Policy & Procedure			
Title:	Research Compliance Financial Conflict of Interest Disclosure	AltaMed	
Policy #:	LD-RES-001		
Issuing Dept.:	Office of Compliance and Ethics (OCE)	**Effective Date:**	10/15/2020
Approved by:	SVP and Chief Compliance Officer	**Revision Date:**	
Distribution:	☒ AltaMed Health Services Corporation ☐ AltaMed Primary Care Services ☐ AltaMed PACE/Senior BuenaCare ☐ Other: (Internal Policy)	**Review Date:**	12/03/2020

Contact information

1. For further information about this policy and procedure, contact the Office of Compliance and Ethics.

Purpose

1. This policy provides the mechanism for the review of financial conflict of interests (FCOI) in order to determine whether such conflict exists and, if so, whether action must be taken to manage the conflict before the contract, grant, gift, or supporting the research may be accepted.

2. To protect research participants, the integrity and credibility of activities related to research and to maintain public trust and confidence in AltaMed and its employees.

Policy

1. Research occurring at, on behalf of, or through AltaMed shall not be adversely affected by the financial interests of persons involved in those activities.

2. Any key research personnel possessing a financial interest related to their organizational responsibilities must disclose the interest to AltaMed at least annually and/or prior to participating in any research activity.

3. AltaMed is responsible for reviewing disclosures and instituting an adequate plan for the elimination, reduction or management of any identified financial conflicts of interest.

4. Persons failing to comply with this policy shall be subject to sanctions as provided herein.

Definitions

1. Financial conflict of interests (FCOI)

2. Explain any key terms that are used differently than the average reader would understand.

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3. No need to list acronyms in this section. To use acronyms, for spell it out and then enter it in parenthesis. Once you've done that for the first time, you will be able to use the acronym throughout the document. Example: Office of Compliance and Ethics (OCE).

Procedure

1. Key Research Personnel are required to:

1.1. Disclose financial interests

1.1.1. Annually;

1.1.2. Within 30 days of discovering or acquiring a financial interest

1.1.3. In the case of Sponsored or Reimbursed Travel, the disclosure must be made within 30 days of the trip end;

1.1.3.1 Regarding the disclosure of sponsored or reimbursed travel, if Key Research Personnel can reasonably anticipate the occurrence of travel, they may elect to disclose such travel up to twelve (12) months in advance of the anticipated travel. If an advance disclosure of travel becomes materially inaccurate, the Key Research Personnel must provide an updated disclosure within 30 days of the change.

1.1.4. Upon direction from AltaMed.

1.2. Certify that their financial disclosure is current at the time of submission of a grant proposal/application.

1.3. Ensure their financial disclosure is current prior to the approval and throughout the lifecycle of an IRB study.

1.4. Disclose individual or family members' financial interests that reasonably appear to be related to their Organizational Responsibilities or have any of the following financial interests in an entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested:

1.4.1. Any remuneration from the entity in the previous twelve months that exceeds $5,000, when aggregated for the individual and their immediate family. (Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship).

1.4.2. Any equity interest in the entity (equity interest includes any stock, stock option, or other ownership interest).

1.4.3. Any intellectual property rights and interests (e.g., patents, copyrights, IP rights assigned to AltaMed Institute for Health Equity, and agreements to share in royalties related to such rights).

1.4.4. Any governance or executive relationship with the entity (e.g., founder, board of director, CEO).

1.5. Comply with any Management Plan established by AltaMed's Office of Compliance and Ethics (OCE)

2. Principal Investigator Responsibilities - in addition to the responsibilities outlined for all Key Research Personnel above, Principal Investigators (PI's) are required to:

2.1. Ensure all Investigators involved in a research project, including newly hired Investigators, have a current financial interest disclosure on file prior to their participation in the project;

2.2. Ensure all Investigators involved in a research project promptly disclose any new or updated financial interests;

2.3. Ensure all Investigators involved in a research project have completed the FCOI training required under this policy;

2.4. Identify the Key Personnel on a research project upon request;

2.5. Indicate, upon submission of a proposal/application if they or any project Investigators have a Significant Financial Interest (SFI) that may be related to the proposed project.

3. Required Financial Conflict of Interest (FCOI) Training:

3.1. All research staff will receive FCOI training through electronic learning system (CITI). Per federal regulations and AltaMed policies, Key Research Personnel are required to complete FCOI training:

3.1.1. At least annually;

3.1.2. As part of the on boarding process after joining AltaMed;

3.1.3. As mandated by AltaMed's Office of Compliance and Risk Management, upon determination of non-compliance with this policy or an existing Management Plan;

3.1.4. When AltaMed revises this policy in any manner that affects the requirements of investigators;

3.1.5. As otherwise dictated by AltaMed.

4. Review of Disclosures

4.1. AltaMed 's OCE shall review Investigators financial interest disclosures and determine if the financial interest is "significant" and if so, determine if the interest is related to the research.

