

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

ProActive Memory Services, Inc.

Adopted Aug 17, 2023

ProActive Memory Services, Inc. (PAMS) promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of all its research, including research funded through the National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI). This FCOI policy addresses requirements regarding FCOI as outlined by NIH, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS)

To insure objectivity, PAMS's policy requires that each investigator, consultant, subcontractor and collaborator conducting research as part of an NIH award to PAMS or any other applicable grant or contract, be in compliance with 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts).

SUMMARY OF PROCESS

Investigators associated with PAMS research shall disclose Significant Financial Interests (SFI) (as defined below) on the PAMS Significant Financial Interest Disclosure Form at the time of application for government-sponsored or company-sponsored funding and when a SFI arise during the course of research. Regardless of whether a SFI exists, all Investigators and key personnel are required to submit a SFI Disclosure Form annually.

The Principal Investigator of each research project has the responsibility to identify to the PAMS Chief Financial Officer (CFO) all individuals who are responsible for the design, conduct or reporting of the study. The CFO then must ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or application for human subjects' approval.

The Significant Financial Disclosure Form and supporting materials are completed by Investigators and forwarded to the Chief Financial Officer (CFO) for review. The CFO will be responsible for evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

Advance approval by the President or CFO is required prior to engaging in government-sponsored research. A SFI review must be completed before any expenses are incurred under an award.

Annual reports are required of all Investigators and key personnel participating in research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the CFO through submission of an updated SFI Disclosure Form. Annual reports and newly acquired interests are reported using the Significant Financial Interest Disclosure Form.

TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all PAMS Investigators, consultants and employees engaged in NIH-funded research. The course is accessed at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Upon completion of this training, Investigators must provide the CFO a certificate of completion, which the CFO shall keep in company compliance files. Investigators also should retain a copy for their records. This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by PAMS due to changes in the FCOI policy, non-compliance of the Investigator, or when an Investigator is new to PAMS. At a minimum, the FCOI training shall be taken every four (4) years.

KEY DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

Institution – means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for, or receiving NIH research funding.

Investigator – means the project director or principal investigator and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research funded by the NIH, including co-investigators, collaborators and consultants.

Institutional responsibilities – means an Investigator's professional responsibilities on behalf of PAMS, and as defined by PAMS, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial interest – means anything of monetary value, whether or not the value is readily ascertainable.

Financial conflict of interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Manage – means taking an action to address a financial conflict of interest, 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.

Senior/Key Personnel – means the Project Director/Principal Investigator and any other person identified as senior/key personnel by PAMS in the grant application, progress report, or any other report submitted to the NIH by PAMS under the regulation.

Significant Financial Interest (SFI) –

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000 (ii) With regard to any non-publicly traded for profit entity other than PAMS, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or (iii) Upon receipt of income related to intellectual property rights and interests (e.g. patents, copyrights)

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities to PAMS, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by PAMS directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to PAMS relating to the trip, such as purpose of the trip, identity of the payer/sponsor, destination and duration. PAMS is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCOI with NIH-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by PAMS to the Investigator if the Investigator is currently employed or otherwise appointed by the PAMS; (ii) intellectual property rights assigned to PAMS and agreements to share in royalties related to such rights; (iii) any ownership interest in PAMS held by the Investigator (PAMS is a commercial and for-profit organization); (iv) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; (v) income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or (vi) income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

PROCEDURES

A. Identification of Persons Required to Disclose a Significant Financial Interest

It shall be the responsibility of the Principal Investigator of a research project to identify all Investigators who have a SFI requiring disclosure under this policy and to ensure that they prepare and submit a SFI Disclosure Form. In addition, the Principal Investigator shall be

responsible for ensuring that annual reports and new or increased financial interests are disclosed.

B. Submission and Review of Significant Financial Interest Disclosure Form

Every individual having a SFI requiring disclosure under this policy shall prepare a fully-completed SFI Disclosure Form that shall be submitted to the CFO. An initial review of the SFI Disclosure Form will be conducted by the CFO to determine whether a potential for conflict of interest exists. If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to address the SFI identified in the SFI Disclosure Form. A management plan may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Investigator and the Chief Financial Officer. Compliance of the management plan shall be monitored by the Finance Department.

C. Annual Reporting and After-Acquired Significant Financial Interests – All Investigators shall provide annual SFI Disclosure reports or more frequently if required by the management plan. Any Investigator who acquires a new or increased SFI shall promptly submit a new SFI Disclosure Form within 30 days of discovering or acquiring the new SFI. It is the Principal Investigator's responsibility to ensure that any newly acquired Investigator on a research project submits the required SFI report to the CFO.

D. Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, the CFO shall make recommendations to the President regarding the impositions of sanctions or disciplinary proceedings against the violating individual.

In addition, PAMS shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

E. Record Keeping – Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the CFO for three (3) years from the date the final expenditure report is submitted to the NIH, or as required by 45 CFR 74.53(b) and 92.42(b) for different situations.

F. Sub-recipient Requirements – Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)* and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, they are required to notify the CFO of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced or eliminated in accordance with federal regulations.

G. Public Accessibility – In accordance with federal requirements, PAMS shall post information on its website regarding any disclosed SFI which a) was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by PAMS in the grant application, progress report, or any other required report submitted to the NIH; b) PAMS determines is related to the NIH-funded research; and c) PAMS determines is an FCOI. At a minimum, PAMS will include in the posting the Investigator's name, title and role with respect to the research project, the name of the entity in which the SFI is held, the nature of the SFI, and the approximate dollar value of the SFI (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). If there are no relevant disclosed SFI, the statement "No PAMS Investigators have significant financial interests (SFI) that represent a financial conflict of interest (FCOI) with its NIH-funded research."

H. Federal Reporting – The Chief Operating Officer (COO) is responsible for the reporting disposition of matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by the NIH and are submitted through eRA Commons:

i. Initial report – prior to PAMS's expenditure of any funds under a NIH-funded research project, PAMS must provide to the NIH an FCOI report regarding any Investigator SFI found by PAMS to be a financial conflict of interest in accordance with the regulation.

ii. During on-going NIH-funded research projects – PAMS shall submit an FCOI report within 60 days after its determination that a new FCOI exists. If a FCOI was not disclosed timely, PAMS shall submit a FCOI report to the NIH within 60 days of the discovery, as well as complete a retrospective review within 120 days of discovery of noncompliance.

iii. Annual FCOI report – For any FCOI previously reported to the NIH, PAMS shall provide an annual FCOI report addressing the status of the FCOI and any changes to its related management plan.