

ProVerity

Financial Conflict of Interest Policy

Promoting Objectivity in Research — PHS/NIH-Funded Research

Institution	ProVerity, Inc. www.proverityai.com
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Approved by	Douglas Furtado, Chief Executive Officer
Applies to	All Investigators and personnel of ProVerity participating in research funded, or proposed for funding, by the U.S. Public Health Service, including the National Institutes of Health
Regulatory authority	42 C.F.R. Part 50, Subpart F — Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought (2011 revised FCOI regulation); NIH Grants Policy Statement
Review cycle	Annually, and upon any change in the governing regulation
Public posting	www.proverityai.com

1. Purpose

ProVerity, Inc. ("ProVerity" or the "Institution"), with its principal place of business at [REDACTED] is committed to ensuring that the design, conduct, and reporting of research it performs are free from bias resulting from the financial interests of the individuals who carry out that research. This Financial Conflict of Interest ("FCOI") Policy establishes the written, enforced administrative process by which ProVerity identifies, reviews, manages, reports, and — where required — eliminates financial conflicts of interest in research funded by the U.S. Public Health Service ("PHS"), including the National Institutes of Health ("NIH").

This Policy is adopted pursuant to **42 C.F.R. Part 50, Subpart F** and is intended to meet or exceed every requirement of that regulation. Where this Policy imposes an obligation more stringent than the regulation, the more stringent obligation governs at ProVerity.

1.1 Institutional Certification

By submitting an application for PHS funding, ProVerity certifies that it:

- Has in effect at that time this up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which PHS funding is sought or received;
- Shall promote and enforce Investigator compliance with 42 C.F.R. Part 50, Subpart F, including the disclosure of Significant Financial Interests;
- Shall manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component;
- Agrees to make information available promptly upon request to the U.S. Department of Health and Human Services ("HHS") relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in a determination of an FCOI; and
- Shall fully comply with all requirements of 42 C.F.R. Part 50, Subpart F.

2. Scope and Applicability

This Policy applies to each **Investigator** — as defined in Section 3 — who is planning to participate in, or is participating in, PHS-funded research conducted by or under the authority of ProVerity. It applies without regard to the Investigator's employment classification and therefore reaches ProVerity employees, officers, owners, members, directors, consultants, contractors, collaborators, and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research.

This Policy applies to research funded through any PHS mechanism, including research grants, cooperative agreements, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects, and Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) awards, and to research funded by any other agency or entity that has adopted 42 C.F.R. Part 50, Subpart F by reference.

No PHS funds will be expended by ProVerity on any project until the disclosure, review, management, and reporting requirements of this Policy have been satisfied for every Investigator on that project.

2.1 Relationship to Other Policies

This Policy governs financial conflicts of interest in PHS-funded research specifically. It supplements, and does not replace, ProVerity's general conflict of interest, ethics, procurement, and code of conduct policies. Where an interest is permissible under a general ProVerity policy but constitutes an FCOI under this Policy, this Policy controls with respect to the affected PHS-funded research.

3. Definitions

The following definitions are drawn from 42 C.F.R. § 50.603 and apply throughout this Policy and all associated forms and procedures.

Term	Definition
Designated Official (DO)	The institutional official designated by ProVerity under 42 C.F.R. § 50.604(d) to solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, PHS-funded research. See Section 4.
Disclosure of Significant Financial Interests	An Investigator's disclosure of Significant Financial Interests to ProVerity.
Financial Conflict of Interest (FCOI)	A Significant Financial Interest that ProVerity reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
FCOI Report	ProVerity's report of a financial conflict of interest to a PHS Awarding Component.
Financial Interest	Anything of monetary value, whether or not the value is readily ascertainable.
Institutional Responsibilities	An Investigator's professional responsibilities on behalf of ProVerity, which for purposes of this Policy include: research; research consultation; teaching; professional practice; institutional committee memberships; and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
Investigator	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 the PHS, or proposed for such funding. This may include, as applicable, postdoctoral associates, students, collaborators, and consultants. ProVerity determines, in advance of each application, which individuals meet this definition for each project and records that determination in the project file.
Manage	To take action to address an 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.
PD/PI	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.
PHS Awarding Component	The organizational unit of the PHS that funds the research subject to this Policy (for NIH awards, the funding Institute or Center).
Public Health Service (PHS)	The Public Health Service of the U.S. Department of Health and Human Services, and any components to which the authority involved may be delegated, including NIH.

Term	Definition
Research	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 and product development, and includes any activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement.
Senior/Key Personnel	The PD/PI and any other person identified as senior/key personnel by ProVerity in the grant application, progress report, or any other report submitted to the PHS.
Subrecipient	Any subaward recipient, subcontractor, or consortium member that carries out part of a PHS-funded project under an agreement with ProVerity.

