

2022 printing svg file-001	PhotoSound Technologies, Inc. QUALITY SYSTEM POLICY	Revision A
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INTRODUCTION

THIS POLICY IS TO ESTABLISH A MEANS OF ADDRESSING *FINANCIAL CONFLICTS OF INTEREST* (FCOI) AT PROTOSOUND TECHNOLOGIES, INC.– PhotoSound Technologies, Inc. (PST) is constantly concerned with conducting business in a fair and equitable manner. Not only is it important for PST to create and maintain an atmosphere of high ethical standards within the company, it is also critical that the same high standards are always presented to our investors, sponsors, and customers. In particular, when PST is taking part in research it is critical that there is no actual or perceived bias introduced in the design of the research protocols, the execution of the research, or the analyses of the resulting data, that would jeopardize the value of that research.

To this end, it is the goal of PhotoSound Technologies to provide financial transparency that will ensure the integrity of research. This policy is based on the regulations established in the U.S. Code of Federal Regulations for research sponsored by grants, and in particular grants from the National Institutes of Health (NIH), part of the Public Health Service (PHS) as of 2011. It is also to be used for all other sponsored or contracted research done by PhotoSound, including that which may be done to create Intellectual Property.

PhotoSound Technologies does not take part in clinical studies and therefore has not made any effort to include provisions for clinical studies in this policy at this time.

DEFINITIONS, for the purpose of this policy:

“**Compensation**” means any remuneration, including, without limitation, salary and payment for services not otherwise identified as salary such as consulting fees, payment of personal travel expenses, honoraria, and paid authorship.

Specific exclusions are:

- Salaries, royalties and remunerations normally paid to an employee.
- Payments from PhotoSound derived from royalties and fees paid by third parties to PhotoSound for IP owned by or assigned to PhotoSound
- Mutual funds or retirement accounts, as long as the investigator does not have any control of them.
- Income from seminars, lectures and courses conducted at the direction of PhotoSound
- Income from advisory committees or review panels sponsored by a local, state, or Federal government or an affiliated research institute.

“Conflict Management Plan” means a written plan instituted by the PhotoSound for the management, reduction or elimination of a Financial Conflict of Interest.

“Consortium” means an association of two or more individuals, companies, or organizations participating in a research project.

“Disclosure of significant financial interests” refers to the investigators’ disclosure to PhotoSound of Significant Financial Interests (SFI) which could create a bias in the design, conduct, or reporting of research.

“Financial Conflict Of Interest” (FCOI) means a significant interest that could directly and significantly affect the design, conduct, or reporting of research.

“FCOI” report means an institution’s report of a financial conflict of interest to a PHS Awarding Component

“Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable.

“Gift” means anything of economic value but for which no consideration is given.

“HHS” means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

“Information Technology” (IT) means the collection, security, and dissemination of data related to a research study.

“Innovator” means any PhotoSound employee, consultant or subcontractor, regardless of title or position, who has created in whole or in part any Intellectual Property in which PhotoSound has any right or interest.



“Institution” means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, research funding.

“Institutional responsibilities” means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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.

“Investigator” means any PhotoSound employee consultant, or subcontractor, regardless of title or position, responsible for the design, conduct, or reporting of PhotoSound research. Investigator includes, but is not limited to, the Principal Investigator, project director, co-principal investigator, and may also include other Senior/Key Personnel, interns or trainees, staff members, collaborators, or consultants, IT personnel, depending on the person's role in the Research. The primary factors to be used in determining who is an Investigator are the significance of the tasks assigned to the individual with regard to the design, conduct and reporting of the Research and the degree of independence that individual may have in performing such Research-related tasks.

“Manage” means taking 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.

“PD/PI” means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

“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 involved may be delegated, including the National Institutes of Health (NIH).

“Public Health Service” (PHS) means the Public Health Service of the U.S. Department of Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, Food and Drug Administration, and all of their constituent agencies.



“Public Health Service Act” or PHS Act means the statute codified at [42 U.S.C. 201 et seq.](#)

“Regulation” refers to 42 CFR Part 50 Subpart F, “Promoting Objectivity in Research, which applies to both grants and cooperative agreements.

“Remunerations” means salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship). Equity includes any stock, stock options, or other ownership interests.

“Report” refers to PhotoSound’s report of identified FCOIs to the funding entity.

“Research” means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional 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 the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

“Significant Financial Interest” (SFI) means 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:

- 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 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 includes any stock, stock option, or other ownership interest, as determined through reference to public prices or 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 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
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Sponsored Travel - 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, a medical center, or a 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 an FCOI with the PHS-funded research.

Excluded from SFIs are the following types of financial interests:

- Salary, 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 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, 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

- 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.

