Financial Conflict of Interest (FCOI) Policy

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Approved By: Sepehr Kiani, Chief Executive Officer
Policy Owner: Designated Official for Financial Conflict of Interest
Entity: Vivid BioInnovations, PBC
Public Website: https://www.vivid-bio.com/fcoi_policy

1. Purpose

Vivid BioInnovations, PBC is committed to conducting federally funded research, development, product development, and related technical work with integrity, objectivity, transparency, and freedom from bias resulting from Investigator financial conflicts of interest.

This Financial Conflict of Interest (“FCOI”) Policy establishes Vivid’s process for identifying, disclosing, reviewing, managing, reducing, eliminating, and reporting financial conflicts of interest in Covered Research.

This Policy is intended to comply with applicable federal requirements, including:

- 42 CFR Part 50 Subpart F, “Promoting Objectivity in Research,” for Public Health Service (“PHS”) grants and cooperative agreements;

- 45 CFR Part 94, “Responsible Prospective Contractors,” for PHS research contracts;
- NIH Grants Policy Statement requirements relating to FCOI;
- Applicable terms and conditions in federal grants, cooperative agreements, contracts, subcontracts, task orders, Other Transaction Agreements (“OTAs”), Broad Agency Announcements (“BAAs”), and other federally funded research or development instruments that incorporate FCOI or similar requirements.

This Policy also provides Vivid’s internal standard for managing financial conflicts of interest in federal research and development work, including SBIR/STTR Phase II, Direct-to-Phase II, Fast-Track, and future Phase III work, where applicable.

2. Applicability

This Policy applies to each Investigator who is planning to participate in, is participating in, or is responsible for the design, conduct, or reporting of Covered Research performed by or on behalf of Vivid.

Covered Research includes:

- PHS-funded research supported by grants or cooperative agreements, including NIH awards;
- PHS-funded research contracts subject to 45 CFR Part 94;
- SBIR/STTR Phase II, Direct-to-Phase-II, Fast-Track, and future Phase III federal work, unless exempt or unless the applicable award terms state otherwise;
- Federal research, development, testing, evaluation, product-development, clinical, regulatory, or technical work under contracts, subcontracts, task orders, OTAs, BAAs, or similar instruments when the solicitation, award, prime contract, subcontract, or agency terms require FCOI compliance;
- Subrecipient, subcontractor, consultant, collaborator, or contractor work that constitutes a substantive part of Covered Research.

Federal FCOI regulations generally do not apply to SBIR/STTR Phase I applications or awards. However, Vivid may require internal disclosure, review, and management of financial interests for SBIR/STTR Phase I work when required by an award, requested by a sponsor, required by a prime contractor, or deemed appropriate by Vivid to protect research integrity.

This Policy complements, but does not replace, other Vivid policies or contract-specific procedures concerning organizational conflicts of interest, personal conflicts of interest, procurement integrity, research misconduct, human-subjects protection, animal-subjects protection, data integrity, confidentiality, export controls, cybersecurity, or government-contract compliance.

3. Definitions

3.1 Covered Research

“Covered Research” means research, development, product development, testing, evaluation, clinical, regulatory, technical, or scientific work conducted by or on behalf of Vivid that is funded or proposed for funding

by a federal agency or through a federally funded prime award, and that is subject to this Policy under Section 2.

3.2 Designated Official

“Designated Official” or “DO” means the individual appointed by Vivid to solicit and review Significant Financial Interest disclosures, determine whether an SFI is related to Covered Research, determine whether an FCOI exists, develop and implement management plans, maintain records, and coordinate required reporting.

Unless otherwise designated in writing, Vivid’s Chief Executive Officer serves as the Designated Official.

3.3 Financial Conflict of Interest

“Financial Conflict of Interest” or “FCOI” means a Significant Financial Interest that Vivid reasonably determines:

- Is related to Covered Research; and
- Could directly and significantly affect the design, conduct, or reporting of the Covered Research.

3.4 Financial Interest

“Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable.

3.5 Institution

“Institution” means any domestic or foreign, public or private organization, excluding a federal agency, that applies for or receives federal research funding. For purposes of this Policy, Vivid is the Institution for work it applies for, receives, conducts, or administers.