3.1 Significant Financial Interest (SFI)

A **Significant Financial Interest** is a financial interest consisting of one or more of the following, held by the Investigator (or the Investigator's spouse or dependent children), that reasonably appears to be related to the Investigator's Institutional Responsibilities:

1. **Publicly traded entity.** Remuneration received from the entity in the twelve (12) months preceding the disclosure plus 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 (for example, 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.
2. **Non-publicly traded entity.** The aggregate value of any remuneration received from the entity in the twelve (12) months preceding the disclosure exceeds **\$5,000**; **or** the Investigator (or the Investigator's spouse or dependent children) holds **any equity interest** of any value (including stock, stock options, warrants, membership units, partnership interests, or other ownership interest).
3. **Intellectual property.** Income received from intellectual property rights and interests (for example, patents and copyrights) upon receipt of income related to such rights and interests, other than income from ProVerity itself.

3.1.1 Travel

In addition to the categories above, each Investigator must disclose the **occurrence** of any reimbursed or sponsored travel — that is, travel that is paid on the Investigator's behalf and not reimbursed to the Investigator so that the exact monetary value may not be readily available — that is related to the Investigator's Institutional Responsibilities. Disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration; ProVerity will additionally request the monetary value where determinable. The Designated Official will determine whether any such travel constitutes an FCOI. 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; a medical center; or a research institute that is affiliated with an institution of higher education.

3.1.2 Exclusions from Significant Financial Interest

The term Significant Financial Interest does **not** include:

- Salary, royalties, or other remuneration paid by ProVerity to the Investigator, if the Investigator is currently employed or otherwise appointed by ProVerity, including intellectual property rights assigned to ProVerity and agreements to share in royalties related to such rights;
- **Any ownership interest in ProVerity itself held by the Investigator.** ProVerity, Inc. is a commercial, for-profit organization, and equity in ProVerity is therefore excluded from the definition of Significant Financial Interest by 42 C.F.R. § 50.603. **This exclusion is limited to ProVerity equity.** Equity, remuneration, royalties, board service, or any other financial interest in **any other entity** related to the Investigator's Institutional Responsibilities remains fully disclosable, including interests in affiliates, spin-outs, licensees, and portfolio companies;
- Income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in those 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; or
- Income from service on advisory committees or review panels for 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.

Investigators are not required to determine for themselves whether a disclosed interest is related to their research or constitutes an FCOI. That determination rests solely with the Designated Official. When in doubt, the Investigator discloses.

4. Designated Official and Institutional Responsibilities

Pursuant to 42 C.F.R. § 50.604(d), ProVerity designates the following institutional official(s) to solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, PHS-funded research, including the Significant Financial Interests of the Investigator's spouse and dependent children related to the Investigator's Institutional Responsibilities:

Role	Individual	Contact
Designated Official (DO)	Douglas Furtado, Chief Executive Officer	dfurtado@proverityai.com 774-901-4601
Alternate Designated Official	Matthew White, Chief Technology Officer	mwhite@proverityai.com 303-681-6556
Institutional address for FCOI matters		dfurtado@proverityai.com 774-901-4601

4.1 Duties of the Designated Official

The Designated Official is responsible for:

- Soliciting and reviewing disclosures of Significant Financial Interests from each Investigator, and from each Investigator's spouse and dependent children, related to the Investigator's Institutional Responsibilities;

- Determining, prior to ProVerity's expenditure of any funds under a PHS-funded research project, whether any disclosed Significant Financial Interest relates to that PHS-funded research;
- Determining whether a related Significant Financial Interest is an FCOI — that is, whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research;
- Developing, implementing, documenting, and monitoring management plans as needed to manage identified FCOIs;
- Preparing and submitting initial, annual (ongoing), and revised FCOI Reports to the PHS Awarding Component, including reports covering Subrecipient Investigators;
- Conducting or overseeing retrospective reviews and preparing Mitigation Reports where required;
- Maintaining FCOI records in accordance with Section 12;
- Ensuring the public accessibility requirements of Section 10 are satisfied; and
- Administering training, enforcement, and sanctions under Sections 5 and 13.

4.2 Written Guidelines for the Related/FCOI Determination

Consistent with 42 C.F.R. § 50.604(f), ProVerity adopts the following guidelines, which the Designated Official shall apply in determining whether an Investigator's Significant Financial Interest is related to PHS-funded research and, if so related, whether it is an FCOI.

Step 1 — Relatedness. A Significant Financial Interest is **related to** the PHS-funded research when the Designated Official reasonably determines that the SFI: (a) could be affected by the PHS-funded research; **or** (b) is in an entity whose financial interest could be affected by the research. In making this determination the DO shall consider, at minimum:

- Whether the entity manufactures, sells, licenses, or is developing a product, technology, service, or intellectual property that is the subject of, an input to, a comparator in, or a foreseeable commercialization pathway for the research;
- Whether the entity competes with, or would be commercially advantaged or disadvantaged by, the results of the research;
- Whether the Investigator's role in the research could plausibly influence the value of the interest; and
- Whether the entity is a subrecipient, vendor, licensor, licensee, or collaborator on the project.

