H3Pelvic Therapy Systems

Policy on Financial Conflicts of Interest in PHS-Funded Research

Effective date	09/20/2026
Version	1.0
Designated Official	Zachary Wood Lyon / CEO
Independent Reviewer	Brandon Fox / Business Strategy Advisor
Approved by	Zachary Wood Lyon / CEO
Review cycle	Annually
Public location	https://www.h3pelvic.com/research-programs/fcoi-policy

1. Purpose and Scope

H3Pelvic Therapy Systems (H3Pelvic) is committed to objectivity in research. This Policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH), will be free from bias resulting from an Investigator's financial conflict of interest. It implements 42 CFR Part 50, Subpart F (the "Regulation").

This Policy applies to each Investigator (defined in Section 2) on any PHS-funded award to H3Pelvic, including NIH SBIR/STTR Phase II awards, and on any proposal for such funding. If this Policy and the Regulation conflict, the Regulation controls.

2. Definitions

- **Designated Official:** the person named in Section 3.1, who solicits and reviews disclosures and determines whether a financial conflict of interest exists.
- **Independent Reviewer:** the person named in Section 3.2, who performs the reviews described there.
- **Investigator:** the project director/principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, or of research proposed for such funding. This may include collaborators, consultants, and subrecipient personnel.
- **Institutional responsibilities:** an Investigator's professional responsibilities on behalf of H3Pelvic, as defined in this Policy, including research, product development, clinical, regulatory, and business-development activities, consulting, management and advisory roles, teaching, professional practice, committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.
- **Financial interest:** anything of monetary value, whether or not the value is readily ascertainable.
- **Senior/key personnel:** the project director/principal investigator and any other person identified as senior/key personnel in the grant application, a progress report, or any other report submitted to the PHS.
- **Subrecipient:** a person or entity that carries out part of the PHS-funded research under a written agreement with H3Pelvic, including consortium and subaward partners.

2.1 Significant financial interest (SFI)

An SFI is a financial interest of the Investigator, or of the Investigator's spouse or dependent children, that reasonably appears to be related to the Investigator's institutional responsibilities and consists of one or more of the following:

- **Publicly traded entity:** the value of any remuneration received from the entity in the twelve months before the disclosure, plus the value of any equity interest in the entity as of the disclosure date, together exceeds $5,000. Remuneration includes salary and any payment for services not identified as salary, such as consulting fees, honoraria, and paid authorship. Equity includes stock, stock options, and other ownership interests, valued by public prices or another reasonable measure of fair market value.
- **Non-publicly traded entity:** the value of any remuneration received from the entity in the twelve months before the disclosure exceeds $5,000, or the Investigator (or spouse or dependent children) holds any equity interest, such as stock, a stock option, or another ownership interest.
- **Intellectual property:** intellectual property rights and interests, such as patents and copyrights, upon receipt of income related to those rights and interests. There is no minimum dollar amount for this category.
- Travel: any reimbursed or sponsored travel (paid on behalf of the Investigator and not reimbursed to the Investigator) related to the Investigator's institutional responsibilities. The disclosure must include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. There is no minimum dollar amount. Investigators should disclose covered sponsored travel before the travel occurs whenever practicable, and in all cases no later than thirty (30) days after the occurrence. This does not apply to travel reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute affiliated with a U.S. institution of higher education.
- **Foreign financial interests:** domestic and foreign interests are both covered. The exclusions in Section 2.2 for income from seminars, lectures, teaching engagements, and advisory committee or review panel service, and the travel exception above, apply only to U.S. entities. Income from, and reimbursed or sponsored travel by, a foreign entity (including a foreign institution of higher education or a foreign government at the national, state, provincial, local, or equivalent level) is disclosed when it meets the disclosure threshold, for example income above $5,000.