3.6 Institutional Responsibilities

“Institutional Responsibilities” means an Investigator’s professional responsibilities performed on behalf of Vivid, including but not limited to:

- Research, development, engineering, design, testing, validation, and reporting;
- Product development, prototype development, assay development, diagnostic development, software development, and manufacturing-process development;
- Grant, contract, proposal, budget, regulatory, clinical, quality, and compliance activities;
- Publication, presentation, authorship, data analysis, and scientific communication;
- Business development, fundraising, commercialization, licensing, and intellectual-property activities;
- Service on scientific advisory boards, review boards, steering committees, data-safety monitoring boards, institutional review boards, or similar bodies;
- Supervision or management of employees, consultants, collaborators, subcontractors, or subrecipients engaged in Covered Research.

3.7 Investigator

“Investigator” means the Project Director, Principal Investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Covered Research.

Investigators may include employees, officers, founders, consultants, contractors, subcontractor personnel, collaborators, subrecipient personnel, advisors, and other individuals who exercise independent responsibility over the design, conduct, or reporting of Covered Research.

Vivid determines who is an Investigator based on the individual’s role and responsibilities, not solely on job title, seniority, employment status, or whether the individual is named as senior/key personnel.

3.8 Manage

“Manage” means taking action to address an FCOI, including reducing or eliminating the conflict, to ensure to the extent possible that the design, conduct, and reporting of Covered Research will be free from bias.

3.9 PHS

“PHS” means the Public Health Service of the U.S. Department of Health and Human Services and any PHS component to which relevant authority is delegated, including the National Institutes of Health.

3.10 PHS/NIH-Funded Research

“PHS/NIH-Funded Research” means any research funded or proposed for funding by PHS or NIH through a grant, cooperative agreement, contract, subcontract, or other funding mechanism, except where an exemption applies.

3.11 Research

“Research” means a systematic investigation, study, experiment, development effort, or product-development activity designed to develop or contribute to generalizable knowledge relating broadly to public health, medicine, biology, diagnostics, therapeutics, engineering, data science, or related scientific and technical fields.

Research includes basic research, applied research, translational research, clinical research, product development, diagnostic development, assay development, medical-device development, software or data-analysis development, and related scientific or technical work.

3.12 Senior/Key Personnel

“Senior/Key Personnel” means the Project Director, Principal Investigator, and any other individual identified as senior/key personnel by Vivid in a federal application, proposal, progress report, contract submission, or other report submitted to a federal sponsor or prime recipient.

For purposes of this Policy, the term “Senior/Key Personnel” is especially relevant to public accessibility requirements for certain FCOIs.

3.13 Significant Financial Interest

“Significant Financial Interest” or “SFI” means a domestic or foreign Financial Interest consisting of one or more of the interests described below, held by the Investigator or by the Investigator’s spouse, domestic partner, or dependent children, that reasonably appears to be related to the Investigator’s Institutional Responsibilities.

Vivid requires disclosure of interests held by an Investigator’s spouse, domestic partner, and dependent children. This requirement is intentionally at least as broad as the federal minimum.

Publicly Traded Entity

For a publicly traded entity, an SFI exists if the aggregated value of remuneration received from the entity in the twelve months preceding disclosure and the value of any equity interest in the entity as of the date of disclosure exceeds $5,000.

Remuneration includes salary and any payment for services not otherwise identified as salary, including consulting fees, honoraria, paid authorship, advisory fees, speaker fees, or similar payments.

Equity interest includes stock, stock options, warrants, or other ownership interests, as determined through public prices or other reasonable measures of fair market value.

Non-Publicly Traded Entity

For a non-publicly traded entity, an SFI exists if:

- The aggregated value of remuneration received from the entity in the twelve months preceding disclosure exceeds $5,000; or
- The Investigator, spouse, domestic partner, or dependent children hold any equity interest in the entity, regardless of dollar value.

Equity interest includes stock, stock options, membership interests, partnership interests, warrants, convertible instruments, profit interests, or other ownership interests.

Intellectual Property Rights and Interests

Intellectual property rights and interests, including patents, patent applications, copyrights, software, data rights, royalties, licensing income, milestone payments, or similar interests, may constitute an SFI upon receipt of income related to such rights or interests.