Step 2 — Conflict. Where an SFI is related to the research, the Designated Official shall determine whether the SFI **could directly and significantly affect** the design, conduct, or reporting of that research, considering:

- The nature of the interest (equity versus fee-for-service versus royalty) and whether its value is contingent on research outcomes;
- The magnitude of the interest relative to indicators of significance available to the DO;
- The Investigator's degree of independent control over study design, subject or sample selection, data collection, analysis, interpretation, or publication;
- The proximity of the interest to the specific aims and endpoints of the funded project; and
- Whether an objective observer would reasonably question the integrity of the research were the interest to remain unmanaged.

Step 3 — Documentation. The Designated Official shall document, in writing and in the project record, the analysis and the conclusion at each step, including where the conclusion is that no relationship or no conflict exists. Documentation shall be retained under Section 12.

4.3 Conflicts Involving the Designated Official

Where the Designated Official is also an Investigator on the project, or otherwise holds a financial interest in the matter under review, the **Alternate Designated Official** shall perform all review, determination, management-plan, monitoring, and reporting functions for that matter. The Designated Official shall recuse himself or herself from the review in writing, and the recusal shall be documented in the project record. Where both the Designated Official and the Alternate are conflicted, ProVerity shall engage a qualified, independent external reviewer to perform the review and shall document that engagement.

Because ProVerity, Inc. is a small entity in which senior personnel commonly hold equity, ProVerity expressly acknowledges that the disclosure, review, management, and reporting obligations of this Policy apply to the Institution's owners, officers, and directors in their capacity as Investigators to the same extent as to any other Investigator.

5. Training Requirements

Consistent with 42 C.F.R. § 50.604(b), ProVerity requires each Investigator to complete training on financial conflicts of interest and to be informed of the Institution's FCOI Policy, the Investigator's disclosure responsibilities, and the federal regulation.

5.1 Informing Investigators

The Designated Official shall inform each Investigator, in writing and in a manner documented in the FCOI training record, of:

- **ProVerity's FCOI Policy** — this document, provided in full and identified by its public posting location;
- **The Investigator's responsibilities regarding disclosure** of Significant Financial Interests, including what must be disclosed, on whose behalf (the Investigator, spouse, and dependent children), when, and how; and
- **The federal regulation** — 42 C.F.R. Part 50, Subpart F, provided by link and available in hard copy on request.

Notice is delivered at the time of training, at the time of each disclosure solicitation, and whenever this Policy is materially revised. Each Investigator acknowledges receipt on **Form C — FCOI Training and Policy Acknowledgment**.

5.2 When Training Is Required

Each PHS-supported Investigator must complete FCOI training:

1. **Prior to engaging in research related to any PHS-funded grant** — no Investigator may begin work on a PHS-funded project, and ProVerity will not expend funds attributable to that Investigator, until training is complete and documented;
2. **At least every four (4) years** thereafter, for as long as the Investigator participates in PHS-funded research; and
3. **Immediately**, when any of the following occurs:
 - ProVerity revises this FCOI Policy or its related procedures in any manner that affects the requirements of Investigators;

- An Investigator is new to ProVerity (including a newly engaged consultant, contractor, or collaborator who meets the definition of Investigator); or
- ProVerity determines that an Investigator is not in compliance with this Policy or with an FCOI management plan.

5.3 Acceptable Training and Documentation

Training shall consist of the **NIH Financial Conflict of Interest tutorial** (or an equivalent PHS-recognized course) together with a ProVerity-specific briefing on this Policy and its forms. The Designated Official maintains a training log recording, for each Investigator: the name of the training completed, the completion date, the certificate or confirmation of completion, the next due date (not more than four years later), and the reason for any immediate re-training. Training records are retained under Section 12.

The Designated Official reviews the training log at least quarterly and before the submission of any PHS application, and issues re-training notices in advance of each four-year due date.

6. Disclosure of Significant Financial Interests

Consistent with 42 C.F.R. §§ 50.603 and 50.604(e)(1)–(3), each Investigator must disclose to the Designated Official all of the Investigator's Significant Financial Interests — and those of the Investigator's spouse and dependent children — that are related to the Investigator's Institutional Responsibilities. Disclosure is made on **Form A — Significant Financial Interest Disclosure**.

