

Financial Conflict of Interest Policy

Purpose: This Financial Conflict of Interest Policy (“**FCOI Policy**”) has been established to prevent bias resulting from financial conflicts of interest as defined in the Regulation (an “**FCOI**”) in the design, conduct and reporting of research conducted by Primrose Bio, Inc. (“**Primrose**”) that is funded under Public Health Service (“**PHS**”) grants in compliance with 42 CFR Part 50 Subpart F. This FCOI Policy applies to all Primrose personnel (regardless of title) who are responsible for the design, conduct and reporting of research funded by the PHS (each, an “**Investigator**”). Regulations governing FCOI can be found under 42 CFR Part 50 Subpart F (the “**Regulation**”).

Investigators must disclose any actual or anticipated significant financial interest that reasonably appears to be (or is anticipated to be) related to the Investigator’s responsibilities with respect to PHS funded research as defined in the Regulation (an “**SFI**”) and otherwise comply with this FCOI Policy as indicated. A SFI may exist if the Investigator, or the Investigators’ spouse and dependents hold a significant financial interest in the following:

- Ownership of stock, equity, or other financial interest in a company/entity which has products that might be used in or benefit from or harmed by the results of the project
- Employment, office or directorship in any company/entity involved or potentially involved
- Personal compensation from any company/entity involved or potentially involved
- Consulting/advisory arrangements with any company/entity involved or potentially involved
- Involvement with grants, contracts, research, training or other support (restricted or unrestricted) from any company/entity involved or potentially involved
- Travel grants to attend educational symposia provided by any company/entity involved or potentially involved
- Intellectual property rights (i.e., copyright, patent, trademark) related to the activities of the project
- Relationship with a company/entity that may affect academic advancement or status

Further details on what constitutes an SFI or an FCOI may be found in the applicable regulations at https://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm or by consulting with the IO.

Disclosure, Training, Review and Monitoring.

All those who may serve as an Investigator will be provided a copy of this policy and will undergo FCOI training at least once every 4 years or, in any event, prior to engaging in research related to any PHS-funded grant, and will immediately undergo FCOI training if this FCOI Policy is revised in a manner that affects Investigators, the Investigator is new to Primrose, or the Investigator is determined to be not in compliance with this FCOI Policy.

If an Investigator believes that he/she may have SFI, the Investigator must provide the following information in writing and submit it to Simon Latimer, Primrose Chief Financial Officer, who is the designated Institutional Official (IO) for this FCOI Policy.

- Name of the individual(s)
- Name of the entity with which the Investigator(s) has or may have a financial conflict of interest
- The nature of the significant financial interest
- The value of the financial interest
- Description of how the financial interest relates to the research project

The above information must be disclosed prior to the funding of a project/grant and should be disclosed prior to beginning funding solicitation.

The IO will review any such disclosure prior to the research start date to determine whether there is an SFI as described in 42 CFR Part 50 Subpart F Section 50.603(1), and whether the SFI is related to the PHS funded research and ultimately make a determination as to whether an FCOI exists. If the IO determines the existence of an FCOI, the IO will implement appropriate measures to restrict or eliminate the FCOI. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- 1) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- 2) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 3) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- 4) Modification of the research plan;
- 5) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- 6) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- 7) Severance of relationships that create financial conflicts.

If a new SFI develops during the research period, or if the Investigator did not previously disclose an existing SFI prior to the research start date, the Investigator must immediately submit a disclosure as described above and the IO must, promptly evaluate the SFI and, if determined to be an FCOI, within 60 days of such determination, develop a management plan to address the FCOI. The IO must execute the plan, including monitoring compliance with the plan until completion of the project.

The IO will periodically monitor Investigator compliance under this policy throughout the research period. Questions or concerns regarding this policy should be directed to the IO.

Reporting Requirements.

If an Investigator is found to have an FCOI, the IO will submit an FCOI report to the PHS agency or Awarding Component prior to expending funds for the PHS research. If an FCOI is first discovered during the research period, the IO will submit an FCOI report and a management plan, as described above, to the PHS Awarding Component within 60 days of identifying the FCOI. The FCOI report will include:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the financial conflict of interest;
4. Name of the entity with which the Investigator has a financial conflict of interest;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. 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;
7. A description of how the financial interest relates to the PHS-funded research and the basis for Primrose's determination that the financial interest conflicts with such research; and

8. A description of the key elements of the Primrose'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.

If an FCOI report is submitted, the IO will provide an annual FCOI report to the PHS Awarding Component that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists.

If an FCOI is not identified or managed in a timely manner, the IO will complete a retrospective review of the Investigator's activities and the PHS funded research within 120 days of the discovery of noncompliance to determine whether the design, conduct, or reporting of the PHS funded research has been tainted by bias during the period of noncompliance. The review will be documented with the following information:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

If bias is found, the IO will notify the PHS Awarding Component and submit a mitigation report that contains the information found during the review and that complies with the Regulation.

Maintenance of Records.

FCOI disclosures and reports will be maintained for a period of 3 years after the end of the research period, or from other dates as specified in 45 CFR 75.361 where applicable.

Enforcement, Remedies and Noncompliance.

Violations of this policy will be fully investigated. Individual(s) found in violation of this policy will be removed from the project and will be subject to disciplinary action including but not limited to administrative leave, and/or termination.

Under certain circumstances, if the HHS determines that an FCOI resulted in bias in the PHS funded research, the Investigator with the FCOI may be required to disclose the FCOI at each public presentation of the results.

Subrecipient Requirements.

FCOI regulations apply to subcontractors used in any PHS funded research. Subcontractors must have their own compliant FCOI policy or use Primrose's policy if none exists. The contracting agreement should certify that the subcontractor shall comply with the Regulation. The agreement should also specify the time period to submit disclosure forms and FCOI reports to Primrose.

Public Accessibility.

Primrose will make disclosures relating to FCOI's available as required by the Regulation.

A copy of this policy can be found on Primrose's website at www.primrosebio.com. FCOI requests may be submitted in writing to Primrose Bio Inc. at 10790 Roselle St, San Diego, CA 92121.

If an SFI was 1) disclosed and is still held by the Investigator, 2) the SFI is related to PHS funded research, and 3) the SFI is determined to be a financial conflict of interest, Primrose will issue a written response to FCOI requests within 5 days of the written request. The information will include 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 (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.

Primrose will include in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

[End of FCOI Policy]

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