

Cloudbreak Therapeutics

Financial conflicts of interest (FCOI) in federally sponsored research activities

Description:

The responsibility of key personnel to disclose significant financial conflicts of interest (FCOI) when conducting research sponsored by the Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS), (i.e. CDC, NIH, HRSA, AHRQ, ATSDR, etc.)

Purpose:

To promote the objectivity in research by establishing standards that preserve the integrity of research, protect the rights and safety of research subjects, and prevent bias in the design, conduct and reporting of research funded under PHS grants or cooperative agreements that may result from any financial conflict of interest by investigators or key personnel.

Applicability:

All programs that apply for, or that receive, DHHS PHS funding through a grant or cooperative agreement for the purposes of research, and to each investigator and key personnel who participate, or are participating, in such research.

Failure to Comply:

Failure to comply with this policy may lead to disciplinary or corrective action including removal from research project, suspending or terminating project, and other remedies that may be legally available.

Policy

1. Investigator and Key personnel Responsibility

- a. Any Cloudbreak employee that serves as an investigator or key personnel and who is planning to participate in PHS-funded research must disclose to the FCOI Officer any significant financial interest (and those of the investigator's or key personnel's spouse and dependent children) no later than the time of application for PHS-funded research using the FCOI form provided by the FCOI Officer.
- b. Investigators or key personnel who are currently participating in PHS-funded research must disclose any significant financial interest (and those of the investigator's or key personnel's spouse and dependent children) no later than January 31, 2021, and every year thereafter, using the prescribed FCOI form.
- c. Annual FCOI reports submitted to the FCOI Officer shall include any information that was not previously disclosed.

d. Within 30 days of discovering or acquiring a significant financial interest, an investigator or key personnel shall submit an updated FCOI form to the FCOI Officer.

2. Institution Responsibility

a. Cloudbreak shall update and enforce this written policy in accordance with 42 CFR 50, Subpart F and will make the policy available on the company website.

b. Cloudbreak will inform each investigator and key personnel about the following:

A. Information about this policy and the corresponding federal regulations;

B. Responsibility of an investigator and key personnel to disclose any significant financial interest to the FCOI Officer;

C. Mandatory FCOI training requirements including:

i. Completion of initial FCOI training for existing and new staff;

ii. Completion of FCOI training every four years;

iii. Additional training if an investigator or key personnel is not in compliance with this policy; and

iv. Updated information on any revisions to this policy that affects the responsibilities of the investigator or key personnel.

c. If Cloudbreak subcontracts elements of the PHS-funded research to an outside entity, each subrecipient investigator or key personnel shall be required to comply with this policy or provide documentation that the subrecipient institution is in compliance with 42 CFR 50, Subpart F.

A. A written agreement with the subrecipient must identify whether the subrecipient investigator and key personnel will comply with the FCOI provisions of the subrecipient institution or Cloudbreak;

B. If the subrecipient will comply with his or her institutional FCOI policy, the written agreement must specify that any FCOI disclosures reported to the subrecipient's institution must be reported to the FCOI Officer of Cloudbreak within 30 days.

C. Cloudbreak will report subrecipient significant financial interest to the PHS prior to the expenditure of any funds or within 60 days of receiving subrecipient disclosure of significant financial interest.

d. Cloudbreak will identify an official to seek and review disclosures of significant financial interest from each investigator or key personnel who is planning to participate in, or is participating in, PHS-funded research. This official will serve as the FCOI Officer.

e. All records relating to disclosures of financial interest, including any review and actions taken by Cloudbreak, will be maintained by the FCOI Officer for a period of five years from the date the final grant expenditure report is submitted to the PHS.