6.1 Disclosure Timing

Trigger	Deadline	Citation
Initial disclosure for a project	No later than at the time of application for PHS-funded research. ProVerity requires the completed Form A in hand before the application is submitted.	§ 50.604(e)(1)
Ongoing disclosure	At least annually during the period of the award, on a date set by the Designated Official and, in any event, no later than the anniversary of the budget period start date. The annual disclosure updates the information previously provided and discloses any newly acquired SFI.	§ 50.604(e)(2)
New or newly discovered SFI	Within thirty (30) days of discovering or acquiring a new Significant Financial Interest (for example, through purchase, marriage, or inheritance).	§ 50.604(e)(3)
Investigator newly joining a project	Before the Investigator begins work on the project, and in any event before ProVerity expends funds attributable to that Investigator.	§ 50.605(a)(2)

6.2 What Must Be Disclosed

Form A requires, for each disclosed interest: the name of the entity; the relationship of the Investigator (or spouse or dependent child) to the entity; the nature of the interest (equity, salary, consulting fee, honorarium, paid authorship, royalty or other intellectual property income, board or officer service, or other); the value or applicable dollar range; the date acquired; and a description of the interest's relationship, if any, to the Investigator's Institutional Responsibilities. Reimbursed or sponsored travel is disclosed under Section 3.1.1.

An Investigator with no Significant Financial Interests to report must nonetheless submit Form A affirmatively stating that fact. A **"no interests" disclosure is a required disclosure, not an omission.**

6.3 Solicitation of Disclosures

The Designated Official actively solicits disclosures and does not rely on Investigators to initiate them. The DO issues disclosure requests: at the outset of preparation of each PHS application; upon the addition of any Investigator to a funded project; on the annual disclosure date for each active award; and upon any event that would reasonably prompt an update. Solicitations, responses, and non-responses are logged.

7. Review, Determination, and Management of FCOI

7.1 Review Prior to Expenditure of Funds

Consistent with 42 C.F.R. § 50.605(a)(1), **prior to ProVerity's expenditure of any funds under a PHS-funded research project**, the Designated Official shall:

1. **Review all Investigator disclosures** of Significant Financial Interests for that project;
2. **Determine whether any Significant Financial Interest relates** to the PHS-funded research, applying the guidelines in Section 4.2;
3. **Determine whether a financial conflict of interest exists** — that is, whether a related SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research; and
4. **Develop and implement a management plan** that shall specify the actions that have been, and will be, taken to manage each identified FCOI.

The Designated Official documents each determination in writing, including determinations that an SFI is not related or is not a conflict, and files the documentation in the project record.

7.2 New Investigators and Newly Disclosed Interests

Consistent with 42 C.F.R. § 50.605(a)(2), whenever an Investigator who is **new to participating** in a PHS-funded research project discloses a Significant Financial Interest, or an **existing Investigator discloses a new** Significant Financial Interest, the Designated Official shall, **within sixty (60) days** of the disclosure: review the disclosure; determine whether it is related to the PHS-funded research; determine whether an FCOI exists; and, if so, implement — on at least an interim basis — a management plan specifying the actions taken and to be taken to manage the FCOI. Where an interim management plan is used, the DO shall complete and document the final plan without undue delay.

7.3 Interests Not Disclosed Timely or Not Previously Reviewed

Consistent with 42 C.F.R. § 50.605(a)(3) and (a)(3)(i)–(iii), whenever ProVerity identifies a Significant Financial Interest that was **not disclosed timely** by an Investigator, or that was not previously reviewed by ProVerity during an ongoing PHS-funded research project — including an interest disclosed by an Investigator who is new to participating in the project — the Designated Official shall, **within sixty (60) days**: review the SFI; determine whether it is related to the PHS-funded research; determine whether an FCOI exists; and, if so, implement on at least an interim basis a management plan specifying the actions taken and to be taken to manage the FCOI going forward.

Where a determination of noncompliance is made, the additional retrospective review obligations of Section 8 are triggered.

7.4 Elements of a Management Plan

A management plan is documented on **Form B — FCOI Management Plan** and shall, at a minimum, specify: the Investigator's role and principal duties on the research project; the conditions of the management plan; how the plan is designed to safeguard objectivity in the research; confirmation of the Investigator's written agreement to the plan; how the plan will be monitored to ensure Investigator compliance; and any other information deemed necessary by the Designated Official.

Examples of conditions or restrictions that may be imposed to manage an FCOI include, but are not limited to:

- Public disclosure of the financial conflict of interest (for example, in presentations, publications, and when presenting or discussing the research);
- For research projects involving human subjects research, disclosure of the FCOI directly to participants;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (for example, sale of an equity interest); or
- Severance of relationships that create the financial conflict.

7.5 Actions to Manage and Ongoing Monitoring

Consistent with 42 C.F.R. §§ 50.604(g) and 50.605(a)(4), ProVerity shall take such actions as are necessary with respect to management of an identified FCOI, **including any financial conflicts of interest of a Subrecipient Investigator**, and shall **monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research project**.