“Small Business Innovation Research” (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

“Subrecipient” means non-PhotoSound entities who may indirectly receive funds from PhotoSound for sponsored research, such as subgrantees, contractors, subcontractors, consortium partners, collaborators, or consultants.

“Technology Transfer Transaction” means a transaction through which the PhotoSound conveys or transfers or negotiates to convey or transfer a PhotoSound Intellectual Property right to a third-party

POLICY

PhotoSound Technologies, Inc. shall institute and maintain a plan to ensure that there are no financial conflicts of interest (FCOI) associated with the investigators who design, conduct, or report on scientific research. This policy will be directed at sponsored research but shall also apply to any research that is intended for publication and which are intended to support and promote the efforts of PhotoSound.

RESPONSIBILITIES

This policy applies to all investigators, whether principal-investigator (PI) or co-investigator or not. Others who must be considered for inclusion are Project Directors (PD), study coordinators, IT personnel, senior or key PhotoSound personnel, statisticians, collaborators, consultants, contractors, subcontractors, and those responsible for procurement for research projects. It may also apply to those involved with Technology Transfer Transactions.

IN GENERAL.....

PhotoSound Technologies (PST), as a company, is responsible for:

- Creating, maintaining, and enforcing this policy
- Making this policy accessible to the public, either on the PST website or within 5 working days of a request.
- Making this policy and the associated regulations known to all employees via training, including their responsibility for observing it. In particular such training for investigators must be completed prior to conducting research and no less that every four years.
- Training must occur for all investigators whenever PhotoSound revises this policy or any associated procedures or if it is found that an Investigation is not in compliance with this policy or an associated conflict of interest management plan.
- Ensuring that this policy is observed for all research activities, whether funded or not.
- Identifying PhotoSound officials to solicit and review disclosures from investigators who will, or plan to, take part in funded research. These will be referred to as Designated Officials.
- Ensuring that disclosures of SFIs are submitted initially and every year thereafter.
- Providing guidelines for determining whether an investigator's SFI is related to the funded research and determining whether the SFI is an FCOI.
- Completing and documenting retrospective reviews when bias is found, including the development and submission of a Conflict Management Plan.
- Making all SFI and FCOI information available to the sponsoring organization immediately upon request.
- Ensuring that subrecipients observe the requirements of this policy, including any management plans associated with their involvement.
- Providing initial and annual FCOI reports to sponsors.
- Establishing adequate and appropriate enforcement mechanisms, employee sanctions, or other administrative actions to ensure investigator compliance.
- Managing the timely FCOI reports and actions of subrecipients to a sponsoring organization.

IN PARTICULAR.....

The Chief Executive Officer (CEO) of PhotoSound is responsible for the overall implementation and execution of the FCOI policy.

Designated Officials (DO) may be assigned by the CEO to ensure the proper execution of this FCOI policy. The DO is responsible for the solicitation and review of disclosures of Significant Financial Interests from each investigator who is participating in, or planning to participate in, research, and the subsequent certification of those investigators. The DO will determine who should be allowed as an investigator for each study. The DO will determine if any SFI creates an FCOI; if there is an FCOI, the DO will determine if it can be resolved or mitigated and will formulate and manage a Conflict Management Plan when necessary for the mitigation. The DO will report the status of the operation to the CEO of the FCOI monthly.

The DO will determine that an SFI is related to the funded research if the DO finds that the SFI could be affected by the funded research, or that the SFI is in an entity whose financial interest could be affected by the research.

An FCOI exists when the DO reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of funded research.

Principal Investigators (PI) will be approved by the DO and will be responsible for conducting the research, including establishing study protocols, selecting researchers for the study, and formulating the analysis of the data.

All Investigators, and other entities that may conduct research or assist with the conduct of research, are responsible for the integrity of the data in accordance with their assigned role in each study. They are also responsible for disclosing their initial Significant Financial Interests and for disclosing changes to those disclosures. They must:

- Follow PhotoSound's FCOI policy
- Complete the PhotoSound training for this policy,
 - o Whenever this policy is changed or updated
 - o Upon joining PhotoSound as an employee
 - o If and when an investigator is not in compliance with this policy or an FCOI management plan
- Submit a disclosure form showing their known Significant Financial Interests as well as those of their spouse or domestic partner and their dependent children.

Subrecipients must, in a written agreement, show that they have an appropriate FCOI policy that they will follow, or that they will observe the requirements of the PhotoSound policy. The agreement must specify the time periods for the subrecipient to report all identified FCOIs and related actions to PhotoSound. The time periods must allow enough time for PhotoSound to comply with its review, management, and reporting obligations.