4.1.1. If additional information is needed during the review process, the OCE shall send a request for clarification to the Investigator explaining the details of such request.

4.1.2. Depending on the nature of the disclosed SFI, the OCE may implement measures regarding the Investigator's participation in the research project between the date of disclosure and the completion of the SFI review.

4.2. The OCE will provide a summary of the interim plan to the investigator and Institutional Review Board (IRB) of record.

5. Management of FCOI

5.1. The OCE's VP, Corporate Compliance determines the criteria used for, and adequacy of all management plans. FCOI management plans will address the following key areas:

5.1.1. the nature of the conflict;

5.1.2. the relatedness of the conflict to the research;

5.1.3. the perceived risk to the integrity of the research as a result of the conflict;

5.1.4. if applicable, the specific risks to human subjects;

5.1.5. if the conflict can be sufficiently managed by a management plan;

5.1.6. the perceived risk to the reputation of the organization.

5.2. The OCE's charge is to review and manage financial conflicts of interest (FCOI) of key research personnel involved in research at AltaMed in accordance with this Policy. The OCE will develop new and review renewals of FCOI management plans.

5.3. If the OCE determines that a reported SFI constitutes an FCOI relating to a research project, it shall develop and implement a Management Plan specifying terms and conditions that have been, or will be, taken that in the reasonable judgment of the OCE will reduce or manage the FCOI and may contain one or more of the following terms and conditions:

5.3.1. Disclosure of financial interest(s) relating to conflicted research study(ies) in publications, presentations, and any public communication of research results;

5.3.2. Disclosure of financial interest(s) relating to conflicted research study(ies) to all research personnel affiliated with and potential human subjects participating in the research;

5.3.3. Prohibited from obtaining informed consent of human subject participants;

5.3.4. Prohibited from production of data involving subjective scoring or similar

methods;

5.3.5. Prohibited from conducting data analysis;

5.3.6. Prohibited from performing adverse event causation analysis;

5.3.7. If decision maker, recuse oneself from making future decisions on behalf of AltaMed relating to financial interest(s);

5.3.8. Upon request, provide a Management Plan Compliance Report to Director of the Institute for Health Equity;

5.3.9. Upon request, make available all research data and results for independent data monitoring;

5.3.10. Upon request, provide information for independent review of study design;

5.3.11. Prohibited from using AltaMed assets and facilities relating to conflicted entity(ies);

5.3.12. Prohibited from participating in negotiations on behalf of AltaMed and conflicted entity(ies);

5.3.13. Prohibited from disclosing proprietary information belonging to AltaMed to conflicted entity(ies).

5.4. In developing a Management Plan, the OCE may conduct factual inquiries and consult with and receive recommendations from such persons or committees as the deems necessary and appropriate.

5.5 For PHS-funded research, the actions detailed above will be completed prior to the expenditure of any research project funds, or within 60 days of a disclosure of an SFI during the course of a research project by existing or new Key Research Personnel.

5.6. Whenever a Management Plan is implemented, the OCE shall take such actions as it deems reasonable to audit and/or monitor compliance with the Management Plan, including obtaining regular reports from individuals and committees

charged with oversight responsibilities in connection with FCOI management plans. This audit and/or monitoring of compliance will be conducted until the completion of the research project or until the Management Plan is no longer required.

6. Management of Other Interests

6.1. When a disclosure of SFI is determined not to constitute an FCOI, or disclosure of non-SFI related to human subjects research, the OCE may determine that some type of management or oversight of the interest is appropriate before certain research activities may proceed. The OCE may specify additional terms and conditions to manage these other interests.

7. FCOI Reporting to PHS Awarding Components for PHS-Funded Research

7.1. AltaMed will submit FCOI reports to a PHS Awarding Component:

7.1.1. Prior to expenditure of any funds under a PHS-funded research project, if an FCOI has not been eliminated;

7.1.2. Within 60 days of identifying an FCOI during an ongoing research project;

7.1.3. Annually for any FCOI previously reported regarding an ongoing PHS-funded research project. The report shall specify the status of the FCOI (if the FCOI is still being managed or explain why it no longer exists) and if appropriate, any changes to the Management Plan. The report shall be submitted annually for the duration of the research project at the same time as the submission to NIH of the annual progress report, multi-year progress report, if applicable, or at the time of extension.

7.2. Any FCOI report submitted to a PHS Awarding Component shall include the minimum elements as required by 42 CFR Part 50, Subpart F and contain sufficient information to understand the nature and extent of the financial conflict and assess the appropriateness of the Management Plan.