Monitoring is performed by the Designated Official, is documented on Form B, and includes at minimum: a scheduled monitoring interval of not less than every six (6) months and, for management plans involving human subjects research or an independent monitor, not less than quarterly; review of the Investigator's adherence to each plan condition; review of relevant publications, presentations, and protocol modifications; and a written monitoring entry for each review. Failure of an Investigator to comply with a management plan is handled under Section 13.

8. Retrospective Review, Bias Determination, and Mitigation Report

8.1 When a Retrospective Review Is Required

Consistent with 42 C.F.R. § 50.605(a)(3), ProVerity shall complete and document a **retrospective review within one hundred twenty (120) days** of ProVerity's determination of noncompliance, in each of the following circumstances:

- An Investigator fails to disclose a Significant Financial Interest that is determined to be an FCOI in a timely manner;
- ProVerity fails to review or manage an FCOI in a timely manner, including failure by an Investigator to comply with a management plan; or
- An FCOI is not identified or managed in a timely manner, including where an SFI was not previously reviewed by ProVerity during an ongoing PHS-funded research project.

The purpose of the retrospective review is to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance was biased in its design, conduct, or reporting.

8.2 Documentation of the Retrospective Review

The retrospective review is documented on **Form F — Retrospective Review and Mitigation Report** and shall document, at a minimum:

1. The project number, project title, PD/PI (or contact PD/PI if a multiple PD/PI model is used), name of the Investigator with the FCOI, and name of the entity with which the Investigator has the FCOI;
2. The reason(s) for the retrospective review;
3. A detailed methodology used for the retrospective review (for example, whether the research project was reviewed chronologically, whether personnel were interviewed, whether laboratory notebooks and source data were reviewed, whether analyses were reproduced, and the identity of the reviewers);
4. The findings of the review; and
5. The conclusions of the review.

Based on the results of the retrospective review, ProVerity shall, if appropriate, **update the previously submitted FCOI Report**, specifying the actions that will be taken to manage the FCOI going forward.

8.3 Mitigation Report

Consistent with 42 C.F.R. § 50.605(a)(3)(iii), if bias is found, ProVerity shall **promptly notify the PHS Awarding Component** and submit a **Mitigation Report** to the PHS Awarding Component. The Mitigation Report shall include, at a minimum: the key elements documented in the retrospective review above; a description of the impact of the bias on the research project; and ProVerity's plan of action, or actions already taken, to eliminate or mitigate the effect of the bias. Examples include impact on the research project, the extent of harm done (including any qualitative and quantitative data to support any actual or future harm), and the analysis of whether the research project is salvageable.

Thereafter, ProVerity shall submit FCOI Reports annually as required under Section 9. Depending on the nature of the FCOI, ProVerity may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of ProVerity's retrospective review.

9. Reporting to the PHS Awarding Component (NIH)

Consistent with 42 C.F.R. §§ 50.604(h) and 50.605(b), ProVerity shall provide initial, ongoing (annual), and revised FCOI Reports to the PHS Awarding Component. Reports are submitted through the NIH electronic system of record (eRA Commons FCOI Module) by the Designated Official or authorized signing official.

9.1 Reporting Deadlines

Report	Deadline	Citation
Initial FCOI Report	Prior to ProVerity's expenditure of any funds under the PHS-funded research project. No FCOI Report is required if the financial conflict of interest is eliminated prior to the expenditure of funds.	§ 50.605(b)(1)
Report for a newly participating Investigator	Within sixty (60) days of the date that ProVerity identifies an FCOI for an Investigator who is newly participating in the project.	§ 50.605(b)(2)
Report for a new or newly identified FCOI of an existing Investigator	Within sixty (60) days of identification, for FCOIs that are identified subsequent to the initial FCOI Report during an ongoing project (including as a result of a new SFI, an untimely disclosure, or a subrecipient report).	§ 50.605(b)(2)
Annual (ongoing) FCOI Report	At least annually , submitted at the same time as ProVerity is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension, to provide the status of the FCOI and any changes to the management plan, until completion of the project.	§ 50.605(b)(4)
Revised FCOI Report	Following a retrospective review , to update a previously submitted FCOI Report, if appropriate. Where bias is found, a Mitigation Report is submitted promptly with, or in addition to, the revised report.	§ 50.605(a)(3)(ii)–(iii)
Subrecipient FCOI	ProVerity reports identified FCOIs of Subrecipient Investigators to the PHS Awarding Component within the same deadlines above, based on subrecipient reports received under Section 11.	§ 50.604(c); § 50.605(b)

9.2 Required Elements of an FCOI Report

Each FCOI Report shall include, at a minimum, the elements required by 42 C.F.R. § 50.605(b)(3). ProVerity uses **Form G — FCOI Report Data Worksheet** to assemble these elements before entry into the NIH system:

- Project number;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Nature of the financial interest (for example, equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest, stated in the following ranges — **\$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000 and \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000** — or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

- A description of how the financial interest relates to the PHS-funded research and the basis for ProVerity's determination that the financial interest conflicts with such research; and
- A description of the key elements of ProVerity's management plan, including: the Investigator's role and principal duties 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; how the management plan will be monitored to ensure Investigator compliance; and other information as needed.

