

FCOI Policy for Aquora (AQUORA)

[Financial Conflict of Interest on Federal Grants Policy]

Effective Date: December 15, 2023

I. Purpose

This Financial Conflict of Interest on Federal Grants Policy (hereinafter referred to as the "policy") was designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by federal grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. It applies to all staff involved in federally funded research. This policy was crafted in response to federal regulations that require that all investigators disclose any potential financial conflict of interest to Aquora Research and Consulting, LLC, prior to undertaking federally funded research. This policy is applicable to federally funded sponsored project activity at Aquora Research and Consulting (Aquora; Holland, MI) including projects funded with federal flow-through, when the sponsoring agency policy requires a financial conflict of interest disclosure.

II. Definitions

The following definitions apply to this policy unless a specific federal policy uses a different definition, in which case that agency's definition will apply

Disclosure of significant financial interests: means an investigator's disclosure of significant financial interests (SFI) to Aquora Research and Consulting.

Aquora: Aquora Research and Consulting

FCOI: means financial conflict of interest or more fully described as a significant financial interest (SFI), real or perceived, that could directly and significantly affect the design, conduct, or reporting of federally funded research.

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

Investigator: means the project director (PD) or principal investigator (PI), co-principal investigator (Co-PI), and any other senior/key personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research, which may include, for example, collaborators or consultants.

DGC: Director of Grants Compliance

Research: encompasses any basic and applied research, be it bench work, creative activity (e.g., a published article, book, or book chapter), or product development (e.g., clinical trials, diagnostic test, or drug). As used in this policy, the term includes any such activity for which research funding is available from a federal agency through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.

Senior/key personnel: means the PD/PI and any other person identified as senior/key personnel by Aquora in the grant application, progress report, or any other report submitted on the research to the federal funding agency by Aquora under the scope of this policy.

Significant financial interest (SFI): means one of the following:

- A. A significant financial interest exists if the following situations apply to the investigator and/or the investigator's spouse, children, and immediate relatives (siblings and parents) involving companies that reasonably appear to be related to the proposed research:
 - i. For publicly traded companies, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure. Examples of income include salary, consulting fees, honoraria, paid authorship, stock, stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value).
 - ii. For non-publicly traded companies, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure, or when any equity interest is held (e.g., stocks, stock options, or other ownership interests).
 - iii. If any income is received from intellectual property rights and interests (e.g., patents, copyrights) in excess of \$5000.
- B. Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their company responsibilities in excess of \$5000; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency located in the United States, an United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an United States institution of higher education. This disclosure will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. In accordance with Aquora's FCOI policy, the DGC will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the federally funded research.
- C. The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by Aquora to the Investigator if the Investigator is currently employed or otherwise appointed by Aquora, including intellectual property rights assigned to Aquora and agreements to share in

royalties related to such rights; any interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency located in the United States, an United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an United States institution of higher education; or income from any service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, an United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an United States institution of higher education.

For further clarification about the policies listed above, we have also included NIH FAQ E.36 and E.37 related to foreign disclosure requirements and pasted below:

E.36. Are Investigators required to disclose income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; and reimbursed or sponsored travel that are received from a foreign government which includes local, provincial, or equivalent governments of another country or foreign Institutions of higher education when such income meets the threshold for disclosure (e.g., income more than \$5,000)? (Institution and Investigator)

Yes. Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure. See NIH Guide Notices NOT-OD-18-160 and NOT-OD-22-210 for more information.

E.37. Are the exclusions referenced in the definition of “Significant Financial Interest” limited to a United States government agency or a United States Institution of higher education? (Institution and Investigator)

Yes. The disclosure exclusions for financial interests associated with a federal, state or local government agency or Institutions of higher education as defined in 20 U.S.C. 1001(a) is limited to those entities located within the United States. Therefore, when these interests are associated with the governments of another country, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States) or foreign Institutions of higher education, they must be disclosed.

III. Financial Conflict of Interest Committee

A. Membership

This committee will consist of all three majority owners of Aquora (Best, Krueger and Tintle) and the DGC, if a separate individual. The chair of the committee is the President of Aquora (Best).

B. Duties

This committee will review the FCOI forms and the associated management/ monitoring and either accept or suggest modifications to manage or eliminate the potential conflicts.