For income related to intellectual property rights or interests received from an outside entity, the Investigator must disclose the source and aggregate value of such income received in the twelve months preceding disclosure when the income exceeds $5,000, unless a lower disclosure threshold is required by applicable law, sponsor requirement, award term, contract term, or the Designated Official.

Intellectual property rights assigned to Vivid and agreements to share in royalties related to those rights are excluded from the definition of SFI to the extent permitted under this Policy.

A new patent, patent application, copyright, software right, or similar intellectual property right does not by itself constitute a new SFI unless income has been received, the source of income has changed, the aggregate value has changed in a way requiring disclosure, or the Designated Official determines that disclosure is necessary to evaluate a potential relationship to Covered Research.

Reimbursed or Sponsored Travel

Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities, including travel paid on behalf of the Investigator and not reimbursed directly to the Investigator, unless the travel is excluded under Section 3.14.

For the initial disclosure, Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities that occurred during the twelve months preceding disclosure.

During Covered Research, Investigators must disclose new reimbursed or sponsored travel within 30 days of the travel occurrence if the travel was not previously disclosed, was not reasonably anticipated in a prior disclosure, or materially differs from a prior disclosure.

Travel disclosures must include, at minimum:

- Purpose of the trip;
- Sponsor or organizer;
- Destination;
- Duration;
- Approximate value, if known;
- Relationship of the travel to the Investigator's Institutional Responsibilities or Covered Research.

Vivid may request additional information, including the monetary value of the travel, to determine whether the travel constitutes an SFI, whether it is related to Covered Research, and whether it creates an FCOI.

Vivid may, in its discretion and where permitted by applicable requirements, apply a $5,000 de minimis threshold aggregated by sponsor or organizer over the twelve months preceding disclosure when determining whether disclosed reimbursed or sponsored travel requires further SFI review. Vivid may require disclosure or review of travel below that threshold when the travel involves a foreign entity, is directly related to Covered Research, is required to be disclosed by a sponsor or award term, or otherwise presents a potential risk to research objectivity.

3.14 Exclusions from Significant Financial Interest

The term "Significant Financial Interest" does not include:

- Salary, royalties, equity compensation, or other remuneration paid by Vivid to the Investigator if the Investigator is currently employed or otherwise appointed by Vivid;
- Intellectual property rights assigned to Vivid and agreements to share in royalties related to those rights;

- Ownership interests in Vivid held by the Investigator, where the exclusion is permitted because Vivid is a commercial or for-profit institution;
- Income from investment vehicles such as mutual funds, exchange-traded funds, index funds, or retirement accounts, provided the Investigator does not directly control the investment decisions made in those vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), 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;
- Income from 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 as defined at 20 U.S.C. 1001(a), 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;
- Travel reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), 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.
- The exclusions in this Section 3.14 are limited to the U.S. entities described above. They do not automatically apply to income, service, advisory roles, review-panel roles, reimbursed travel, or sponsored travel involving foreign governments, foreign institutions of higher education, foreign academic institutions, foreign hospitals, foreign medical centers, foreign research institutes, foreign non-profit organizations, or other foreign entities.

3.15 Foreign Financial Interests

Investigators must disclose Financial Interests originating from or sponsored by foreign entities, including foreign companies, foreign universities, foreign research institutes, foreign hospitals, foreign governments, foreign local or provincial governments, foreign non-profit organizations, and foreign academic institutions, when the interest otherwise meets the disclosure standard in this Policy.

The exclusions for U.S. government agencies, U.S. institutions of higher education, U.S. academic teaching hospitals, U.S. medical centers, and U.S.-affiliated research institutes do not automatically apply to foreign entities.

4. Responsibilities

4.1 Investigator Responsibilities

Each Investigator is responsible for:

- Reviewing this Policy;
- Completing required FCOI training;
- Disclosing SFIs completely, accurately, and on time;
- Updating disclosures as required;
- Cooperating with Vivid’s review of disclosures;

- Complying with any FCOI management plan;
- Disclosing managed FCOIs in publications, presentations, informed-consent documents, study-team communications, or other contexts when required by a management plan;
- Promptly notifying the Designated Official of changes that may affect a prior disclosure or management plan.

