Cansera

FINANCIAL CONFLICTS OF INTEREST

A. Purpose and Definition

Cansera, Inc. is dedicated to upholding the public's confidence in the integrity of research supported by the Public Health Service ("PHS"), including the National Institutes of Health ("NIH"). To safeguard this trust, the company is committed to preventing investigator financial conflicts of interest ("FCOI") from influencing any aspect of its publicly funded research. In accordance with Title 42 of the Code of Federal Regulations ("CFR"), Part 50, Subpart F—Responsibility of Applicants for Promoting Objectivity in Research (the "FCOI Regulations")—Cansera, Inc. will ensure objectivity by implementing standards that provide reasonable assurance that the design, conduct, and reporting of PHS-funded research, including NIH grants and cooperative agreements, remain free from bias stemming from investigator financial interests.

This FCOI Policy applies to investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by PHS or NIH. Pursuant to this Policy, all investigators planning to participate or participating in PHS or NIH-funded research are required to disclose to Cansera, Inc. their known significant financial interests (and those of their spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities.

B. Definitions

1. The term "investigator" refers to the project director or principal investigator, as well as any other individual—regardless of title or role—who is responsible for the design, conduct, or reporting of research funded by the PHS, including the NIH, or research proposed for such funding. This may also include collaborators, consultants, or similar contributors.

2. The term "senior/key personnel" refers to the project director or principal investigator, as well as any additional individuals designated as senior or key personnel in the grant application, progress report, or any other submission to the PHS, including the NIH.

3. The term "research" refers to any systematic investigation, study, or experiment conducted to develop or contribute to generalizable knowledge related broadly to public health, including behavioral and social sciences. This definition includes both basic and applied research (such as published articles, books, or book chapters) as well as product development activities (such as creating diagnostic tests or drugs).

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4. The term “institutional responsibilities” refers to the professional duties an investigator performs on behalf of Cansera, Inc. These responsibilities may include research and research consultation, clinical or other professional practice, participation in scholarly activities, membership on institutional committees, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

5. The term “significant financial interest” refers to any financial interest—meaning anything of monetary value, whether or not its exact worth can be determined—held by an investigator, as well as by the investigator’s spouse and dependent children, that reasonably appears to be related to the investigator’s institutional responsibilities.

    a. Privately Held Entities (non–publicly traded), a significant financial interest exists when the total value of any remuneration received from the entity in the preceding twelve months exceeds $5,000, or when the investigator—or the investigator’s spouse or dependent children—holds any equity interest in the entity (such as stock, stock options, or other ownership interests).

    b. Intellectual Property – Intellectual property rights and interests—such as patents and copyrights—must be disclosed when any related income (e.g., royalties) is received. In addition, the filing of any patent application also should be disclosed.

    c. Travel Expenses - Investigators must disclose any reimbursed or sponsored travel—meaning travel paid on behalf of the investigator rather than reimbursed to them—for activities related to their institutional responsibilities if, in the twelve months prior to disclosure, the aggregated value of such travel exceeds $5,000. This requirement does **not** apply to travel funded by a federal, state, or local government agency; an institution of higher education (as defined in 20 USC § 1001(a)); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education. Travel disclosures must include, at minimum, the purpose of the trip, its duration, the sponsor or organizer, and the destination.

6. The term “significant financial interest” **does not include** the following types of financial interests:

    a. Salary or consulting fees paid by Cansera, Inc. to the investigator if the investigator is currently employed or otherwise appointed by Cansera, Inc.

    b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local agency, an institution of higher education, an academic

teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

d. Travel by a PHS or NIH-funded investigator that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

7. "Immediately" shall mean the training is provided or made accessible and the investigators participate in the training expeditiously following the event that triggers the training requirement.

8. "Manage" means taking action to address an FCOI, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

C. Investigator Training Requirements

Cansera's FCOI administrator, or their designee(s), will be responsible for the procedures under this FCOI Policy. Further, the FCOI administrator is responsible for ensuring that each investigator is informed about: (i) this FCOI Policy, (ii) the investigator's responsibilities regarding disclosure of significant financial interests relating to the investigator's institutional responsibilities, and (iii) the FCOI Regulations.

The FCOI administrator shall ensure that each investigator completes training regarding items (i) through (iii) prior to engaging in research related to any PHS or NIH-funded grant or cooperative agreement, immediately upon being hired and at least every four years. Investigators are required to complete the FCOI training module prior to being engaged in PHS or NIH-supported research at least every four years, and immediately under the designated circumstances:

(1) Cansera's FCOI policies change in a manner that affects investigator requirements,
(2) an investigator is new to Cansera, or
(3) Cansera finds an investigator noncompliant with Cansera's FCOI Policy.

The FCOI administrator shall further ensure that each investigator completes training immediately when any of the following applies:

(1) this FCOI Policy or procedures are revised in any manner that affects the requirements of the investigators, or

(2) Cansera finds that an investigator is noncompliant with this FCOI Policy or a management plan.

D. Disclosure Requirements

Prior to or in connection with the submission to PHS or NIH of an application for a research grant, the principal investigator shall identify to the FCOI administrator: (1) all investigators anticipated to be participating in the research, (2) those who are senior/key personnel, and (3) those who are subrecipients and the institution(s) employing them.