IV. Institutional Responsibilities and Procedures

A. Investigator Training

In order to facilitate compliance with the federal policy, Aquora is responsible for investigator training, collection and evaluation of FCOI forms, and enforcement of this policy. In addition to making this policy and associated forms available on its web site, training will be provided by the DGC for all investigators prior to engaging in federally funded research. Training must be repeated at least every four years, and immediately when Aquora revises its FCOI policies or procedures in any manner that affects the requirements of Investigators; an investigator is new to Aquora; or an investigator is found to be in non-compliance with Aquora's FCOI policy or management plan.

B. Disclosure requirements

At the time of submission of a grant to a federal agency, all participating investigators are required to fill out and submit a Financial Interest on Federal Grants Disclosure Statement (FCOI form) to the DGC. The DGC will assess the potential for a conflict and initiate the review and response procedures outlined below. In addition, all investigators must submit an updated FCOI form annually during the period of the award (by deadlines established by the DGC) to include any information that was not disclosed previously to Aquora, and to include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest). Any newly discovered or acquired significant financial interest (e.g., through purchase, marriage, or inheritance) must be disclosed within thirty days. New Investigators added to a project after the start date of the project must also complete a disclosure form. This includes situations where a non-Investigator employee's status is changed to that of Investigator. New or changed Investigators must also complete the training, as described above.

C. Subcontracts

If the federally funded research involves a subrecipient (e.g., subcontractors or consortium members), Aquora (as the awardee institution) will take reasonable

steps to ensure that any subrecipient investigator complies with the federal policies by:

- i. Establishing in writing with the subrecipient whether the financial conflicts of interest policy of Aquora or that of the subrecipient will apply to the subrecipient's investigators.
 - a. If the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify that its policy is in compliance with federal policies. In the absence of this certification, the agreement will state that subrecipient investigators are subject to the financial conflicts of interest policy of Aquora for disclosing significant financial interests that are directly related to the subrecipient's work for Aquora.
 - b. Additionally, if the subrecipient's investigators must comply with the subrecipient's financial conflicts of interest policy, the written agreement will specify a deadline for the subrecipient to report all identified financial conflicts of interest to Aquora so that Aquora can provide timely FCOI reports, as necessary, to the relevant federal agency.
 - c. Alternatively, if the subrecipient's Investigators must comply with Aquora's financial conflicts of interest policy, the written agreement will specify a deadline for the subrecipient to submit all Investigator disclosures of significant financial interests to Aquora so that Aquora can provide timely FCOI reports, as necessary, to the relevant federal agency.
- ii. Providing FCOI reports to the federal agency regarding all financial conflicts of interest of all subrecipient investigators consistent with this policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI

D. Review of FCOI and management of conflicts

An investigator's significant financial interest is related to federally funded research when Aquora reasonably determines that the significant financial interest: 1) could be affected by the research, or 2) is in an entity whose financial interest could be affected by the research. A FCOI exists when Aquora reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the federally funded research. At the time of submission of a grant to a federal agency, all participating investigators are required to fill out and submit a FCOI form along with the proposal and the Proposal/Award Checklist. Signed FCOI forms will be reviewed by the DGC; outcomes may include:

- i. If a FCOI form indicates no significant financial interest, the forms will be filed with the DGC. The proposal will be submitted by the DGC to meet agency deadlines.
- ii. If a FCOI form indicates a potential financial conflict of interest, the proposal will be submitted by the DGC to meet agency deadlines but the DGC will contact the investigator for additional information. If the DGC

then determines that a conflict of interest may exist, the potential FCOI will be addressed by one of the following approaches:

- a. The DGC will work with the investigator to develop a management plan to eliminate the conflict of interest. The DGC will report the management plan to the Financial Conflict of Interest Committee. The Committee will notify appropriate institutional and funding agency administrators, as required by the agency's guidelines.
 - b. If it is not possible to eliminate the conflict of interest, a plan to reduce or manage the conflict must be developed by the investigator in consultation with the DGC. The DGC will forward it on to the Financial Conflict of Interest Committee for review and input. The Committee will notify appropriate institutional and funding agency administrators of the conflict, as required by the agency's guidelines as discussed below.
 - c. All conflicts of interest must be resolved and management plans approved by the appropriate institutional administrators before the research project can begin. Grant awards will not be released to the researcher until the conflict is appropriately addressed. In rare cases, Aquora may be required to decline the award if the conflict cannot be resolved or managed as discussed below.
- iii. If a disclosure of a new conflict arises or the discovery of an undisclosed conflict is uncovered, the Financial Conflict of Interest Committee will review and make recommendations within 60 days of the new conflict disclosure or unreported disclosure discovery.