4.2 Designated Official Responsibilities

The Designated Official is responsible for:

- Maintaining this Policy and related procedures;
- Identifying Investigators subject to the Policy;
- Soliciting and reviewing SFI disclosures;
- Determining whether disclosed SFIs are related to Covered Research;
- Determining whether related SFIs constitute FCOIs;
- Developing, implementing, and monitoring management plans;
- Submitting required FCOI reports to federal sponsors, NIH, PHS awarding components, contracting officers, prime recipients, or other required parties;
- Ensuring public accessibility of this Policy and required FCOI information;
- Maintaining required records;
- Coordinating subrecipient, subcontractor, consultant, and collaborator compliance;
- Taking or recommending enforcement action for noncompliance.

4.3 Company Responsibilities

Vivid will maintain an up-to-date, written, enforced FCOI policy and will make the Policy publicly accessible on its website.

Vivid will submit, certify, or otherwise provide this Policy to federal sponsors, NIH, PHS, prime recipients, contracting officers, or other parties when required by award terms or applicable law.

5. Disclosure Requirements

5.1 Timing of Disclosures

Each Investigator must disclose all SFIs to the Designated Official:

- No later than the time of application, proposal, bid, quotation, contract offer, subcontract proposal, or other funding request for Covered Research, unless the Investigator has a current disclosure on file with Vivid and certifies that there are no new or changed SFIs requiring disclosure;
- Before participating in Covered Research if the Investigator joins after submission or after award;
- At least annually during the period of Covered Research, on or before April 1 unless the Designated Official specifies another annual deadline;

- Within 30 days of discovering or acquiring a new SFI, including through purchase, marriage, domestic partnership, inheritance, employment, consulting, appointment, licensing, intellectual-property income, or other means;
- Within 30 days of each new reimbursed or sponsored travel occurrence related to the Investigator's Institutional Responsibilities, unless the travel was previously disclosed, was reasonably anticipated in a prior disclosure, or is excluded under Section 3.14;
- Within 30 days of any material change to a previously disclosed SFI, including a material change in value, source, relationship to Covered Research, or other information needed by Vivid to evaluate the SFI;
- As otherwise required by a federal sponsor, prime recipient, contract, subcontract, award term, solicitation, management plan, or the Designated Official.

Vivid may require Investigators to confirm, update, or certify the accuracy of SFI disclosures at proposal submission, prior to expenditure of funds, prior to or during Just-in-Time or other pre-award processes, or at other times when Vivid determines that confirmation is necessary to meet sponsor, award, contract, or compliance requirements.

5.2 Scope of Disclosure

SFI disclosures must relate to the Investigator's Institutional Responsibilities and are not limited to the Investigator's specific funded project.

The disclosure must include sufficient information for Vivid to determine:

- The nature of the Financial Interest;
- The entity in which the interest is held;
- The approximate value or value range;
- The relationship of the interest to the Investigator's Institutional Responsibilities;
- The potential relationship of the interest to Covered Research;
- Whether the interest could be affected by the Covered Research;
- Whether the entity's financial interests could be affected by the Covered Research.

5.3 Disclosure Form

Vivid may require Investigators to use a Company-approved SFI Disclosure Form.

At minimum, the form should collect:

- Investigator name and role;
- Covered Research project, proposal, award, contract, or subcontract;
- Entity name;
- Entity type and location;
- Nature of the Financial Interest;
- Approximate value or value range;
- Whether the entity is publicly traded or privately held;
- Whether the interest is domestic or foreign;

- Whether the interest is held by the Investigator, spouse, domestic partner, or dependent child;
- Travel details, if applicable;
- Intellectual property or licensing details, if applicable;
- Investigator certification of accuracy and completeness.

6. Review of Disclosures

The Designated Official will review each SFI disclosure to determine whether the SFI is related to Covered Research and whether it constitutes an FCOI.

For each disclosed SFI, the Designated Official will determine whether:

- The SFI could be affected by the Covered Research;
- The SFI is in an entity whose financial interests could be affected by the Covered Research;
- The SFI could directly and significantly affect the design, conduct, or reporting of the Covered Research.

