

AmebaGone Inc. (AG) Company Policy – Financial Conflict of Interest (FCOI) Policy, updated 2/5/2021

Objective research is of paramount importance to AG and our subgrantees and defined vendors herein, to ensure public trust and meet scientific, program and ethical goals of our National Institutes Health (NIH) grant efforts. To address the increasing complexities related to financial interests held by biomedical and behavioral researchers, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) has published their final rules. AG believes we have fully addressed the requirements (including those of our defined sub-level vendors) of this ruling although we will continue to update this policy as needed, particularly related to any changes in personnel FCOI issues or upon further DHHS guidance.

AG's policy requires that each investigator, subrecipients, subgrantees and collaborators affiliated with AG, by NIH 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). In addition, this legislation spells out NIH's commitment to preserving the public's trust that the research supported by them is conducted without bias and with the highest scientific and ethical standards. AG intends to use this same FCOI standard for all other Federal agency grant and contract efforts, as tailored or amended accordingly.

The following are key term definitions and AG's policy guidance for principal or program investigators, subrecipients, subgrantees and collaborators affiliated with AG. This policy and all FCOI AG guidance are also available at https://amebagone.com/files/FCOI_policy.pdf so that all interested parties, including the general public have access to this Company policy.

Investigator

An Investigator is any person (including subrecipients, subgrantees and collaborators) who is responsible for the design, conduct or reporting of research funded by PHS.

Training Requirement

1. AG and non-AG key research personnel will receive training on this material at time of implementation and whenever this policy is updated.
2. The training must be updated no-less than every four years or as designated based on grant or role circumstances. Information and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site. (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>).

3. New key research personnel will receive training as part of their orientation.
4. Training will be conducted immediately if this policy is revised and affects the requirements of Investigators, an Investigator is new to an Institution or if an Investigator is not in compliance with the policy or management plan.

Significant Financial Interest (SFI)

Significant Financial Interest is defined by the regulations as:

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 reasonable appears to be related to the Investigators institutional responsibilities:

- 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. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations 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 interests (e.g., stock, stock options, or other ownership interest) or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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, medical center, or research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the

duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

3. The term significant financial interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership 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 retirements 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 an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for 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.

Financial Conflict of Interest (FCOI)

A Financial conflict of interest exists when AG reasonably determines that a Significant Financial Interest (defined above) could directly and significantly affect the design, conduct or reporting of NIH-funded research.

Management of a FCOI

Means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information. The Management Plan must include the following:

- The role and principal duties of the conflicted Investigator in the research project
- Conditions of the management plan
- How the management plan is designed to safeguard objectivity in the research project

- Confirmation of the Investigator's agreement to the management plan
- How the management plan will be monitored to ensure Investigator compliance
- Other information as needed

PHS Awarding Component

The PHS awarding component is any sub-agency of the Public Health Service or Department of Health and Human Services.

Consortiums

- Consortium agreements of subcontracts will be modified to accept this policy or to reference an institutional FCOI policy that will be maintained and enforced
- If the subrecipient chooses to accept this policy, a Consortium Agreement will include a requirement to solicit and review subrecipient Investigator disclosures that enable AG to identify, manage and report identified FCOIs to the NIH
- If the subrecipient chooses to use its institutional FCOI policy, the subrecipient will provide a certification that its FCOI policy complies with the regulation. In addition, the institutional FCOI policy must report identified FCOIs for its Investigators in a time frame that allows AG to report identified FCOIs to the NIH as required by the regulation
- Most commonly AG collaborates with the University of Wisconsin-Madison, and their policies can be found below at:

<https://policy.wisc.edu/library/UW-4001>

<https://research.wisc.edu/wp-content/uploads/sites/2/2021/01/Conflict-of-Commitment-Policy.pdf>

<https://policy.wisc.edu/library/UW-4002>

Disclosures/Reporting Process

AG's designated official will review all disclosures and evaluate whether they contain any FCOI. If no FCOI is found the "disclosure forms" will be filed in the SFI binder. If a FCOI is identified, it will be put on the FCOI report through the eRA Commons FCOI module prior to expending any funds. If any interests are identified as conflicting subsequent to the initial report, they must be reported to AG within 30 days. AG will then report it to the PHS awarding component that has issued the award within 60 days. Each investigator must submit an updated disclosure of an SFI not less than annually. If a PHS-funded project is conducted by an investigator or SO with a conflict that was not disclosed or managed, AG is required to disclose the conflict in each public presentation related to the results of the research.

Records Management

The records of all financial disclosures and all actions taken by AG will be maintained for at least three years from the date of submission of the final expenditures report.

Research

PHS research is any project governed by PHS regulation but excluding applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Compliance and Penalties for Non-Performance

If an investigator fails to comply with AG's FCOI policy, within 120 days, AG shall complete a retrospective review of the Investigator's activities to determine bias. If a bias is found, AG shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions it has taken to mitigate the bias. AG will work with the Investigator to set up an FCOI management plan to mitigate the situation. Companywide, AG is required to mandate the Investigator disclose the FCOI in each public presentation with research results if it was not reported up front. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.