



Thermaquil, Inc.
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Thermaquil Financial Conflict of Interest Policy

Preamble

Thermaquil, Inc. requires that each investigator, subrecipient, subgrantee and collaborator affiliated with grants or contracts funded by NIH or other US government programs, be in compliance with 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" and 45 CFR 94 regarding grants and cooperative agreements. Thermaquil holds the same values as NIH regarding the criticality of preserving the public's faith that all research, including NIH-funded research, is conducted without bias and with the highest scientific and ethical standards.

Policy Scope

This policy applies to individuals who are responsible for the design, conduct or reporting of research funded by the Public Health Service (PHS), which includes the National Institutes of Health (NIH), or proposals for such funding.

If a research project involves subcontractors, subgrantees, or sub-awardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Institute of Health (NIH) funds be subcontracted by Thermaquil to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

Failure to comply with this policy may result in disciplinary action up to and including immediate for-cause termination of employment and/or advisory/consulting agreements.

Definitions

Financial Conflict of Interest means a Significant Financial Interest (as defined below) related to a research program or project that could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.



Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's spouse and/or dependent children, 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 paid to the Investigator if the Investigator is currently employed or otherwise appointed by the institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by a 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;
- 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; or
- e) income from service on advisory committees or review panels for a federal, state or local government agency an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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 means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities (and/or those of the Investigator's spouse and/or dependent children), 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 (e.g., patents, trade secrets and copyrights) rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities, such disclosures including at a minimum: the purpose of the trip, the destination, the duration, and, if known, the monetary value.

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 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.

Conflict of Interest Policy

Any Thermaquil employee meeting the definition of Investigator must disclose all significant financial interests (SFIs) that are relevant to their research responsibilities, within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has been eliminated. All Thermaquil employees that meet the definition of Investigator are required to complete the disclosure form annually, even if they have no financial interest to report.

Investigator Responsibilities. Investigators are required to disclose all Significant Financial Interests and provide updates to disclosed information as needed, complete the



annual disclosure form even if they have no financial interests to report, and complete all required training and education. If acting as the PI/PD, Investigator will provide a list of individuals who meet the definition of “Investigator” and any other requested information within the required disclosure timeline. Reports of financial conflicts of interest shall be submitted to Thermaquil within the requested disclosure timeline. Any interests that arise or are eliminated subsequent to the initial report must be reported to Thermaquil within 30 days of such an event.

Training Requirements. The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education on what constitutes financial conflict of interest. This course is required for any individual meeting the definition of Investigator. As of September 2021, the course is accessible at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html . Upon completion of the training, the certificate of completion must be submitted to Thermaquil’s President or other appointed Signing Official. This training is required prior to engaging in research relating to any NIH-funded grant awarded to Thermaquil, or as deemed necessary by the Company due to changes in the FCOI policy, whether the changes are initiated by Thermaquil or by the federal government, upon any determination of non-compliance of the Investigator/Key Personnel or newly hired or contracted by Thermaquil and meeting the definition of Investigator. At a minimum, the FCOI training shall be taken every four years.

Financial Conflict of Interest (FCOI) Review and Decision. An FCOI exists when Thermaquil reasonably determines that a SFI could directly and significantly affect the design, conduct or reporting of PHS- or NIH-funded research.

Management of an 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.

Disclosures/Reporting Process. Thermaquil’s designated Signing Official will review all disclosures and evaluate whether they contain any FCOI. If no FCOI is found, the disclosure forms will be kept on file. If an FCOI is identified, the form 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 Thermaquil within 30 days. Thermaquil 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 whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment is conducted by an investigator or SO with a conflict that was not previously disclosed or managed, the Investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored research.



Reporting. Thermaquil will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:

Initial Report: Prior to expenditure of any funds under the NIH- or PHS-funded research project, Thermaquil will provide a FCOI report regarding any SFI found to be a FCOI. Thermaquil will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project, or when Thermaquil identifies a FCOI not previously disclosed. The report will include information mandated by PHS guidelines, including Grant/Contract Number and its Principal Investigator, the Name of Investigator with the FCOI, the nature of the FCOI and its value (or relevant description in cases where value cannot be readily defined), a description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research, and key elements of the FCOI action plan.

Annual updates will be submitted to the PHS Awarding Component for the duration of the research project, describing the status of the FCOI, and, as necessary, updates to the action plan or justification that an FCOI no longer exists.

Records Management and Confidentiality. The records of all financial disclosures and all actions taken by Thermaquil will be maintained for at least three years from the date of submission of the final expenditures report. Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

Compliance and Penalties for Non-Performance. If an investigator fails to comply with this FCOI policy, within 120 days, Thermaquil will perform a retrospective review of the Investigator's activities to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research. If a bias is found, Thermaquil will develop an FCOI management plan to mitigate the situation, and will report to the NIH, in accordance with 42 CFR 50.605(b)(3), the impact of the bias on the research project and the actions taken to mitigate the bias. In extreme cases of bias, the Investigator may lose the right to work on the project or receive any future NIH funding.

Public availability of FCOI procedure and information. While Thermaquil does not have a public-facing website, requests for copies of this policy document should be directed to Thermaquil's Point of Contact (below), who will provide a copy within 5 days of receipt of request. Thermaquil will arrange for a link to this document within 30 days of establishing a public website. As required by 42 CFR 50.605(a)(5)(i)-(iv), Thermaquil will make the following information publicly accessible, either by direct request or via the



website (once available): information concerning identified FCOIs held by senior/key personnel, which will be updated at least annually or within 60 days of identification of a new FCOI; such information to remain available for 3 years.

Point of Contact. Questions, comments and submission of forms and training records should be directed to Stephen Popielarski, Thermaquil's Signing Official at info@thermaquil.com.

Approved by:

Stephen Popielarski, PhD

President and CEO

Thermaquil Inc.

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