3. Reviewing Disclosures

a. Within 60 days of receipt of a significant financial disclosure, the FCOI Officer shall review the report to determine whether an investigator's or key personnel's significant financial interest is related to PHS-funded research, and if so, whether the significant financial interest is a financial conflict of interest.

b. A significant financial interest is related to PHS-funded research if the significant financial interest:

A. could be affected by the PHS-funded research;

B. is in an entity whose financial interest could be affected by the research; or

C. could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

c. In reviewing a disclosure, the FCOI Officer may seek additional information from the investigator or key personnel in determining whether the disclosure is a significant financial interest that relates to the PHS-funded research.

d. If the FCOI Officer determines that a significant financial interest exists that is related to PHS-funded research, the Officer shall identify actions, if any, that must be taken by the investigator or key personnel to manage the financial conflict of interest.

A. Actions to manage the financial conflict of interest may include but are not limited to:

i. Public disclosure of the financial conflict of interest when submitting articles for publication or presenting a paper about the research;

ii. Informing clinical sites directly about the financial conflict of interest;

iii. Appointment of an independent monitor that is capable of taking appropriate measures to protect the design, conduct and reporting of the research against bias resulting from the financial conflict of interest;

iv. Modifying the research protocol;

v. Changing the staff or staff responsibilities in all or part of the research;

vi. Disqualifying staff from participating in the research;

vii. Reducing or eliminating the financial interest; or

viii. Severing relationships that create the financial conflict.

B. The actions required to manage the financial conflict of interest shall be identified in a management plan and compliance with the management plan shall be monitored by the FCOI Officer or designee on an ongoing basis until completion of the PHS-funded research project.

C. If the actions required to manage the conflict result in revisions to the research protocol or disclosing information to a research subject, Investigator's must submit revised material to the Public Health IRB for review and approval.

D. Depending on the nature of the significant financial interest, the FCOI Officer may determine that additional interim measures are necessary with regard to the investigator's or key personnel's participation in the research between the date of disclosure and the completion of the FCOI Officer review.

e. If the FCOI Officer identifies that a significant financial interest exists that was either not disclosed or not disclosed in a timely manner by an investigator or key personnel, the FCOI Officer shall follow the same procedures as outlined in this section.

f. If a financial conflict of interest is not identified or managed in a timely manner including failure by the investigator or key personnel to report a significant financial interest that constitutes a FCOI; failure of Cloudbreak to review or manage a FCOI, or failure by the investigator or key personnel to comply with a management plan, the FCOI Officer shall:

A. Within 120 days, complete a retrospective review of the research including the investigator or key personnel's activities to determine whether the research conducted during the time period of the noncompliance was biased in design, conduct or reporting of such research.

B. The retrospective review will be documented and include the following elements:

i. Project number;

ii. Project title;

iii. Name(s) of project director or principal investigator;

iv. Name of the investigator or key personnel with the FCOI;

v. Name of the entity with which the investigator or key personnel has a FCOI;

vi. Reason(s) for the retrospective review;

vii. Detailed methodology of the review process, composition of the review panel and the documents reviewed;

viii. Findings of the review; and

ix. Conclusions of the review.

C. Based on the findings of the retrospective review, if appropriate, the FCOI Officer shall update any previously submitted FCOI reports, specifying actions taken to manage the FCOI.

D. If the retrospective review determines that the research was biased, the FCOI Officer will promptly notify the PHS organizational unit that funds the research and submit a mitigation report. The mitigation report will include, but is not limited to, the following information:

i. All information described in (3)(f)(B);

ii. A description of the impact of the bias on the research project;

iii. Cloudbreak plan of action or actions taken to eliminate or mitigate the effects of the bias.

4. Reporting FCOI to DHHS, Public Health Service

a. The FCOI Officer or designee shall provide initial and ongoing financial conflict of interest reports to the DHHS, PHS. Reports shall be issued no less than once per year for the duration of the project period.

A. The annual report for FCOI previously reported where the activity is an ongoing PHS-funded research project shall address the status of the FCOI and any changes to the management plan for the duration of the project.

