teaching hospital, a United States medical center, or a research institute affiliated with such a United States institution of higher education.

Foreign financial interests must be disclosed in accordance with the regulation. The domestic exclusions described above for government agencies and institutions of higher education do not extend to foreign governments or foreign institutions of higher education. Accordingly, Investigators must disclose otherwise reportable foreign remuneration, equity, intellectual property income, advisory or teaching income, and reimbursed or sponsored travel received from foreign entities when the applicable disclosure threshold is met.

*Financial Conflict of Interest (FCOI)*

A Financial Conflict of Interest exists when Origent, through its Designated Institutional Official, reasonably determines that an Investigator's SFI is related to Funded Research and could directly and significantly affect the design, conduct, or reporting of that research. An SFI is related to Funded Research when it could be affected by the research or is held in an entity whose financial interest could be affected by the research. For

purposes of this determination, significantly means that the financial interest could have a material effect on the research.

**Investigator Training Requirements**

Origent will inform each Investigator of this Policy, the applicable federal FCOI regulation, and the Investigator's responsibility to disclose all required domestic and foreign SFIs, including those of the Investigator's spouse and dependent children.

Each Investigator must complete FCOI training prior to engaging in research related to an NIH-funded grant and at least once every four years thereafter. An Investigator must complete training immediately when: (1) Origent revises this Policy in a manner that affects Investigator requirements; (2) the Investigator is new to Origent or newly becomes an Investigator on applicable Funded Research; or (3) Origent determines that the Investigator is not in compliance with this Policy or an FCOI management plan.

Origent may use NIH training resources as part of its training program, but Investigator training will also address Origent's own Policy, disclosure process, and internal requirements. Origent will maintain records of required training.

**Investigator Disclosure Requirements**

Each Investigator planning to participate in Funded Research must disclose to the Designated Institutional Official all required SFIs of the Investigator, spouse, and dependent children no later than the time an application for Funded Research is submitted and before the Investigator begins work on an awarded project if the Investigator joins after application.

Each Investigator participating in Funded Research must submit an updated disclosure at least annually, by a deadline established by Origent.

Each Investigator must disclose a new SFI within thirty (30) days of discovering or acquiring the SFI, including through purchase, marriage, inheritance, a new outside relationship, or another event that creates a reportable financial interest.

Reimbursed or sponsored travel subject to the $5,000 per-entity de minimis threshold must be disclosed as part of the Investigator's initial disclosure for the preceding twelve (12) months. Thereafter, the Investigator must disclose within thirty (30) days any new reportable travel occurrence or any occurrence that causes the aggregate value of travel from an entity to exceed the threshold. The Investigator must provide any additional information requested by the Designated Institutional Official.

Disclosures are made to Origent, not directly to NIH. Investigators must provide complete and accurate information and cooperate with requests for clarification or supporting information.

## Institutional Review, Determination, and Management

Prior to Origent's expenditure of funds under an applicable NIH award, the Designated Institutional Official will review all Investigator SFI disclosures, determine whether each SFI is related to the Funded Research, determine whether any related SFI constitutes an FCOI, and, when an FCOI exists, develop and implement an appropriate management plan. The Investigator may provide information relevant to the relatedness determination, but the final determination is made by Origent.

When an Investigator newly participates in an ongoing project or an existing Investigator discloses a new SFI, the Designated Institutional Official will, within sixty (60) days, review the disclosure, determine relatedness and whether an FCOI exists, and, if necessary, implement at least an interim management plan.

If Origent identifies an SFI that was not timely disclosed or was not previously reviewed during an ongoing project, the Designated Institutional Official will, within sixty (60) days, review the SFI, determine whether it is related to the Funded Research and whether an FCOI exists, and implement at least an interim management plan when necessary.

Management actions will be tailored to the circumstances and may include public disclosure of the FCOI; disclosure to research participants when appropriate; monitoring by an independent reviewer; modification of the research plan; change of personnel or personnel responsibilities; disqualification of personnel from all or part of the research; reduction or elimination of the SFI; severance of relationships that create the FCOI; or other conditions necessary to safeguard the objectivity of the research.

The Designated Institutional Official will monitor Investigator compliance with each management plan through completion of the project and will document the management actions and monitoring performed.

## Reporting FCOIs to NIH

When Origent determines that an FCOI exists, including an FCOI involving a subrecipient Investigator when applicable, Origent will submit required initial, annual, and revised FCOI reports to the applicable NIH Awarding Component through the eRA Commons FCOI Module. If no FCOI is identified, Origent does not submit an FCOI report solely because an Investigator disclosed an SFI.

For an FCOI identified before expenditure of award funds, Origent will submit the required FCOI report before expending funds. For an Investigator who becomes newly participating in an ongoing NIH-funded project, or for a new or newly identified FCOI involving an existing Investigator, Origent will submit the required report within sixty (60) days of identification.

For each previously reported FCOI that remains ongoing, Origent will submit an annual FCOI report at the time the annual progress report or multi-year progress report is due, or

at the time of an extension when applicable, until the FCOI no longer exists. The annual report will address the status of the FCOI and any changes to the management plan.