In addition, prior to submission of the application, the FCOI administrator shall ensure that each investigator submits a listing of their known significant financial interests and those of their spouse and dependent children that reasonably appear to be related to the investigator's institutional responsibilities, if any. The FCOI administrator shall also ensure that subrecipient investigators either comply with this FCOI Policy or require that their institution(s) confirm, in writing, that the subrecipient will comply with their own compliant FCOI policy. In either case, the FCOI administrator shall ensure that the proper documentation as required under the FCOI Regulations is executed. Subrecipients who rely on their own FCOI policy must report identified financial conflicts of interests to Cansera in sufficient time to allow Cansera to report the FCOI to the PHS awarding component. A subrecipient's failure to promptly comply with these requirements may be considered grounds for termination by Cansera of any applicable subaward.

All disclosures must be updated annually during the period of the award or within 30 days of discovering or acquiring (e.g., through purchase, marriage, inheritance, or expansion of responsibilities) a new significant financial interest. The FCOI administrator shall ensure that annual update forms are sent to and promptly returned by each investigator (one annual disclosure is sufficient to cover all ongoing PHS or NIH awards). Each investigator is responsible for submitting disclosure forms within 30 days of discovering or acquiring a new significant financial interest. Disclosures shall be provided by an investigator at any other time upon request.

E. Review of Disclosures and Monitoring and Reporting FCOI

The FCOI administrator shall be responsible for reviewing all forms disclosing a significant financial interest, making the requisite determinations and taking any subsequent action. Prior to the expenditure of funds or, with respect to an ongoing PHS or NIH-funded project, within 60 days of the disclosure or discovery of a significant financial interest, the FCOI administrator shall: (1) Review all disclosure forms and determine whether: (a) an investigator's significant financial interest is related to PHS or NIH-funded research, and (b) if so related, whether the significant financial interest is an FCOI; (2) In the case of an FCOI, develop and implement a management plan specifying actions that have been and shall be taken to manage the FCOI; and (3) Submit initial and ongoing FCOI reports to the PHS awarding component as required under the FCOI Regulations.

An FCOI exists when the FCOI administrator reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS or NIH-funded research. In determining whether there is an FCOI, the FCOI administrator will consider all relevant factors and information, including, but not limited to, the nature of the research, the magnitude of the financial interest and degree to which it is related to the research, the extent to which the interest could be directly and substantially impacted by the research, and the degree of risk to the human subjects, if any, that is inherent in the research protocol.

Prior to making the decision of whether an FCOI exists, the FCOI administrator may impose interim measures, may ask the investigator to submit additional information, and may meet or communicate with the investigator. The investigator may be encouraged to suggest procedures, protocols, or other measures designed to manage the FCOI. In the event of an actual or potential FCOI, the FCOI administrator may impose conditions or restrictions, including, but not limited to:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

2. For research involving human subjects, disclosure of financial conflicts to research participants;

3. Monitoring of the research by independent reviewers/monitors to protect the design, conduct, and reporting of the research;

4. Modification of the research plan;

5. Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;

6. Reduction or elimination of the financial interest; and/or

7. Severance of relationships that create such conflicts.

For all management plans, the FCOI administrator shall: (1) monitor ongoing investigator compliance, and (2) submit annual updates to the PHS awarding component at the time and in the manner specified by the PHS awarding component, both until the completion of the PHS or NIH-funded research project to which the FCOI relates. With respect to FCOI related to research sponsored by NIH, annual FCOI reports will be submitted through the eRA Commons FCOI Module for the duration of the project period (including extensions with or without funds) at the same time annual progress reports are required to be submitted and at the time of extension (if any). If the FCOI is identified and eliminated prior to the expenditure of any PHS or NIH-awarded funds, no FCOI report needs to be submitted.

F. Noncompliance and Remedies

If an investigator has failed to comply with a management plan or, for whatever reason, an FCOI was not identified, reviewed, or managed in a timely manner, the FCOI administrator shall within 120 days of the determination of noncompliance conduct a retrospective review of the investigator's activities and the research project to determine whether any PHS or NIH-funded research or portion thereof conducted during the period of noncompliance was biased in design, conduct, or reporting. The review shall be documented consistent with the FCOI Regulations. If bias is found during the course of the review, the FCOI administrator will promptly notify the PHS awarding component (which may take its own action and/or require further action by Cansera and/or the investigator, as it deems appropriate) and submit a mitigation report consistent with the FCOI Regulations. If appropriate, the FCOI administrator will update the previously submitted FCOI report. In any event, the FCOI administrator shall submit FCOI reports annually thereafter.

If the Department of Health and Human Services determines that a PHS or NIH-funded project of clinical research 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 properly disclosed or managed as required under the FCOI Regulations, the investigator shall disclose the FCOI in each public presentation of the results of the research (such as articles, manuscripts, and oral presentations), and Cansera shall request an addendum to previously published presentations.

G. Maintenance of Records

The FCOI administrator shall maintain all disclosure forms and related records of determinations made and actions taken for a period of three years from the date of submission of the final expenditures report to the PHS or NIH.

H. Enforcement Mechanism and Sanctions

All persons to whom this FCOI Policy applies are expected to fully and promptly comply with it. Failure on the part of an investigator to comply with this Policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the investigator, and/or any other enforcement action mandated by the applicable PHS awarding component agency or Cansera.

I. Public Accessibility Requirements

This FCOI Policy will be posted on Cansera's publicly accessible website. To the extent there is an identified FCOI held by senior/key personnel, Cansera shall make such information available to a public requester's written request within five business days of receipt of the written request. The information provided shall include the name of senior/key personnel, their

role in the research project, the name of the entity in which the FCOI exists, the nature of the FCOI, and the approximate value of the FCOI or a statement that said value cannot be reasonably determined. The information shall remain available for three years from the date the information was most recently updated. Informational requests may be made to Cansera via email at compliance@cansera.com.