The Designated Official may consult with the Investigator, project leadership, legal counsel, compliance advisors, scientific advisors, contracting officers, grants management specialists, prime recipients, or other appropriate parties when evaluating relatedness or potential bias.

The Designated Official will complete the review before expenditure of funds whenever required and, for newly disclosed SFIs during an active project, within 60 days of disclosure or identification.

No Investigator may expend funds or participate in Covered Research when Vivid determines that a management plan is required until the Investigator has agreed in writing to comply with the management plan, unless the Designated Official authorizes interim participation with appropriate safeguards.

7. FCOI Management

If Vivid determines that an SFI constitutes an FCOI, the Designated Official will develop and implement a written management plan designed to manage, reduce, or eliminate the conflict.

Management strategies may include one or more of the following:

- Public disclosure of the FCOI in publications, presentations, press releases, posters, abstracts, regulatory submissions, or other research communications;
- Disclosure to project personnel, collaborators, subrecipients, subcontractors, consultants, advisory boards, IRBs, IACUCs, data-safety monitoring boards, or other oversight bodies;
- Disclosure to human research participants through informed-consent documents;
- Appointment of an independent monitor or reviewer;
- Modification of the research plan, analysis plan, testing plan, validation plan, publication plan, or reporting structure;
- Change in personnel responsibilities;

- Recusal from specific decisions, analyses, procurements, vendor selections, publications, or reporting activities;
- Disqualification from participation in all or part of the Covered Research;
- Reduction or elimination of the Financial Interest, including divestiture;
- Severance of the relationship creating the conflict;
- Additional oversight, documentation, quality review, data audit, or sponsor reporting;
- Other measures deemed appropriate by Vivid.

The management plan will identify:

- The Investigator with the FCOI;
- The Covered Research affected;
- The nature of the FCOI;
- The conditions or restrictions imposed;
- The method for monitoring compliance;
- The timing of required updates or certifications;
- The consequences of noncompliance.

The Investigator must sign the management plan and comply with all conditions.

8. Monitoring

Vivid will monitor Investigator compliance with each management plan for the duration of the Covered Research.

Monitoring may include:

- Periodic Investigator certifications;
- Review of publications, presentations, and reports for required disclosures;
- Review of study records, data, analyses, procurement decisions, or technical decisions;
- Confirmation of divestiture, recusal, or role modification;
- Independent scientific, technical, or compliance review;
- Subrecipient, subcontractor, or consultant compliance checks;
- Other monitoring appropriate to the risk presented by the FCOI.

The Designated Official will document monitoring activities and any corrective actions.

9. Public Accessibility

9.1 Public Access to Policy

Vivid will make this Policy publicly accessible on its website.

Vivid may maintain a public webpage that summarizes the Policy and links to the full current policy document.

For NIH-funded grants and cooperative agreements, Vivid will submit this Policy to NIH through the eRA Commons Institution Profile Module when required.

9.2 Public Access to Certain FCOIs

Before expenditure of funds under PHS/NIH-funded Covered Research, Vivid will make information publicly accessible concerning any SFI that meets all of the following criteria:

- The SFI was disclosed and is still held by Senior/Key Personnel;
- Vivid determined that the SFI is related to the Covered Research;
- Vivid determined that the SFI constitutes an FCOI.

Vivid will provide the required information by written response within five business days of a request unless Vivid elects to post the information on a publicly accessible website.

9.3 Required Public Information

For each publicly accessible FCOI, Vivid will provide at least:

- Investigator's name;
- Investigator's title and role with respect to the Covered Research;
- Name of the entity in which the SFI is held;
- Nature of the SFI;
- Approximate dollar value of the SFI using the following ranges:
    - USD 0–USD 4,999
    - USD 5,000–USD 9,999
    - USD 10,000–USD 19,999
    - USD 20,000–USD 100,000 by increments of USD 20,000 amounts above USD 100,000 by increments of USD 50,000

The written response will state that the information is current as of the date of the response and is subject to updates at least annually and within 60 days of Vivid's identification of a new publicly accessible FCOI.

Information concerning publicly accessible FCOIs will remain available for at least three years from the most recent update.