CERTIFICATE OF COMPLIANCE

At the time PhotoSound applies for funding, PhotoSound will provide certification that it has an up-to-date, written, and enforced administrative policy and process to identify and manage FCOIs with respect to all research projects for which funding is sought or received. The certification will also state that it promotes and enforces investigator compliance with all regulatory requirements including those pertaining to the disclosure of SFIs, and that it manages all FCOIs and reports them to the sponsor organization as required. This certification will state that PhotoSound will comply with all required regulations, including consent to promptly making information available regarding disclosures, SFIs and determinations of FCOIs and plans for their mitigation.

This certification may be via the Registry for FCOI Certified Entities:

<http://thefdp.org/default/fcoi-clearinghouse/>

All consultants, contractors and subcontractors shall provide evidence that they have been certified in FCOI to the same or greater degree than that stated in this policy. If there is no such certification, they shall agree to become certified under this PhotoSound policy.

There shall be a record maintained by the Designated Official that show, as a minimum, the name of each individual who has been certified, when the certification was last updated, and which research projects were involved. It shall also record the training of each employee who may be involved with research.

TRAINING

All PhotoSound personnel who may be involved with the design, execution, or reporting of research must receive training in this policy as evidenced by records of training maintained by PhotoSound. These records will state that the individual has read and understood this policy, and has viewed the NIH FCOI Tutorial, https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html or an equivalent tutorial as applies to PhotoSound Technologies.

DISCLOSURE

A Disclosure form must be used for stating all SFIs and will include detailed instructions. The disclosure must include, as a minimum:

- Investigator information: Name, email address, phone number, department
- FCOI Training certification
- Funding agency identification
- Reason for the disclosure
- Income/Equity Interest (Publicly Traded) in excess of \$5,000
- Income/Equity Interest (Private) in excess of \$5,000
- Intellectual Property Rights and Interest in excess of \$5,000
- Travel Expenses in the past 12 months
- Travel Expenses anticipated in the next 12 months
- Management/Control/Consulting related to an outside entity

A disclosure must be submitted when the person is identified as a potential investigator, and then maintained in accordance with this policy, even if there is not an awarded research project.

DISCLOSURE REVIEW PROCESS

All disclosure forms must be reviewed and approved by the Designated Official. If it is determined by the DO that there is, or may be, an FCOI, the DO will determine the extent of the conflict and then create a Management Plan to mitigate the effects of that conflict.

CONFLICT MANAGEMENT PLANS

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts.

NON-COMPLIANCE

Disciplinary action may be required in severe cases of non-compliance and may range from a reprimand to the personnel folder of the person responsible, to terminating that employee. The research must be evaluated to determine if the integrity of the data may actually be biased, or if the integrity of the data could be perceived to be biased thus calling into question whether the results are useful.

If PhotoSound determines that a FCOI was not identified and addressed in a timely manner, PhotoSound will conduct a retrospective review of the investigator and the research to determine if there was bias in the design, conduct, or reporting of the research. This review will contain, as a minimum:

- Project name
- Project title
- Contact PD/PI
- Name of the investigator with the FCOI
- Name of the entity with which the investigator has a financial interest
- Reason for the retrospective review
- Detailed methodology used for the review (e.g. the method of the review process, the panel members, the documents reviewed)
- Findings of the review, and
- Conclusions of the review.

REPORTING

Prior to spending any awarded funds, PhotoSound shall submit an FCOI report to the funding organization showing any identified FCOIs of each investigator and how each FCOI is managed, both within PhotoSound and for any subrecipient investigators. If an FCOI is eliminated prior to the submission of the initial report, that FCOI report will not need to be submitted.

An FCOI report must contain these elements:

- The project number
- The contact PD or PI
- The name of the investigator with the FCOI
- The name of the entity with which the investigator has the FCOI
- The nature of the financial interest, such as equity interest, consulting fee, travel reimbursement, honoraria

- The approximate dollar value of the financial interest, or a statement that the value cannot be reasonably established with public information.
 - o Permissible approximation ranges are: \$0 to \$5K, \$5K to \$10K, \$10K to \$20K, \$20K to \$100K in \$20K increments, and >\$100K in \$50K increments.
- A description of how the financial interest relates to the funded research and the basis for the determination that the interest conflicts with such research
- A description of the key elements of PhotoSound's management plan, including:
 - o The role and principal duties of the conflicted investigator in the project
 - o The conditions of the management plan
 - o How the management plan is designed to safeguard objectivity in the project
 - o Confirmation of the investigator's agreement to the management plan
 - o How the plan will be monitored to ensure investigator compliance
 - o Other significant information.

After funding has been awarded, and while the funded research is ongoing, PhotoSound shall submit an FCOI report to the funding organization for any FCOI that is discovered after the initial FCOI reports have been submitted. The report for the new FCOI must occur within 60 days.