2.2 Exclusions

The following are not SFIs:

- Salary, royalties, or other remuneration paid by H3Pelvic to an Investigator who is currently employed or otherwise appointed by H3Pelvic, including intellectual property rights assigned to H3Pelvic and agreements to share in royalties related to those rights.
- Any ownership interest in H3Pelvic held by the Investigator, because H3Pelvic is a commercial or for-profit organization.
- Income from investment vehicles such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions.
- Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute affiliated with a U.S. institution of higher education. This exclusion does not apply to foreign entities (see Section 2.1).

Interests in entities that invest in, supply, license technology to or from, compete with, or contract with H3Pelvic (including Subrecipients) are not excluded and ordinarily reasonably appear related to an Investigator's institutional responsibilities.

2.3 Related to the research; financial conflict of interest (FCOI)

- An SFI is **related to** PHS-funded research when the Designated Official reasonably determines that the SFI could be affected by the research, or is in an entity whose financial interest could be affected by the research.
- A **financial conflict of interest** is an SFI that the Designated Official reasonably determines could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

3. Roles and Responsibilities

3.1 Designated Official

H3Pelvic designates Zachary Lyon / CEO as the Designated Official. The Designated Official may not review or decide on his or her own disclosures. The Designated Official:

- solicits and reviews Investigator disclosures, determines whether each SFI is related to the research, and determines whether a related SFI is an FCOI;
- develops, implements, and monitors management plans;
- ensures Investigator training is completed and recorded;
- reports to NIH as required by Section 8, and ensures the public accessibility required by Section 10;
- coordinates with Subrecipients under Section 9;
- conducts retrospective reviews under Section 11; and
- maintains the records described in Section 12.

3.2 Independent Reviewer

H3Pelvic designates Brandon Fox / Business Strategy Advisor as the Independent Reviewer. The Independent Reviewer has no financial or family relationship with the Investigator whose matter is under review. The Independent Reviewer performs the disclosure review, FCOI determination, and management-plan approval for (a) the Designated Official, (b) any Investigator who is an officer of H3Pelvic with authority over the Designated Official, including the chief executive officer and any principal investigator in that position, and (c) any matter in which the Designated Official has a conflict. The Independent Reviewer completes the same training as Investigators.

3.3 Investigators

Each Investigator completes training (Section 5), submits disclosures (Section 4), complies with any management plan, and promptly informs the Designated Official of any change in circumstances that may create or affect an SFI.

3.4 H3Pelvic leadership

H3Pelvic leadership provides the resources needed to administer this Policy and enforces it under Section 11.

Because officers and other key officials exercise institutional decision-making authority, they are held to a heightened standard of objectivity. A leader with an actual or apparent conflict involving an Investigator disclosure, management decision, procurement, intellectual-property matter, or other research-related decision must disclose the conflict and recuse from that decision. The matter will be referred to the Independent Reviewer or another disinterested official designated by H3Pelvic.

4. Disclosure of Significant Financial Interests

Each Investigator discloses all domestic and foreign SFIs that are related to his or her institutional responsibilities, including those of his or her spouse and dependent children, to the Designated Official on the Disclosure Form (Appendix A):

- no later than the time of application for PHS funding, and before beginning any work on a PHS-funded project;
- at least annually during the period of the award, including any information not previously disclosed and updated information on previously disclosed SFIs (for example, the updated value of an equity interest);
- within thirty (30) days of discovering or acquiring (for example by purchase, marriage, or inheritance) a new SFI; and
- within thirty (30) days of each occurrence of reimbursed or sponsored travel covered by Section 2.1.

An Investigator with no SFIs submits the form and so states. Failure to disclose in a timely manner is noncompliance under Section 11.

Initial implementation. Within 14 days after the Effective Date, each Investigator on an active PHS-funded award completes training and submits an initial disclosure.

5. Training

Each Investigator completes training on this Policy, the Investigator's disclosure responsibilities, and the Regulation, using an NIH-provided FCOI tutorial or equivalent training approved by the Designated Official:

- before engaging in research related to any PHS-funded award;
- at least every four years; and
- immediately when the Policy is revised in a way that changes Investigator requirements, when an Investigator is new to H3Pelvic, or when an Investigator is found not to be in compliance with this Policy or a management plan.