9.3 Notification of Bias and Corrective Action

Consistent with 42 C.F.R. §§ 50.605(a)(3)(iii) and 50.606(a), ProVerity shall **promptly notify the PHS Awarding Component** and submit a Mitigation Report if bias is found in the design, conduct, or reporting of PHS-funded research. Separately, if the failure of an Investigator to comply with this Policy or with an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, ProVerity shall **promptly notify the PHS Awarding Component of the corrective action taken or to be taken**. The PHS Awarding Component may take its own action or refer the matter to ProVerity for further action, which may include directions to ProVerity on how to maintain appropriate objectivity in the funded project.

9.4 Availability of Records to HHS

ProVerity shall, upon request from HHS or the PHS Awarding Component, promptly make available all records of Investigator financial interest disclosures and of ProVerity's review of, and response to, such disclosures — whether or not the disclosure resulted in ProVerity's determination of an FCOI — and shall submit or permit on-site review of all such records. Where HHS determines that a particular FCOI has not been managed or reported in compliance with the regulation, ProVerity shall take such additional corrective action as HHS may require.

10. Public Accessibility

10.1 Public Availability of This Policy

Consistent with 42 C.F.R. § 50.604(a) and the NIH Grants Policy Statement, ProVerity shall **make this FCOI Policy publicly accessible** by posting it on ProVerity's public website at **www.proverityai.com**. The posted version is the current, approved version and is updated whenever the Policy is revised.

If ProVerity at any time does not have a publicly accessible website, ProVerity shall make this Policy available to any requestor **within five (5) business days of a written request**, directed to dfurtado@proverityai.com or to the institutional address in Section 4.

10.2 Public Availability of Identified FCOI Information

Consistent with 42 C.F.R. § 50.605(a)(5)(i)–(iv), **prior to ProVerity's expenditure of any funds** under a PHS-funded research project, ProVerity shall ensure that information concerning any identified FCOI held by **senior/key personnel** is publicly accessible.

10.2.1 Minimum information provided

The information made available shall include, at a minimum:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the Significant Financial Interest is held;
- The nature of the Significant Financial Interest; and
- The approximate dollar value of the Significant Financial Interest, stated in the ranges \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000 and \$100,000 by increments of \$20,000; and amounts above \$100,000 by increments of \$50,000 — or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

10.2.2 Method, timing, and duration

- **Method.** The information shall be posted on ProVerity's publicly accessible website at www.proverityai.com. If ProVerity does not have a publicly accessible website, the information shall be provided by written response to any requestor **within five (5) business days of the request**, as required by 42 C.F.R. § 50.605(a)(5)(ii). **ProVerity adopts the stricter internal standard of five (5) calendar days, using Form E — Public Accessibility Response.**
- **Annual update.** Website information shall be **updated at least annually**. Any response to a written request shall include the updated information.
- **60-day update.** Website information shall be **updated within sixty (60) days** of either: (i) ProVerity's receipt or identification of information concerning any **additional** Significant Financial Interest of senior/key personnel on the project that was not previously disclosed and that ProVerity determines is an FCOI; or (ii) the disclosure of a Significant Financial Interest that is determined to be an FCOI by senior/key personnel **newly participating** in the project. Any response to a written request shall include the updated information.
- **Duration.** The information shall **remain available for at least three (3) years** from the date the information was most recently updated.

The Designated Official maintains a dated log of every posting, update, and written-request response, and retains screenshots or archived copies of each posted version as evidence of compliance.

11. Subrecipients

Consistent with 42 C.F.R. § 50.604(c)(1)(i)–(iii) and NIH Grants Policy Statement § 15.2.1, when ProVerity carries out PHS-funded research through a subrecipient — including a subawardee, subcontractor, or consortium member — ProVerity shall take reasonable steps to ensure that the subrecipient complies with 42 C.F.R. Part 50, Subpart F.

11.1 Written Agreement Required

ProVerity shall incorporate as part of a **written agreement** with each subrecipient, executed before any subrecipient work begins and before ProVerity expends funds under the subaward, terms that establish **whether the FCOI policy of ProVerity or that of the subrecipient will apply** to the subrecipient's Investigators. The determination is documented on **Form D — Subrecipient FCOI Certification and Agreement Terms**.