10. Reporting Identified Financial Conflicts of Interest

Prior to spending any funds under a Covered Research award, Vivid will submit an identified FCOI report, when required, for any Investigator SFI determined by Vivid to constitute an FCOI.

For NIH-funded grants and cooperative agreements, Vivid will submit required FCOI reports through the NIH eRA Commons FCOI Module.

For PHS research contracts subject to 45 CFR Part 94, Vivid will report identified FCOIs to the PHS Awarding Component and, as applicable, the Contracting Officer, Contracting Officer's Representative, or other

designated contract official in accordance with 45 CFR Part 94, the contract, and applicable agency instructions.

For other federal contracts, subcontracts, task orders, OTAs, BAAs, or similar instruments, Vivid will follow the reporting requirements in the solicitation, award, prime contract, subcontract, agency guidance, or flow-down terms.

Vivid will designate an institutional official to act as the FCOI Signing Official or equivalent responsible official for submitting FCOI reports.

FCOI reports are submitted only when an award, contract, or covered project is active and Vivid has identified an FCOI, unless the applicable sponsor, contract, or agency guidance requires otherwise.

10.1 Required FCOI Reports

Report Type	Content	Required When / Submission Route
New FCOI Report / Initial Report	Grant, cooperative agreement, contract, subcontract, or project number; project title, if available; PI/PD or project lead; name of Investigator with the FCOI; name of the entity in which the SFI is held; nature of the SFI; value or value range of the financial interest; description of how the financial interest relates to the Covered Research; basis for Vivid's determination that the SFI constitutes an FCOI; key elements of the management plan.	Required before expenditure of funds on a new NIH/PHS award when an FCOI has been identified; within 60 days of identifying any new FCOI during an active NIH/PHS award or covered contract; and within 60 days of identifying an FCOI for a new Investigator joining an active Covered Research project. For NIH grants and cooperative agreements, Vivid will submit through the NIH eRA Commons FCOI Module. For PHS research contracts, Vivid will submit to the PHS Awarding Component and, as applicable, the Contracting Officer, Contracting Officer's Representative, or other designated contract official. For other federal contracts or subcontracts, Vivid will submit as required by the solicitation, award, prime contract, subcontract, agency guidance, or flow-down terms.
Annual FCOI Report	Status of the FCOI, including whether it is still being managed or no longer exists; any changes to the management plan; confirmation of continued management, if applicable; any additional information required by the sponsor, PHS Awarding Component, Contracting Officer, prime recipient, or award terms.	Required annually for the duration of an NIH award, including extensions when required, at the same time as the RPPR, multi-year progress report, continuation report, or other required sponsor report. For PHS research contracts and other covered contracts, Vivid will submit annual or continuing FCOI reports when and as required by the contract, PHS Awarding Component, Contracting Officer, prime recipient, or applicable flow-down terms.
Revised FCOI Report	Updates to a previously submitted FCOI report, including revised management actions, new information discovered during review, changes to the relationship between the SFI and Covered Research, changes to the management plan, or other corrections or updates required by the sponsor or contract terms.	Required when Vivid determines that a previously submitted FCOI report must be revised, including after retrospective review, discovery of new information, modification of a management plan, or when required by NIH, PHS, another federal sponsor, a PHS Awarding Component, Contracting Officer, prime recipient, or applicable flow-down terms. Vivid will submit through the same route used for the original FCOI report unless another route is required.

Mitigation Report	Project number; project title; PI/PD or project lead; name of Investigator with the FCOI; name of the entity in which the SFI is held; reason for retrospective review; detailed methodology used for the review; findings; conclusions; description of the impact of any bias on the Covered Research; corrective actions taken or planned to eliminate or mitigate the effect of bias.	Required after retrospective review when Vivid determines that bias occurred in the design, conduct, or reporting of Covered Research, or when otherwise required by NIH, PHS, another federal sponsor, a PHS Awarding Component, Contracting Officer, prime recipient, or applicable flow-down terms. For NIH grants and cooperative agreements, Vivid will submit through the NIH eRA Commons FCOI Module when required. For PHS research contracts, Vivid will submit to the PHS Awarding Component and, as applicable, the Contracting Officer, Contracting Officer's Representative, or other designated contract official.