The Designated Official keeps a training log.

6. Review and Determination

The Designated Official (or the Independent Reviewer under Section 3.2) reviews each disclosure within thirty (30) days of receipt, and in every case in time to meet the reporting deadlines in Section 8. The reviewer:

- determines whether each disclosed SFI is related to the PHS-funded research;
- if so, determines whether it is an FCOI; and
- records the determination and its basis on the Determination and Management Record (Appendix B).

Before any PHS award funds are expended on a project, H3Pelvic completes the review for all Investigators on that project and implements any required management plan. For an SFI disclosed during an ongoing award, H3Pelvic completes the review, and implements a management plan for any FCOI, within sixty (60) days. For an SFI that was not disclosed in a timely manner, or that for any reason was not previously reviewed (including by a Subrecipient), the review is completed within sixty (60) days of identification, with a management plan implemented on at least an interim basis if an FCOI exists. The Designated Official may impose interim measures while a review is pending.

7. Management of Financial Conflicts of Interest

When an FCOI exists, the Designated Official (with the approval of the Independent Reviewer where Section 3.2 applies) develops a written management plan that describes:

- the role and principal duties of the conflicted Investigator on the project;
- the conditions of the plan;
- how the plan is designed to safeguard objectivity in the research;
- the Investigator's written agreement to the plan;
- how compliance will be monitored; and
- any other information needed.

Measures H3Pelvic may require include:

- public disclosure of the FCOI, for example in presentations and publications of the research;
- for human subjects research, disclosure of the FCOI directly to participants;
- monitoring of the research by independent reviewer(s), including appointment of an independent monitor capable of protecting the design, conduct, and reporting of the research against bias;
- modification of the research plan;
- a change in personnel or responsibilities, or disqualification from all or part of the research;
- reduction or elimination of the financial interest, such as sale of an equity interest; or
- severance of the relationship that creates the actual or potential conflict.

The Designated Official monitors Investigator compliance with each management plan on an ongoing basis until the project is completed.

Human subjects research. When an FCOI is identified in research involving human participants, the Designated Official will notify the applicable Institutional Review Board (IRB). The IRB and H3Pelvic may conduct their reviews in parallel, but final IRB approval or continued approval will be conditioned on completion of the FCOI review and implementation of any required management measures.
Research communications. Any management plan may require disclosure of the FCOI in publications, presentations, posters, press releases, media contacts, and other public communications concerning the affected research, consistent with Section 7 and applicable journal, conference, IRB, sponsor, and NIH requirements.

8. Reporting to NIH

8.1 Policy submission

H3Pelvic keeps this Policy on a publicly accessible website at https://www.h3pelvic.com/research-programs/fcoi-policy and submits the publicly accessible Policy to NIH through the Institution Profile (IPF) module in eRA Commons. The submission is made at the institutional level, not with each grant application. H3Pelvic updates the website and its IPF entry whenever the Policy is materially amended. H3Pelvic does not expend PHS award funds while an award term requires NIH confirmation of this step and NIH has not given it.

8.2 FCOI reports

H3Pelvic submits FCOI reports to NIH through the eRA Commons FCOI Module:

- before H3Pelvic expends any funds under a PHS-funded project, for any FCOI identified as of that date;

- within sixty (60) days of identifying a new FCOI, including one arising because an Investigator is new to the project, an Investigator discloses a new or newly identified SFI, or additional information about a previously reported FCOI is identified;
- annually, at the same time as the annual progress report or at the time of an extension, with a status report that says whether the FCOI is still being managed (or explains why it no longer exists) and describes any change to the management plan, for the duration of the project period, including extensions with or without funds; and
- as a revised report after a retrospective review, if new information is found.

If H3Pelvic identifies an FCOI and eliminates it before expending any PHS award funds, it does not submit an FCOI report.