11.2 If the Subrecipient's Policy Applies

If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, ProVerity shall:

1. **Obtain certification from the subrecipient that its FCOI policy complies** with 42 C.F.R. Part 50, Subpart F. If the subrecipient cannot provide that certification, the written agreement shall state that the subrecipient's Investigators are subject to **ProVerity's** FCOI Policy, and Section 11.3 applies; and
2. **Include in the written agreement a time period** for the subrecipient to **report all identified FCOIs of its Investigators to ProVerity**, which time period shall be **sufficient to enable ProVerity to provide timely FCOI Reports to the PHS Awarding Component** as required by Section 9. ProVerity requires subrecipient reporting **within thirty (30) days of the subrecipient's identification of an FCOI**, and in no case later than a date that would prevent ProVerity from meeting its own 60-day or pre-expenditure reporting deadline.

11.3 If ProVerity's Policy Applies

Alternatively, if the subrecipient's Investigators must comply with **ProVerity's** FCOI Policy, the written agreement shall specify a **time period for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to ProVerity**, which time period shall be sufficient to enable ProVerity to comply timely with its review, management, and reporting obligations. ProVerity requires subrecipient disclosures **no later than at the time the subaward is executed, annually thereafter, and within thirty (30) days of a subrecipient Investigator discovering or acquiring a new SFI**. ProVerity shall then solicit and review those disclosures, make relatedness and FCOI determinations under Section 7, manage and monitor any identified FCOI, and report identified FCOIs to the PHS Awarding Component under Section 9.

11.4 ProVerity's Continuing Responsibility

Regardless of which policy applies, ProVerity remains responsible for **reporting to the PHS Awarding Component all identified FCOIs of subrecipient Investigators** and for taking such actions as are necessary with respect to their management. ProVerity shall track subrecipient certifications, disclosure and reporting deadlines, and received reports in the FCOI register maintained by the Designated Official.

12. Maintenance of Records

Consistent with 42 C.F.R. § 50.604(i), ProVerity shall maintain records relating to all Investigator disclosures of financial interests and to ProVerity's review of, and response to, such disclosures — whether or not a disclosure resulted in ProVerity's determination of a financial conflict of interest — and all actions under this Policy or retrospective reviews, for **at least three (3) years from the date the final expenditures report is submitted to the PHS (NIH)**, or, where applicable, **from the other dates specified in 45 C.F.R. § 75.361** for different situations (including, for example, records related to litigation, claims, audits, or other actions that begin before the expiration of the three-year period, which shall be retained until all such matters are resolved and final action taken).

12.1 Records Retained

- All Form A disclosures, including "no interests" disclosures, and all annual and 30-day updates;
- The Designated Official's written relatedness and FCOI determinations, including negative determinations;
- All management plans (Form B), Investigator agreements to those plans, and all monitoring entries;
- Training records and acknowledgments (Form C), including completion dates and next-due dates;
- Subrecipient certifications, written agreement FCOI terms, and subrecipient FCOI reports (Form D);

- Copies of all initial, annual, revised, and subrecipient FCOI Reports submitted to the PHS Awarding Component, with submission confirmations (Form G);
- Retrospective review and Mitigation Report documentation (Form F);
- Public accessibility postings, update log, archived versions, and written-request responses (Form E); and
- All correspondence with the PHS Awarding Component, HHS, and subrecipients concerning FCOI.

12.2 Custody and Confidentiality

Records are maintained by the Designated Official in a secure, access-controlled electronic file with restricted permissions and a documented backup. Disclosure information is treated as confidential and is shared only with individuals who have a legitimate need to know, with the PHS Awarding Component and HHS as required, and as otherwise required by law or by the public accessibility obligations of Section 10.

13. Enforcement, Sanctions, and Noncompliance

Consistent with 42 C.F.R. § 50.604(j), ProVerity establishes and enforces the following enforcement mechanisms and provides for employee sanctions and other administrative actions to ensure Investigator compliance with this Policy.

13.1 Enforcement Mechanisms

- Completion of FCOI training and submission of a current Form A disclosure are **conditions precedent** to an Investigator's participation in PHS-funded research and to the charging of any effort or cost attributable to that Investigator;
- The Designated Official verifies training currency and disclosure completeness before each application submission, before each award's initial expenditure of funds, and at each annual disclosure cycle;
- Management plan compliance is monitored on the schedule in Section 7.5 and documented in writing;
- Written agreement to any applicable management plan is required as a condition of continued participation; and
- Suspected noncompliance may be reported to the Designated Official by any person, including anonymously. **Where the Designated Official is implicated, the report is made to the Alternate Designated Official.** Because the Designated Official also serves as ProVerity's Chief Executive Officer, no report concerning the Designated Official is routed to the Chief Executive Officer; where the Alternate Designated Official is also implicated, the report is referred to an independent external reviewer engaged by ProVerity. ProVerity prohibits retaliation against any person who reports a suspected violation in good faith.