8. PHS-Funded Research through Subrecipients

8.1. If the PHS-Funded Research or portions of it is carried out through a subrecipient, AltaMed will take reasonable steps to ensure that any subrecipient research team complies with 42 CFR Part 50, Subpart F by incorporating the following as part of the written agreement with the subrecipient:

8.1.1. Terms that establish whether this policy or the subrecipient's FCOI policy will apply to the subrecipient Key Research Personnel;

8.1.2. Time period(s) for the subrecipient to report all identified FCOI or for submission of all subrecipient Key Research Personnel SFI disclosures to AltaMed.

9. Publicly Accessible Information

9.1. This policy shall be available via AltaMed's publicly accessible web site.

9.2. For PHS-Funded Research, the OCE shall make information concerning significant financial interests that meet the criteria below available to the public, upon written request for such information:

9.2.1. SFI was disclosed and is still held by Senior/Key Personnel (as defined in this policy);

9.2.2. AltaMed determined the SFI is related to a PHS-Funded Research project;

9.2.3. AltaMed determined the SFI constitutes an FCOI.

9.3. The above information made available shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F and shall be provided by written response to the requestor.

9.4. The above information shall remain available for public request for at least three years from the date that the information was most recently updated.

10. Retrospective Review of PHS-Funded Research

10.1. If the ROI identifies an SFI that was not disclosed in a timely manner or was not

previously reviewed by the OCE during an ongoing PHS-Funded Research project, the OCE shall within 60 days:

10.1.1. Review the SFI;

10.1.2. Determine whether it is related to a PHS-Funded Research project;

10.1.3. Determine whether an FCOI exists;

10.1.4. If the OCE determines an FCOI exists, the OCE shall implement (at least on an interim basis) a Management Plan that specifies the actions that have been taken and will be taken to manage such FCOI.

10.2. Whenever an FCOI related to a PHS-Funded Research project is not identified or managed in a timely manner due to non-compliance by AltaMed or a Key Research Personnel, including if an Investigator fails to comply with a Management Plan, the OCE shall:

10.2.1. Notify the Director of the Institute for Health Equity (or Designee);

10.2.2. Within 120 days of non-compliance identification, complete and document a retrospective review of the Key Research Personnel's activities and the research project. Documentation of the review will include all elements as specified by 42 CFR Part 50, Subpart F;

10.2.3. Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report and specify the actions that will be taken to manage the FCOI moving forward;

10.2.4. If bias is found, notify the PHS Awarding Component promptly and develop and submit a mitigation report. The mitigation report shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F;

10.2.5. Submit FCOI reports to the PHS Awarding Component annually thereafter for the duration of the research project.

11. Sanctions and Remedies for Violation of Policy

11.1. If the OCE determines Key Research Personnel has violated this policy, including failure to submit required disclosures or failure to comply with the requirements of a management plan, the OCE shall report the violation to the Director of the Institute for Health Equity. The Director of the Institute for Health Equity shall take reasonable steps to respond appropriately to violations, including, but not limited to:

11.1.1. Suspending research activity expenditures;

11.1.2. Administratively suspending any research study related to the FCOI;

11.1.3. Instituting disciplinary measures up to and including suspension or termination.

11.2. If required to do so, AltaMed will submit to HHS, or permit on site review of, all records pertinent to compliance with this policy and federal regulations.

11.3. In the case in which it is determined that a PHS-Funded Research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by Key Research Personnel with an FCOI that was not managed or reported, SCRI shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and shall request an addendum to previously published presentations.

12. Record Keeping

12.1. The OCE shall maintain records relating to:

12.1.1. All Key Research Personnel disclosures of financial interests;

12.1.2. The OCE's review and response to such disclosures;

12.1.3. Actions taken under this policy or retrospective reviews.

12.2. For PHS-Funded Research, these records shall be maintained for at least three years from the date the final expenditures report is submitted to the PHS Awarding

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Component or as required by 45 CFR 74.53(b) and 2.42(b). For all other research, these records shall be maintained for at least three years from the date of the final expenditures report.

Education & Training Plan

1. Research staff will receive FCOI training through electronic learning system (CITI) for newly hired research personnel and all research personnel annually.

Implementation Monitoring Plan

1. Monitor completion of new hire FCOI Disclosure forms monthly
2. Monitor completion of new hire FCOI training monthly
3. Monitor completion of annual FCOI Disclosure forms submission.
4. Monitor completion of annual FCOI training.

Forms & Resources

1. AltaMed Health Services Conflict of Interest Disclosure Form.

References & Citations

1. Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F).
2. Responsible Prospective Contractors (45 C.F.R. Part 94).