Each initial report includes the project number; the project director/principal investigator; 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 (for example consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, or reimbursed or sponsored travel); the value of the interest, in the ranges listed in Section 10 or with a statement that the value cannot be readily determined; a description of how the interest relates to the research and the basis for determining that it conflicts; and the key elements of the management plan.

8.3 Certification and availability of records

H3Pelvic's authorized organizational representative certifies compliance with the Regulation in each application for PHS funding. When NIH or HHS requests it, H3Pelvic promptly makes available information about any Investigator disclosure and H3Pelvic's review of, and response to, that disclosure, whether or not it resulted in an FCOI determination. NIH or HHS may inquire at any time before, during, or after an award, and H3Pelvic will submit, or permit on-site review of, all records pertinent to compliance with the Regulation.

9. Subrecipients

Each written agreement with a Subrecipient states whether this Policy or the Subrecipient's own FCOI policy applies to the Subrecipient's Investigators.

- **Subrecipient policy applies:** the Subrecipient certifies in the agreement that its policy complies with the Regulation.
- **H3Pelvic policy applies:** if the Subrecipient cannot give that certification, the agreement provides that its Investigators are subject to this Policy for disclosing SFIs that are directly related to the Subrecipient's work for H3Pelvic.
- **Reporting periods:** the agreement sets time periods, no longer than thirty (30) days after identification, for the Subrecipient to report any FCOI to H3Pelvic, so that H3Pelvic can meet its sixty (60) day reporting deadline to NIH.

H3Pelvic reports Subrecipient FCOIs to NIH as required by Section 8.

10. Public Accessibility

This Policy is posted on H3Pelvic's publicly accessible website at https://www.h3pelvic.com/research-programs/fcoi-policy. Before H3Pelvic expends funds under a PHS-funded project, H3Pelvic makes available, by written response to any requestor within five (5) business days of a request, information about any SFI of senior/key personnel that (a) was disclosed to and is still held by the individual, (b) the Designated Official has determined is related to the PHS-funded research, and (c) the Designated Official has determined is an FCOI. The information provided is:

- the Investigator's name, title, and role with respect to the research;
- the name of the entity in which the SFI is held;

- the nature of the SFI; and
- the approximate dollar value of the SFI, in one of these ranges: $0 to $4,999; $5,000 to $9,999; $10,000 to $19,999; amounts between $20,000 and $100,000 in increments of $20,000; and amounts above $100,000 in increments of $50,000. If the value cannot be readily determined by public prices or another reasonable measure of fair market value, the response says so.

H3Pelvic updates this information at least annually and within sixty (60) days of identifying a new FCOI for senior/key personnel, and keeps each response available for at least three years from the date of the most recent update. Each response states that the information is current as of the date of the response and is subject to update at least annually and within sixty (60) days of H3Pelvic identifying a new FCOI. If H3Pelvic instead posts the information on its website, it posts the same statement and keeps the website current.

11. Noncompliance, Retrospective Review, and Sanctions

If an Investigator fails to disclose an SFI in a timely manner, fails to comply with a management plan, or an FCOI is otherwise not identified or managed in a timely manner, the Designated Official (or Independent Reviewer under Section 3.2) completes a retrospective review within one hundred twenty (120) days of the determination of noncompliance, to decide whether any PHS-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting. The review is documented and includes:

- the project number, project title, and project director/principal investigator;
- the Investigator with the FCOI and the entity with which the Investigator has the FCOI;
- the reason for the review and the methodology used; and
- the findings and conclusions.

If bias is found, H3Pelvic promptly notifies NIH and submits a mitigation report that describes the impact of the bias on the research and the plan of action to eliminate or mitigate its effect. H3Pelvic also submits an FCOI report as required by Section 8 for any FCOI identified through the review.

If an Investigator's failure to comply with this Policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research, H3Pelvic promptly notifies NIH of the corrective action taken or to be taken.