11. Training Requirements for Investigators

Each Investigator must complete FCOI training before engaging in Covered Research, at least once every four years, and promptly when required by this Policy.

Training must also be completed promptly when:

- Vivid revises this Policy or related procedures in a way that affects Investigator responsibilities;
- An Investigator is new to Covered Research;
- Vivid determines that an Investigator has not complied with this Policy or with an FCOI management plan.

For PHS/NIH-funded Covered Research, Vivid requires Investigators to complete the NIH FCOI Training Tutorial or another training resource approved by the Designated Official.

Investigators must provide a copy of the completion certificate or other training documentation to the Designated Official.

Vivid will retain training documentation for audit and compliance purposes.

12. Noncompliance and Corrective Action

Noncompliance includes but is not limited to:

- Failure to disclose an SFI;
- Late, incomplete, inaccurate, or misleading disclosure;
- Failure by Vivid to review or manage an FCOI in a timely manner;
- Failure by an Investigator to comply with a management plan;
- Failure by a subrecipient, subcontractor, consultant, or collaborator to comply with applicable FCOI obligations;
- Bias or apparent bias in the design, conduct, or reporting of Covered Research related to an unmanaged or unreported FCOI.

If Vivid identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the Designated Official will, within 60 days:

- Review the SFI;
- Determine whether the SFI is related to Covered Research;
- Determine whether the SFI constitutes an FCOI;
- Implement an interim management plan if an FCOI exists;
- Submit any required FCOI report.

If Vivid determines that an FCOI was not identified or managed in a timely manner, or that an Investigator failed to comply with a management plan, Vivid will complete and document a retrospective review within 120 days of determining noncompliance.

The retrospective review will determine whether the Covered Research, or any portion of it, was biased in design, conduct, or reporting.

The retrospective review documentation will include, as applicable:

- Project number;
- Project title;
- Principal Investigator or Project Director;
- Name of Investigator with the FCOI;
- Name of the entity in which the SFI is held;
- Reason for retrospective review;
- Detailed methodology used for review;
- Findings;
- Conclusions;
- Corrective actions taken or planned.

If bias is found, Vivid will promptly notify the applicable federal sponsor, PHS/NIH awarding component, contracting officer, prime recipient, or other required party and will submit a mitigation report when required.

The mitigation report will describe the impact of the bias on the research and the actions taken or planned to eliminate or mitigate the effect of the bias.

Depending on the circumstances, Vivid may impose interim measures on the Investigator's participation in Covered Research pending completion of the retrospective review.

13. Clinical Research

If HHS, NIH, PHS, another federal sponsor, or Vivid determines that a clinical research project evaluating the safety or effectiveness of a drug, biologic, diagnostic, device, treatment, intervention, or similar technology was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, Vivid will require appropriate corrective action.

Corrective action may include requiring the Investigator to disclose the FCOI in each public presentation of the research results and to request an addendum to previously published presentations or publications.

For human-subjects research, Vivid may require disclosure of the FCOI to the IRB, study participants, clinical collaborators, data-safety monitoring board, or other oversight bodies.

14. Subrecipients, Subcontractors, Consultants, and Collaborators

Vivid will take reasonable steps to ensure that subrecipient, subcontractor, consultant, collaborator, and contractor Investigators comply with applicable FCOI requirements.

Before engaging a subrecipient or subcontractor to perform a substantive portion of Covered Research, Vivid will include written terms specifying whether:

- The subrecipient's or subcontractor's compliant FCOI policy will apply; or
- Vivid's FCOI Policy will apply.

If the subrecipient's or subcontractor's policy applies, the agreement must require the subrecipient or subcontractor to certify that its policy complies with applicable federal FCOI requirements.

The agreement must require the subrecipient or subcontractor to report identified FCOIs to Vivid in sufficient time for Vivid to meet sponsor reporting deadlines.

For PHS/NIH-funded work, Vivid will generally require subrecipients and subcontractors to report identified FCOIs to Vivid within 50 to 55 days of identification, unless a shorter period is required.

