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1.0 PURPOSE

- 1.1 The purpose of this procedure is to document a methodology and process by which any financial conflicts of interest (FCOI) related to Public Health Service (PHS) funded research will be identified, reviewed, monitored, and disclosed.

2.0 SCOPE

- 2.1 This procedure applies to all employees, consultants, scientific advisors, research collaborators who are listed as “Key/Senior Personnel” on grant applications submitted to any institution within the National Institutes of Health (NIH), the National Science Foundation (NSF), the United States Department of Defense (DoD), or any other federally funded grant making institution as well as their spouse and/or domestic partner, as well as their dependent children.

3.0 APPLICABLE FORMS OR DOCUMENTS

- 3.1 Financial Interests Disclosure Form – 97023
 3.2 Financial Conflict of Interest Frequently Asked Questions (FAQ) – 97021
 3.3 RevBio Employee Handbook – 97000

4.0 DEFINITIONS

- 4.1 Financial Conflict of Interest: A financial conflict of interest (also referred to as a conflict of interest) exists when the recipient's designated officials reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS funded research.
- 4.2 COI Committee: The COI Committee is the group of designated officials who determine if a FCOI exists. These designated officials currently consist of the Company’s Executive Management Team consisting of the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Scientific Officer (CSO).

5.0 RESPONSIBILITIES

- 5.1 All employees, consultants, scientific advisors, research collaborators who are listed as “Key/Senior Personnel” on all of the Company’s grant applications must comply with this FCOI policy.
- 5.2 The Company’s Chief Operating Officer (COO) is responsible for soliciting disclosures from the Company’s employees, consultants, scientific advisors, research collaborators through the submission of the Financial Interests Disclosure Form (97023).
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- 5.3 Chief Executive Officer, Chief Financial Officer, and Chief Scientific Officer are responsible for reviewing Financial Interests Disclosure Forms as the COI Committee.
- 5.4 The Company’s Director of Quality is responsible for maintaining all FCOI-related records, including training records and Financial Interests Disclosure Forms, as part of the Company’s quality management system.
- 5.5 The COI Committee is responsible for reviewing financial disclosures of the individuals who are listed as “Key/Senior Personnel” on the Company’s grant applications and managing any financial conflicts of interest should they arise before and during the conduct of PHS funded research projects.

6.0 GENERAL

6.1 Disclosure Requirements

- 6.1.1 All outside activities, relationships, interests, and investments held by employees or their spouse, domestic partner, and/or dependent children must be disclosed so that the Company can adequately review if any of those activities, relationships, interests, and investments: (a) compromise the integrity or objectivity of research, sponsored projects, or technology transfer agreements; or (b) bias the design, conduct, or reporting of the research.
- 6.1.2 Prior to the submission of a grant application for PHS funding, all employees, research collaborators, advisors and individuals listed as “Key/Senior Personnel” on grant applications must fill out form 97023 entitled “Financial Interests Disclosure Form.”
- 6.1.3 If any individuals are unsure of particular activities, relationships, interest, and investments held by employees or their spouse, domestic partner, and/or dependent children, they may review the document entitled “Financial Conflict of Interest Frequently Asked Questions (FAQ)” (97021) and/or speak to an Executive of the Company for further details.
- 6.1.4 Disclosure is required at least annually and within 30 days of any change to an existing outside activity, relationship, or interest.

6.2 Subrecipient Requirements

- 6.2.1 Subrecipients of Public Health Service (PHS) funded research, such as research collaborators, academic research partners, and scientific
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advisors who are not full time employees of the Company must also follow this FCOI policy and must disclose any outside activities, relationships, interests, and investments held by employees or their spouse, domestic partner, and/or dependent children that could be deemed a financial conflict of interest by completing form 97023 entitled “Financial Interests Disclosure Form.”

- 6.2.2 If applicable, a subrecipient may alternatively provide a certification that they are in compliance with their own Institution’s FCOI policies and procedures and that such Institution’s policy complies with PHS requirements [[42 CFR 50.604\(c\)\(1\)\(i\)-\(iii\)](#)].

6.3 Review Process

- 6.3.1 The COI Committee has the authority and responsibility to review and manage perceived or actual conflicts of interest.
- 6.3.2 Research, sponsored projects, and technology transfer agreements will not be accepted if the outside activity creates a conflict that cannot be satisfactorily managed with appropriate administrative oversight.

6.4 Determinations

- 6.4.1 When potential conflicts of interest involving PHS funded research, is identified by the COI Committee, the committees may require additional information, as necessary, in order to determine whether the outside activity, relationship, or interest could directly and significantly affect the design, conduct, or reporting of the research.
 - 6.4.2 If a conflict of interest exists, the COI Committee may manage the conflict of interest by imposing conditions and stipulations, including: (a) the public disclosure of the conflict of interest; (b) monitoring the research or requiring that the research is managed by independent reviewers; (c) restricting the role or responsibility of the conflicted individual in the conduct of the research; (d) requiring additional contractual agreements; and/or (e) modifying the research plan.
 - 6.4.3 Alternatively, the COI Committee may require the elimination of the conflict of interest by: (a) disqualifying the conflicted individual from participating in all or a portion of the research; (b) requiring the divestiture of the interest; or (c) requiring the severing of the relationship that creates the conflict of interest.
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6.5 Appeal Process

- 6.5.1 An individual may appeal a COI Committee decision in writing within 30 days of the date of the committee’s notification of that decision.
- 6.5.2 Within 30 days of receipt of a written appeal, the COI Committee will decide the appeal.
- 6.5.3 The COI Committee may impose conditions on the arrangement before approval of the appeal.

