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Approved by:

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Approved on: 13-Jul-2021

Financial Conflict of Interest Policy (PHS)

INTRODUCTION

This policy governing financial conflict of interest applies to all employees of Cambridge Polymer Group, Inc. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

DEFINITIONS

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

a) salary, royalties, or other remuneration from the Institution;
b) income from the authorship of academic or scholarly works;
c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds $5,000; or
b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds $5,000; or
c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
d) is income exceeding $5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Institutional official means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the Quality Manager.

Institutional responsibilities means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the Institution on an annual and on an ad hoc basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by March 1st for the previous calendar year or as determined by the subrecipient.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the

course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

d) Significant Financial Interest Disclosure Forms

The financial disclosure form used for "Investigators" to disclose their SFIs to the Institution's designated official(s) for a determination of FCOI should include at a minimum the following information:

- Investigator's name
- Entity name in which the Investigator (and spouse and dependent children) has an SFI
- Disclosure requirement that is consistent with the institution's definition of SFI
- Disclosure of financial interests in the 12 months preceding the disclosure and value of equity interest as of the date of disclosure
- Provide for disclosure of intellectual property (IP) rights and interests (e.g., patents, copyrights), upon the receipt of income related to such rights and interests (Note: Institutions may impose a $5,000 threshold for IP rights and interests as described in the Final Rule on page 53265).
- Provide for the disclosure of reimbursed or sponsored travel that includes at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- Ensure the SFI definition includes the "U.S.C. Code 20 U.S.C. 1001(a)" which refers to "domestic" institutions (see FAQs E.21 and E.24 and NIH Guide Notice NOT-OD-18-160).
- Clarify that disclosure is required for all financial interests received from a foreign institution of higher education or the government of another country (see FAQs E.21 and E.24 and NIH Guide Notice NOT-OD-18-160).
- The value of the SFI.
- Provide a distinction whether the SFI is from a publicly traded or non-publicly traded entity.

- Provide a description of the nature of the SFI (e.g., salary, royalties, consulting fees, honoraria, paid authorship, reimbursed or sponsored travel).
- Provide an indication whether the SFI is related to any Public Health Service application and/or funded project and an explanation for the relatedness. Some information to consider:
- The institution's designated official(s) makes the determination whether the SFI is an FCOI (i.e., an SFI that could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research).
- Per the preamble in the Final Rule (page 53261), "significantly" means "…the financial interest would have a 'material effect on the research'…".

2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it relates to a PHS/NIH funded research, it constitutes a Financial Conflict of Interest (FCOI) and if an FCOI exists (e.g., the SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research). If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of testing and/or research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related testing and/or research; including PHS-sponsored research goes forward.

Examples of conditions or restrictions that might be imposed to manage an Investigator's Financial Conflict of Interest include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants.
- 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.

- Modification of the research plan.
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research.
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

Management Plan for a Financial Conflict of Interest will include:

(A) The 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.

Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the NIH.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan until completion of the project.

3) CLINICAL TRIALS

Not applicable to Cambridge Polymer Group.

4) REPORTING TO PHS

The institutional official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

Send initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the regulation and/or NIH's FAQ H.5, to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients, if applicable, as required by the regulation and as stated below:

- Prior to the expenditure of funds

- Within sixty (60) days of identification for an Investigator who is newly participating in the project
- Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.

Notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation.

The notification will include all reporting elements required by the regulation:
(*1*) Project number

(*2*) Project title

(*3*) Program Director/Principal Investigator or contact Program Director/Principal Investigator if a multiple Program Director/Principal Investigator 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

Notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

Notify NIH promptly and take corrective action for noncompliance with the Institution's policy or the management plan.

5) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

A Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional official, will be described in a written explanation of the decision to the investigator, and will notify the individual of the right to appeal the decision. The institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official will oversee a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

6) TRAINING

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in

research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

7) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a minimum period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

8) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

9) PUBLIC ACCESSIBILITY

This FCOI Policy is posted on the Institution's public Web site

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information that the Institution makes available via a publicly accessible Web site or written response within five business days of a written request shall include, at a minimum, the following:

i. Investigator's name;
ii. Investigator's title and role with respect to the research project;
iii. Name of the entity in which the Significant Financial Interest is held;
iv. Nature of the Significant Financial Interest; and
v. 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.

The information is updated, at least annually (Website only but an response to a written request should include the updated information)

Be updated, within sixty (60) days of a newly identified FCOI (Web site only but any response to a written request should include the updated information)

Remain available for three (3) years from the date the information was most recently updated.

Ensure that in any case in which the Department of Health and Human Services determines that a PHS/NIH-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research, and
- To request an addendum to previously published presentations.

The information to be made available shall be consistent with the requirements of the PHS regulation.

10) Subrecipient Requirements (subcontractors)

The awardee Institution is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. Awardee institutions must incorporate as part of a written agreement with a subrecipient terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the Financial Conflict of Interest to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with the awardee Institution's policy must submit all Investigator disclosures of Significant Financial Interests to the awardee in sufficient time to allow the awardee to review, manage and report identified FCOIs to the NIH.

Awardee Institutions are responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

11) REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.