If a DO fails to meet this 60 day rule, the DO must: Review the SFI to determine if it is related to the research, and then determine if an FCOI exists. If an FCOI exists the DO must implement, at least on an interim basis, a management plan specifying the action items that have, or will be, taken and submit a report to the funding organization. Within 120 days of the discovered non-compliance, the DO must conduct a retrospective review of the investigator's activities to determine if any funded research, or portion thereof, was biased in the design, conduct or reporting of that research. Based on the results of that review, the DO must update the previously submitted report specifying the actions items to manage the FCOI going forward.

At any time during the award, PhotoSound must notify the funding organization immediately when bias is found in the design, conduct, or reporting and conduct a retrospective review. PhotoSound must promptly notify of the results of the review including the mitigation report. The mitigation report must include the key elements documented in the review and a description of the impact of the bias on the research project including the actions taken to eliminate or mitigate the effects of the bias.

RECORD RETENTION

The following records must be retained for three years following the date on which the final expenditures are submitted to the sponsoring organization.

- Investigator disclosures of financial interests
- The review and response to these disclosures
- All actions resulting from the initial review or any retrospective reviews of these disclosures.

Additionally, information concerning identified FCOIs held by senior/key personnel will be made publicly accessible for three years from the most recent update.

PUBLIC ACCESSIBILITY

PhotoSound shall make this FCOI policy accessible to the general public by posting it, in its entirety, on the company website. This posting must occur with 30 calendar days of the awarding of the research funds. In the event that the website is not available or able to support this posting, PhotoSound shall have a secondary plan to make a written copy of the policy available within five working days of a request. Posted information must be updated no less than annually.

For senior/key personnel who are identified in the funding application, progress reports, or any other required reports, the SFI information that was disclosed and is still held by them must be made publicly available if PhotoSound has determined that the SFI is related to the funded research and PhotoSound has determined that the SFI is FCOI. The information must be made available by the PhotoSound website or by written response, as above. The posted information must include:

- The investigator's name
- The investigator's 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, such as equity interest consulting fees, travel reimbursement, honoraria, etc.
- The approximate dollar value of the SFI, or a statement that the value cannot be reasonably established with public information.
 - Permissible dollar ranges are: \$0 to \$5K, \$5K to \$10K, \$10K to \$20K, \$20K to \$100K in \$20K increments, and >\$100K in \$50K increments.

TIMING SUMMARY

1. FCOI Policy Accessibility
 - a. Made available within 5 working days of a request

- b. Or, on the company website, available to the general public within 30 calendar days of the awarding of funds for the research.
 2. Disclosure Form
 - a. For income within the 12 months prior to the disclosure date
 - b. Complete no later than the time of application for funded research.
 - c. Updated every 12 months during time of the award
 - d. Updated within 30 days of acquiring or discovering a new SFI, or a change to an SFI, such as due to marriage, divorce, purchase or inheritance.
 3. FCOIs
 - a. For senior/key personnel, FCOI information shall be made publicly accessible for three years after the most recent update.
 - b. Information for FCOIs must be available prior to the expenditure of funds
 - c. Information for FCOIs must be updated at least annually
 - d. All SFI and FCOI information must be made available to the sponsoring organization immediately upon request.
 - e. Information for newly identified FCOIs must be reported within 60 days of discovery
 - f. If the 60 days rule is not met, a retrospective review must be made and the results reported within 120 days of the determination of non-compliance
 - g. If bias in a research project is discovered, it must be immediately reported to the funding organization.
 - h. Subrecipients must agree in writing to adjusted time periods to allow for processing by PhotoSound within the funding organization's requirements.
 4. Training
 - a. Immediately after this policy is revised
 - b. Immediately after a new investigator is identified.
 - c. Immediately when an investigator is found to be not in compliance with this policy or a management plan.
 - d. Prior to funded research
 - e. Every 4 years

RELATED RESOURCES

Code of Federal Regulations, Title 42 - Public Health, Chapter 1 - Public Health Service, Department of Health and Human Services, Subchapter D - Grants, Part 50 - Policies of General Applicability, Subpart F - Promoting Objectivity in Research: https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#se42.1.50_1601

NIH Information Index: <https://grants.nih.gov/grants/policy/coi/index.htm>

NIH Tutorial on

FCOI: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Registry for FCOI Certified Entities: <http://thefdp.org/default/fcoi-clearinghouse/>

FORMS

Sample Disclosure and Training Form:

<https://fcoi.llnl.gov/content/pages/docs/LL6494.pdf>

PhotoSound FCOI Disclosure Form, 2022-002

PhotoSound Certificate of FCOI Training



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	Created by	Approved by
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