6.6 Enforcement and Remedies for Noncompliance

- 6.6.1 The COI Committee will work cooperatively with the Company’s employees, consultants, scientific advisors, and research collaborators to resolve any minor noncompliance.
- 6.6.2 Flagrant or repeated noncompliance (after notice) will be handled through the disciplinary procedures outlined in the Company’s Employee Handbook (97000), or other contractual arrangements. In the event that the COI Committee determines that an employee’s undisclosed outside activity, relationship, or interest has resulted in bias to the design, conduct, or reporting of research, the Company will promptly report the noncompliance to research sponsors and/or funding agencies, as required.
- 6.6.3 False, fictitious, or fraudulent statements or claims (including intentional omissions) in violation of this policy may result in employee termination for cause, or other disciplinary actions and penalties, in accordance with the Company’s documented employment practices.
- 6.6.4 If a FCOI policy infraction is discovered, a retrospective review of all related FCOI disclosures will be performed within 120 days of Company’s identification of noncompliance with this policy.
- 6.6.5 If a FCOI policy infraction is discovered in a PHS-funded clinical research program to evaluate the safety or effectiveness of a drug or device which was not managed or reported by the Company to the NIH, the Company must: (a) disclose the FCOI in each public presentation of the research, and (b) request an addendum to any previously published presentation.

6.7 Reporting Requirements to the National Institutes of Health (NIH)

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6.7.1 The Company will submit FCOI reports to the NIH in accordance with the following events: (a) prior to the expenditure of any PHS funding; (b) within 60 days of a new investigator starts participating in the research, (c) within 60 days of a new, or newly identified, FCOI for an existing investigator, (c) immediately following a retrospective review to update a previously submitted report, if applicable; and (d) an FCOI report not less than annually which should be submitted at the same time as the annual progress report.

6.7.2 Any FCOI report required under [42 CFR 50.605](#) shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following: (i) Project number; (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used; (iii) Name of the Investigator with the financial conflict of interest; (iv) Name of the entity with which the Investigator has a financial conflict of interest; (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$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; (vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and (viii) A description of the key elements of the Institution's management plan, including: (A) Role and principal duties of the conflicted Investigator in the research project; (B) Conditions of the management plan; (C) How the management plan is designed to safeguard objectivity in the research project; (D) Confirmation of the Investigator's agreement to the management plan; (E) How the management plan will be monitored to ensure Investigator compliance; and (F) Other information as needed.

6.8 Training Requirements

6.8.1 Training on the Company's FCOI policy and how to complete the Financial Interests Disclosure Form (97023) must be conducted initially for each new employee, research collaborator, advisor or individual listed as "Key/Senior Personnel" before engaging in any PSH-funded research activity.

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- 6.8.2 If the Company revises its FCOI policy, individuals listed as “Key/Senior Personnel” on the Company’s grant application must be retrained immediately following the approval of the policy changes.
- 6.8.3 If an individual is not in compliance with the Company’s FCOI policy, they must be retrained immediately after their noncompliance is identified.
- 6.8.4 All individuals involved in PHS-funded research should be retrained on the Company’s FCOI policy not more than 4 years since they were last trained on the Company’s FCOI policy.

6.9 Maintenance of Records

- 6.9.1 All FCOI-related records, including training records and Financial Interests Disclosure Forms, must be maintained for at least 3 years in accordance with [45 CFR § 75.361](#).
- 6.9.2 All FCOI records will be maintained as part of the Company’s quality management system (QMS).

6.10 Public Accessibility Requirements

- 6.10.1 The Company’s Financial Conflict of Interest Policy must be posted on the Company’s public website.
 - 6.10.2 Prior to the Company’s expenditure of any funds under a NIH-funded research project, the Company shall ensure public accessibility, via a publicly accessible website or a written response within five business days of a request, of information concerning any significant financial interest disclosed to the Company that meets the following three criteria: (a) the Company has determined that a FCOI exists, (b) that the FCOI related to a PHS funded research project, and (c) that the FCOI is still held by the senior/key personnel for a NIH-funded research project.
 - 6.10.3 The information that the Institution makes available via a publicly accessible website or written response shall include, at a minimum, the following: (a) the investigator’s name; (b) the investigator’s title and role with respect to the research project; (c) the name of the entity in which the significant financial interest is held; (d) the nature of the significant financial interest; and (e) the approximate dollar value of the conflict of interest using the following dollar ranges: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of
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\$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.

6.10.4 FCOI must be updated at least annually, and any newly identified FCOI should be updated within 60 days.

6.10.5 Publicly available FCOI information should remain available for three years from the date the information was most recently updated.

7.0 METRICS

7.1 None.

8.0 REFERENCES

- 8.1 Disclosure Requirements – [42 CFR 50.603](#) and [42 CFR 50.604\(e\)\(1\)-\(3\)](#)
- 8.2 Subrecipient Requirements – [42 CFR 50.604\(c\)](#) and [42 CFR 50.604\(c\)\(1\)\(i\)-\(iii\)](#)
- 8.3 Institutional Representative – [42 CFR 50.604\(d\)](#)
- 8.4 Enforcement Mechanisms – [42 CFR 50.604\(j\)](#)
- 8.5 Retrospective Reviews – [42 CFR 50.605\(a\)\(3\)](#)
- 8.6 Clinical Research Requirements – [42 CFR 50.606\(c\)](#)
- 8.7 Reporting Requirements to NIH – [42 CFR 50.604\(h\)](#) and [42 CFR 50.605\(b\)](#)
- 8.8 PHS Training Requirements – [42 CFR 50.604\(b\)](#)
- 8.9 Maintenance of Records – [42 CFR 50.604\(i\)](#)
- 8.10 Public Access Requirements – [42 CFR 50.604\(a\)](#) (see also [NIH GPS 4.1.10](#)) and [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#)

9.0 REVISION

Revision	Change Request #	Description	Originator
AA	00247	Initial Release	Gallen