13.2 Sanctions and Administrative Actions

Noncompliance includes failure to submit a required disclosure, failure to disclose timely, submission of an incomplete or inaccurate disclosure, failure to complete required training, and failure to comply with an FCOI management plan. Depending on the nature and severity of the noncompliance, and on whether it is a first or repeated occurrence, ProVerity may impose one or more of the following:

1. Written notice of noncompliance and required immediate re-training under Section 5.2;
2. Required submission or correction of a disclosure within a stated deadline;
3. Imposition of, or amendment to, a management plan, including added monitoring;
4. Written warning or reprimand placed in the individual's personnel or contract file;
5. Restriction, suspension, or removal of the Investigator's role or responsibilities on the PHS-funded project, including disqualification from participation;

6. Required disclosure of the FCOI in presentations and publications, and a request for addenda to previously published presentations, as provided in Section 14;
7. Suspension of the Investigator's eligibility to serve on future PHS-funded applications or awards;
8. Withholding, reduction, or reallocation of effort or compensation charged to the project; and
9. Termination of employment, or termination of the consulting or subcontract agreement, in accordance with applicable law and the terms of the relevant agreement.

The Designated Official documents the noncompliance, the sanction imposed, the rationale, and the date of implementation, and retains the documentation under Section 12. Where the noncompliance triggers a retrospective review, Section 8 applies; where the noncompliance appears to have biased the research, the notification obligation in Section 9.3 applies.

13.3 Investigator Appeal

An Investigator may request reconsideration of a determination or sanction by submitting a written request within ten (10) business days. **The request is decided by the Alternate Designated Official**, or, where the Alternate is also conflicted or was the original decision-maker, **by an independent external reviewer engaged by ProVerity**. Because the Designated Official also serves as Chief Executive Officer, no reconsideration of a determination made by the Designated Official is decided by the Chief Executive Officer. A request for reconsideration does not suspend an interim management plan, a reporting obligation, or any deadline under the regulation.

14. Remedies for Unmanaged or Unreported FCOI in Certain Clinical Research

Consistent with 42 C.F.R. § 50.606(c), in any case in which HHS determines that a PHS-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 financial conflict of interest that was **not managed or reported** by ProVerity as required by the regulation, ProVerity shall require the Investigator involved to:

1. **Disclose the financial conflict of interest in each public presentation of the results of the research;** and
2. **Request an addendum to previously published presentations** to disclose the financial conflict of interest.

The Designated Official shall issue this requirement to the Investigator in writing, shall specify the content of the required disclosure, and shall verify and document that the disclosure and any addendum requests have been made. Failure by the Investigator to comply is itself noncompliance subject to Section 13.

14.1 HHS Inquiry and Remedies Generally

ProVerity acknowledges that the PHS Awarding Component or HHS may at any time inquire into ProVerity's Investigator disclosures and ProVerity's review of, and response to, such disclosures, whether or not a disclosure resulted in a determination of an FCOI, and may require submission of, or on-site review of, all related records. ProVerity shall cooperate fully and promptly with any such inquiry. ProVerity further acknowledges that HHS may impose special award conditions under 2 C.F.R. § 200.208 or suspend funding under 2 C.F.R. § 200.339 where an FCOI has not been managed or reported in compliance with the regulation.

15. Policy Administration

15.1 Review and Revision

The Designated Official shall review this Policy at least **annually** and upon any amendment to 42 C.F.R. Part 50, Subpart F, any change to the NIH Grants Policy Statement affecting FCOI, or any material change in ProVerity's operations. Material revisions are approved by the Chief Executive Officer, assigned a new version number and effective date, posted publicly under Section 10.1, and communicated to all Investigators, who shall complete immediate re-training under Section 5.2 where the revision affects Investigator requirements.

15.2 Associated Documents

Doc. No.	Title
FCOI-POL-001	Financial Conflict of Interest Policy (this document)
FCOI-SOP-001	FCOI Standard Operating Procedures
FCOI-FRM-A	Form A — Significant Financial Interest Disclosure
FCOI-FRM-B	Form B — FCOI Management Plan
FCOI-FRM-C	Form C — FCOI Training and Policy Acknowledgment
FCOI-FRM-D	Form D — Subrecipient FCOI Certification and Agreement Terms
FCOI-FRM-E	Form E — Public Accessibility Response to Written Request
FCOI-FRM-F	Form F — Retrospective Review and Mitigation Report
FCOI-FRM-G	Form G — FCOI Report Data Worksheet
FCOI-XWK-001	FCOI Regulatory Compliance Crosswalk

15.3 Approval

This Policy is adopted and made effective as of the date below.

Approved by	
Name / Title	Douglas Furtado, Chief Executive Officer
Date	
Effective date	August 28, 2026
Next scheduled review	August 28, 2027