B. The annual report shall also specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

b. Prior to the expenditure of any funds under a PHS-funded research project, the FCOI Officer shall provide the organizational unit of the PHS that funds the research an FCOI report regarding any investigator's or key personnel's significant financial interest determined to be conflicting and that includes information about the management plan.

c. In the event that Cloudbreak identifies a FCOI and eliminates it prior to expending any PHS funds, the FCOI Officer or designee shall not submit an FCOI report to the PHS.

d. Subsequent to any initial FCOI reports during an ongoing PHS-funded research project, any new disclosures that are determined conflicting shall be reported within 60 days to the PHS in accordance with section (3).

e. FCOI reports submitted to the organization unit of the PHS that funds the research shall include sufficient information to allow the PHS to understand the nature and extent of the FCOI and assess the appropriateness of Cloudbreak's management plan. Information in the report shall include, but not limited to, the following:

- A. Project number;
- B. Investigator or key personnel contact;
- C. Name of investigator or key personnel with the financial conflict;
- D. Name of the entity with which the individual has the conflict;
- E. Nature of the financial interest;
- F. Value of the financial interest;
- G. Description of how the financial interest relates to the PHS-funded research and basis for the determination that the financial interest conflicts with the research;
- H. Description of the key elements of the management plan including:
 - i. Role and principal duties of the conflicted investigator or key personnel;
 - ii. Conditions of the management plan;
 - iii. How the management plan is designed to safeguard objectivity in the research;
 - iv. Confirmation of the Investigator's agreement to the management plan;
 - v. How the management plan is monitored to ensure compliance; and
 - vi. Additional information as needed.

5. Remedies

- a. If an investigator or key personnel fail to comply with this policy or a FCOI management plan appears to have biased the design, conduct or reporting of the PHS-funded research, the FCOI Officer or designee shall promptly notify the organizational unit of the PHS that funds the research any corrective action taken, or will be taken.
- b. The PHS will consider the information submitted and may require or recommend additional action.
- c. Cloudbreak will submit, or permit on site review of, all records pertinent to the review of a financial disclosure or FCOI to the PHS. The PHS may determine on the basis of any

review that the FCOI will bias the objectivity of the research to such an extent that further corrective action is needed. This may include the imposition of special award conditions or suspension of funding or other enforcement action.

6. Public Accessibility to FCOI Information

a. Prior to the expenditure of any funds under a PHS-funded research project, the FCOI Officer or designee must respond in writing within five days to a requestor for information concerning any significant financial interest disclosures that meet the following criteria:

- A. Any significant financial interest disclosed and is still held by the investigator or key personnel;
- B. The significant financial interest was determined to be related to the PHS-funded research project; and
- C. The significant financial interest was determined to be an FCOI.

b. The information released to the requestor must include the following:

- A. Investigator or key personnel name and title;
- B. The role of the investigator or key personnel in the research project;
- C. The name of the entity in which the significant financial interest is held; and
- D. The nature of the significant financial interest and the approximate dollar range of the significant financial interest; or
- E. A statement that the value cannot be readily determined through reference to public prices or other reasonable measures.
- F. The written response will note that the information provided is current as of the date of the correspondence, that FCOI information is updated biannually or within 60 days of identification of a new FCOI. Requestor would have to make subsequent request to receive information.

c. Cloudbreak may choose to post FCOI disclosures on its website and if posted will update information every six months.

- A. Additional financial interest not previously disclosed or disclosure of financial interest of an investigator or key personnel new to a PHS-funded research project where the FCOI Officer has determined that the updated information relates to the PHS-funded research and is considered a FCOI, will be posted to the web within 60 days.

B. If information is posted on the website, the web page will note that the information provided is current as of the date listed and is subject to updates within 60 days of receiving updated information or on a biannual basis.

d. Information concerning significant financial interests that meet the criteria in (5)(a) shall remain available for public information requests for at least three years from the date that the information was most recently updated.

References:

42 CFR 50 – Policies of General Applicability

45 CFR 94 – Responsible Prospective Contractors

DHS/OHA Policy: Conflict of Interest

Contact:

Name: Rong Yang; Phone: (949) 394-3086; Email: yang_rong@cloudbreaktherapeutics.com