If HHS determines that a PHS-funded clinical research project 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 this Policy requires, H3Pelvic will require the Investigator to disclose the FCOI in each public presentation of the results and to request an addendum to previously published presentations.

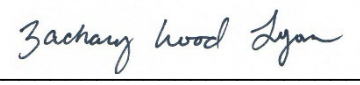
Sanctions for noncompliance will be proportionate to the breach and may include written corrective action, required training, reimbursement of misused institutional resources, restriction or suspension from grant or research activities, removal or suspension from the project, required reduction or elimination of the financial interest, termination of the engagement, and any other action permitted by the Investigator's employment or consulting agreement.

12. Records

H3Pelvic keeps all disclosures, reviews, determinations, management plans, monitoring records, retrospective reviews, training logs, Subrecipient certifications and reports, and NIH reports for at least three years from the date the final expenditure report is submitted to NIH, or longer if required by 2 CFR Part 200 or the award terms.

13. Policy Review and Amendment

The Designated Official reviews this Policy at least annually and after any change to the Regulation. Amendments are approved by Zachary Wood Lyon / CEO. Where a change to the Regulation requires it, H3Pelvic amends the Policy within the time NIH specifies and retrains Investigators as Section 5 requires.

Adopted by:  Zachary Wood Lyon / CEO Date: 09/20/2026

For H3Pelvic Therapy Systems, Inc.

Appendix A. Investigator Financial Disclosure Form

> *Internal form. Complete at application, at least annually, and within 30 days of acquiring a new interest. Include interests of your spouse and dependent children. Exclusions in Section 2.2 of the Policy do not need to be reported, except that they do not apply to interests from foreign entities.*

Investigator name	
Title and role on project(s)	
Project(s) / award number(s)	
Disclosure type	Initial / ~~Annual update / New interest~~ (within 30 days)
Date	

#	Question (past 12 months, or as of today for equity)	Yes / No	If yes: entity, nature of interest, approximate value, and how you believe it relates to the project
1	Publicly traded entity: do remuneration received in the past 12 months plus the value of any equity held today, together, exceed $5,000 for any single entity?		
2	Non-publicly traded entity: did you receive more than $5,000 in remuneration in the past 12 months, or do you hold any equity (stock, option, other ownership)?		
3	Intellectual property: have you received income related to patents, copyrights, or other IP rights (other than IP assigned to H3Pelvic and royalty sharing with H3Pelvic)?		
4	Travel: has any entity other than a U.S. government agency, U.S. institution of higher education, U.S. academic teaching hospital, U.S. medical center, or U.S. affiliated research institute paid for or sponsored travel related to your institutional responsibilities? Give purpose, sponsor/organizer, destination, duration, and travel dates. Disclose before travel whenever practicable and no later than 30 days after the occurrence.		
5	Do you have any other financial interest in an entity that invests in, supplies, licenses to or from, competes with, or contracts with H3Pelvic or any of its subrecipients?		

#	Question (past 12 months, or as of today for equity)	Yes / No	If yes: entity, nature of interest, approximate value, and how you believe it relates to the project
6	Foreign interests: have you received income (including from lectures, seminars, teaching, advisory committees, or review panels) above $5,000, or reimbursed or sponsored travel, from any foreign entity, including a foreign university or government?		

I certify that the information above is complete and accurate. I will update it within 30 days of acquiring a new significant financial interest and within 30 days of each occurrence of reimbursed or sponsored travel.

Signature: _____ Date: _____

Appendix B. Determination and Management Record

> *Internal form, completed by the Designated Official, or by the Independent Reviewer where Section 3.2 applies.*

Project / award number	
Investigator	
Entity	
Nature and value of interest	
Date disclosure received	
Related to the research? (yes / no and basis)	
FCOI? (yes / no and basis)	
Reviewer (Designated Official / Independent Reviewer)	
Management plan (summary, or attach)	
Investigator's agreement to plan (date)	
Monitoring method and schedule	
Reported to NIH via FCOI Module (date)	
Public accessibility information updated (date)	
Reviewer signature and date	