If the subrecipient or subcontractor cannot certify that it has a compliant FCOI policy, Vivid's Policy will apply to the subrecipient or subcontractor Investigators.

When Vivid's Policy applies, subrecipient or subcontractor Investigators must disclose SFIs to Vivid in sufficient time for Vivid to review, manage, and report any FCOIs before expenditure of funds or within applicable reporting deadlines.

Vivid may require similar FCOI terms from consultants, collaborators, vendors, and contractors whose roles meet the definition of Investigator or whose work could affect the design, conduct, or reporting of Covered Research.

Vivid may require subrecipients, subcontractors, consultants, and collaborators to provide copies of their FCOI policy, training certifications, SFI disclosure certifications, FCOI determinations, management plans, and related records as needed for Vivid to meet sponsor, audit, or reporting obligations.

15. Records Retention

Vivid will maintain records of:

- Investigator SFI disclosures;

- Vivid's review of SFI disclosures;
- Determinations of relatedness and FCOI status;
- Management plans;
- Investigator agreements to management plans;
- Monitoring activities;
- Public-access requests and responses;
- FCOI reports;
- Retrospective reviews;
- Mitigation reports;
- Training records;
- Subrecipient, subcontractor, consultant, and collaborator FCOI certifications and reports;
- Other actions taken under this Policy.

Records will be retained for at least three years from the date the final expenditure report is submitted for the applicable award.

For contracts, subcontracts, and other procurement instruments, records will be retained for at least three years after final payment, final closeout, or the period required by the contract, whichever is longer.

Records will be retained longer when required by federal regulations, award terms, audit, litigation hold, dispute, investigation, agency request, or other applicable requirement.

Vivid will make records relating to Investigator financial-interest disclosures and Vivid's review of and response to such disclosures available promptly upon request to HHS, NIH, PHS, another federal sponsor, a Contracting Officer, a prime recipient, or other authorized oversight authority, as applicable.

16. Enforcement

Compliance with this Policy is a condition of participation in Covered Research.

Investigators who fail to comply with this Policy or a management plan may be subject to corrective or disciplinary action, including:

- Required supplemental training;
- Written warning or notice of noncompliance;
- Increased monitoring;
- Modification of research role;
- Recusal from decisions or analyses;
- Restriction on use of research funds;
- Removal from all or part of Covered Research;
- Suspension of participation in proposals or awards;
- Termination of employment, consulting engagement, contract, subcontract, or collaboration;
- Notification to federal sponsors, prime recipients, contracting officers, or other required parties;
- Other remedies permitted by law, contract, or Company policy.

Vivid may also take action against subrecipients, subcontractors, consultants, collaborators, or vendors that fail to comply with applicable FCOI requirements.

17. Useful FCOI and NIH Resources

The following resources may be useful for Vivid personnel, Investigators, subrecipients, subcontractors, consultants, collaborators, and compliance reviewers:

- NIH Financial Conflict of Interest Overview
  https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi
- NIH FCOI Training
  https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training
- NIH FCOI Training Tutorial
  https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm
- 42 CFR Part 50 Subpart F — Promoting Objectivity in Research
  https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F
- 45 CFR Part 94 — Responsible Prospective Contractors
  https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94
- eRA Commons FCOI Module Information
  https://www.era.nih.gov/help-tutorials/fcoi
- eRA Commons FCOI User Guide
  https://www.era.nih.gov/files/fcoi_user_guide.pdf
- NIH Welcome Wagon Letter — Information for New Recipient Organizations
  https://grants.nih.gov/policy-and-compliance/welcome-wagon
- NIH FCOI inquiries: fcoicompliance@mail.nih.gov

18. Point of Contact

Questions about this Policy, requests for public FCOI information, and Significant Financial Interest disclosures should be directed to:

Designated Official for FCOI
Sepehr Kiani
Chief Executive Officer
Vivid BioInnovations, PBC
fcoi@vivid-bio.com

If the Designated Official has a disclosed Significant Financial Interest that requires review under this Policy, Vivid will appoint an alternate Designated Official for that matter, such as another officer, board designee, qualified outside advisor, or legal counsel. The alternate Designated Official will perform the review, relatedness determination, FCOI determination, management-plan approval, and any required reporting for that matter.