The Financial Conflict of Interest Committee will review all of the submitted material and either accept or suggest modifications to further eliminate the conflict. This could involve, at either the committee's request or at the investigator's request, a meeting with the committee. Expert opinions may also be sought by the committee. Examples of approaches that could be used to manage a FCOI include, but are not limited to:

- i. Public disclosure of FCOI (e.g., when presenting or publishing the research).
- ii. Sharing the results of the FCOI with project personnel, the relevant IRB and/or the relevant IACUC
- iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI.
- iv. Modification of the research plan.
- v. Change in personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- vii. Severance of relationships that create financial conflicts.

Whenever Aquora implements a management plan, the Financial Conflict of Interest Committee will monitor investigator compliance with the management plan on an ongoing basis until completion of the affected federally funded research project. In the event of any significant conflicting financial interest that is discovered subsequent to initial reports to federal agencies, the investigator and Aquora will implement a management plan within 60 days and the Financial Conflict of Interest Committee will complete a retrospective review to determine whether the research was biased and, if so provide a mitigation report if required by the relevant federal agency.

D. Reporting of conflicts

Aquora must certify in each application for funding to which this policy applies, that Aquora has a written and enforced administrative process to identify and manage financial conflicts of interests and that they will ensure compliance with all such related federal policies regarding FCOI. Aquora must provide initial and ongoing FCOI reports to the federal agency, as required. Thus, Aquora is required to maintain records relating to all investigator disclosures of financial interests and Aquora's review of, and response to, such disclosures (whether or not a disclosure resulted in Aquora's determination of a FCOI) and all actions under Aquora's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the federal agency, or as required by the specific agency. Aquora must also monitor investigator compliance with approved management plans throughout the duration of the funded project.

E. Public accessibility to FCOI information

Prior to Aquora's expenditure of any funds under a federally funded research project, Aquora shall ensure public accessibility via its web site of information concerning any significant financial interest disclosed to AQUORA that meets the following three criteria:

- i. The significant financial interest was disclosed and is still held by the Investigator as defined by this policy;
- ii. Aquora determines that the significant financial interest is related to the federally funded research; and
- iii. Aquora determines that the significant financial interest is a FCOI.

The information that Aquora must make available via its website will include the following: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; and, the nature of the significant financial interest. This posted information will be maintained and updated at least annually by DGC and will remain accessible for at least three years from the date that the information was most recently updated.

F. Enforcement

Investigators will not be able to access funds prior to disclosure of a FCOI and approval of a management plan. Noncompliance must also be reported to the appropriate federal funding agency. Certain agencies (e.g., NIH grants for clinical research) require public disclosure of FCOI on all public presentations and publications (including addendums for previously published items) for any funded research that did not comply with federal disclosure regulations. Failure of investigators to comply with this policy, including restrictions emplaced by the management plans, will be grounds for discipline and sanctions as determined by the Financial Conflict of Interest Committee.

G. Retrospective review

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by Aquora to constitute a Financial Conflict of Interest;
- Failure by Aquora to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

Aquora shall, within 120 days of Aquora's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

Aquora shall document the retrospective review which must include at least the following key elements:

- A. Project number;
- B. Project title;
- C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- D. Name of the Investigator with the FCOI;
- E. Name of the entity with which the Investigator has a financial conflict of interest
- F. Reason(s) for the retrospective review;
- G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- H. Findings of the review; and
- I. Conclusions of the review.

If bias is found, the Institution must notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report is submitted as a "Revised FCOI Report." (see FAQ H.2.). The mitigation report must include, at a

minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Aquora's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Aquora will submit FCOI reports annually as prescribed by the regulation.

I. Additional rules for clinical research

In any case in which the HHS determines that an NIH-funded 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 a conflicting interest that was not managed or reported by Aquora as required by the regulation, the Institution must require the Investigator(s) involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.