An initial FCOI report will include, as applicable: the grant number and PD/PI; the name of the Investigator with the FCOI; the name of the entity with which the Investigator has the FCOI; the nature of the financial interest; the value of the financial interest using the ranges specified by NIH or a statement that value cannot readily be determined; a description of how the financial interest relates to the NIH-funded research and the basis for Origent's determination that it constitutes an FCOI; and the key elements of the management plan, including the Investigator's role, the conditions imposed, how the plan safeguards objectivity, confirmation of the Investigator's agreement, and how compliance will be monitored.

Origent will promptly make available to NIH/HHS, upon request, information relating to any Investigator disclosure of financial interests and Origent's review of, and response to, the disclosure, whether or not the disclosure resulted in a determination of an FCOI.

**Subrecipient Requirements**

When Origent carries out applicable NIH-funded research through a subrecipient or consortium participant, Origent will take reasonable steps to ensure that each subrecipient Investigator complies with the FCOI regulation. The subaward or other written agreement will state whether the FCOI policy of Origent or the FCOI policy of the subrecipient will apply to the subrecipient's Investigators.

If the subrecipient's FCOI policy applies, the written agreement will require the subrecipient to certify that its policy complies with 42 CFR Part 50, Subpart F, and to report identified FCOIs to Origent within a time frame specified in the written agreement that allows Origent to meet its NIH reporting obligations.

If Origent's FCOI policy applies, the written agreement will specify time period(s) for the subrecipient to submit all Investigator SFI disclosures to Origent that are sufficient to enable Origent to comply timely with its review, management, and NIH reporting obligations.

**Public Accessibility**

Origent will maintain this FCOI Policy on a publicly accessible website and will submit the current policy to NIH through the eRA Commons Institution Profile (IPF) Module as required. Origent will update the publicly available policy and the IPF submission when revisions are required.

Prior to Origent's expenditure of funds under an applicable NIH award, for identified FCOIs held by Senior/Key Personnel that are subject to the public accessibility requirements of 42 CFR 50.605(a)(5), Origent will make the required information available upon written request rather than routinely posting individual FCOI information on its website. Requests may be

submitted to fcoi@origent.com. Origent will provide the required information within five (5) business days of a written request.

The information provided will include the information required by 42 CFR 50.605(a)(5), including the Investigator's name; title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI using the regulatory ranges, or a statement that the value cannot readily be determined. Each written response will state that the information provided is current as of the date of the response, is subject to updates at least annually and within sixty (60) days of Origent's identification of a new FCOI, and that updated information should be requested subsequently by the requestor.

Origent will maintain and make this information available in accordance with the annual update, sixty (60)-day update, and three (3)-year availability requirements of 42 CFR 50.605(a)(5).

**Noncompliance, Retrospective Review, and Mitigation**

Origent will establish adequate enforcement mechanisms and provide for appropriate sanctions or other administrative actions to ensure Investigator compliance with this Policy and any management plan.

Whenever an FCOI is not identified or managed in a timely manner, including failure by an Investigator to disclose an SFI that is determined to constitute an FCOI, failure by Origent to review or manage an FCOI, or failure by an Investigator to comply with an FCOI management plan, Origent will complete a retrospective review within one hundred twenty (120) days of determining the noncompliance to determine whether the NIH-funded research, or any portion of it, was biased in its design, conduct, or reporting.

The retrospective review will be documented and will include, at a minimum: the project number; project title; PD/PI or Contact PD/PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has the FCOI; reason for the retrospective review; detailed methodology used for the review, including the review process, composition of any review panel, and documents reviewed; findings; and conclusions.

Based on the retrospective review, Origent will update any previously submitted FCOI report as required. If bias is found, Origent will notify NIH promptly and submit a mitigation report that includes the key elements of the retrospective review, a description of the impact of the bias on the research, and the actions taken or planned to eliminate or mitigate the effect of the bias. Origent will also take any additional corrective action required by NIH.

If an Investigator's failure to comply with this Policy or a management plan appears to have biased the design, conduct, or reporting of NIH-funded research, Origent will notify NIH promptly. In any case in which HHS determines that NIH-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment

was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required, Origent will require the Investigator to disclose the FCOI in each public presentation of the research results and request an addendum to previously published presentations as required.

**Records Management**

Origent will maintain records relating to all Investigator disclosures of financial interests, Origent's review of and response to those disclosures, and all actions under this Policy or any retrospective review, as required by 42 CFR 50.604(i).

Records will be maintained for at least three (3) years from the date the final Federal Financial Report or final expenditures report is submitted or, when applicable, for the longer period required by 2 CFR 200.334 or another applicable federal record-retention requirement.

**Administration and Policy Review**

The Designated Institutional Official will administer this Policy. Origent may establish forms and procedures needed to implement it and will revise this Policy as necessary to remain compliant with applicable federal requirements.

Questions, disclosures, and written requests concerning this Policy should be directed to the Designated Institutional Official at fcoi@origent.com.

**References**

42 CFR Part 50, Subpart F, Promoting Objectivity in Research; NIH Grants Policy Statement, Section 4.1.10, Financial Conflict of Interest; NIH FCOI Policy Development Checklist (revised June 29, 2026); and 2 CFR 200.334.