

Giner, Inc. Financial Conflict of Interest Policy

The purpose of this policy is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest (FCOI) to safeguard the integrity of Giner, Inc.'s (Company) research and to comply with federal regulations.

Federal regulations require all institutions applying for or receiving research funding from a federal agency to maintain a financial conflict of interest policy. The goal of this policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under any federal grants, contracts and cooperative agreements will be biased by any conflicting financial interest of an Investigator (defined below). This policy has been developed to address and comply with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

DEFINITIONS

The following definitions apply to this policy:

Company means Giner, Inc. and all wholly owned subsidiaries.

Employee refers to any person that is receives a W-2 from Company and is thus deemed to be employed by Giner, Inc. This includes part-time and full-time personnel. An Employee may also hold the designation of an Investigator and/or a Senior/Key Personnel.

Employee's Company Responsibilities means an Employee's professional responsibilities on behalf of the Company which may include but are not limited to: activities such as research, development, design, testing, research consultation, teaching, professional practice, Company committee memberships, and service on panels such as Company Review Boards or Data and Safety Monitoring Boards.

Grantor means any federal funding source such as NIH, NSF, DOD, DOE or other public/private partnerships where public funds are granted and used to support research being conducted by an Investigator, Subrecipient or Company for commercial purposes.

Investigator means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Grantor, or proposed for such funding, which may include, for example, collaborators or consultants known herein as a ***Subrecipient***.

Senior/Key Personnel means the Program Manager or Principal Investigator and any other person identified as senior/key personnel by the Company in the grant application, progress report, or any other report submitted to the Grantor by the Company under the regulation.

Significant Financial Interest (SFI) is a financial interest consisting of one or more of the interests of the Employee (and those of the Employee's spouse and dependent children) that reasonably appears to be related to the Employee's Company Responsibilities. SFIs are defined below.

Subrecipient refers to any Investigator that is not considered an Employee, including collaborators such as subcontractors and consultants.

SIGNIFICANT FINANCIAL INTERESTS

Financial interest of the Employee (and those of the Employee's spouse and dependent children) that reasonably appears to be related to the Employee's Company Responsibilities.

I. Financial Interests that are considered SFIs

a) Remuneration, Equity Interests and Intellectual Property Rights

With regard to any publicly traded entity or any non-publicly traded entity a significant financial interest exists:

- 1) *Remuneration*: if the value of any remuneration received from the entity in the twelve months preceding the 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);
- 2) *Equity*: when the Employee (or the Employee's spouse or dependent children) holds any equity interest including any stock, stock option, or other ownership interest, that when aggregated, exceeds \$5,000 as of the date of the disclosure as determined through reference to public prices or other reasonable measures of fair market value;
- 3) *Intellectual property rights and interests* (e.g., patents, copyrights): upon receipt of income related to such rights and interests that exceeds \$5000.

b) Reimbursed or Sponsored Travel

Employees must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Employee and not reimbursed to the Employee so that the exact monetary value may not be readily available), related to their research and job responsibilities at Company, 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.

II. Financial Interests that are not considered SFIs

- a) Salary, stock options, intellectual property, retirement accounts and/or royalty payments from Company.
- b) Income from investment vehicles such as mutual funds, retirement accounts, and 401K plans as long as the Employee does not directly control the investment decisions within the vehicle.
- c) Income from seminars, teaching engagements, or lectures, 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.
- d) Income from service on advisory committees or review panels 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.
- e) A non-Company equity interest that when aggregated for the Employee and the Employee's spouse and dependent children, meets both of the following tests: (1) does not exceed \$5,000 in value as determined through reference to market rates or other reasonable measures of fair market value, and (2) does not represent more than a five percent (5%) ownership interest in any single entity; or
- f) Salary, royalties or other payments from any public or nonpublic entity other than Company that when aggregated for the Employee and the Employee's spouse and dependent children over the next twelve months, are not expected to exceed \$5,000.

Financial Conflict of Interest (FCOI) exists when the Company's designated official(s) reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of Grantor-funded research. The regulations set forth herein and in 45 CFR § 50.F are used as guidance to determine whether an SFI is considered a FCOI.

EMPLOYEE OBLIGATIONS

To comply with federal law, federal regulation and the Company's Financial Conflict of Interest Policy, all Employees must perform the following tasks:

- 1) Complete FCOI training within 10 days of employment commencement.
- 2) Repeat FCOI training at least every two years.
- 3) Training must be completed immediately, if:
 - a) Company revises its FCOI policy in a manner that affects Investigator or Employee requirements;
 - b) Employee is not in compliance with the policy or management plan.
- 4) Disclose any SFI(s) using the SFI Disclosure form provided to you upon completion of training.
- 5) Provide an FCOI Compliance Certification form and update your SFI Disclosure form(s) if necessary at each of the following time points:
 - a) At the time of each new grant application for which Employee is listed as Key Personnel;
 - b) At the time of any new grant award or assignment to a new project where employee is an Investigator;
 - c) At least every year from the date of last disclosure;
 - d) Within 30 days of discovering or acquiring a new SFI.

All training certificates and disclosure forms should be submitted to the Company's designated official (listed at end of this document). If there is any uncertainty about what classifies as an SFI or if you have questions about our Company FCOI policy, please contact the Company's designated official. All Employees should use the Company designated official as a resource for questions pertaining to their own SFI reporting and to report any perceived SFI or FCOI throughout the company. In the latter case, the Company designated official will be responsible for follow-up.

The designated Company official will review and determine if there appears to be a potential financial conflict of interest. If so, then the designated FCOI committee will review the potential conflict of interest and initiate steps to manage, reduce and/or eliminate the conflict(s) as appropriate.

All Employees must comply with the Company's FCOI policy to reduce, manage, and/or eliminate all potential financial conflicts of interest. In the event an FCOI is present or there has been noncompliance of the FCOI policy, the Employee must cooperate with the management plan set forth to remedy the FCOI or noncompliance. The Company may consult outside legal counsel with FCOI expertise for the evaluation of potential FCOI and FCOI management plans.

Confidentiality. Except to the extent required by law and federal regulations, the information disclosed will be kept confidential, released internally only on a need-to-know basis to those evaluating the FCOI and/or implementing an FCOI management plan. You should know, however, that the Company is required to report the existence of real or potential conflicts of interest to certain federal agencies. Specifically, the NIH (PHS) requires companies to report to the PHS the existence of any conflicting interests and to assure that the interest has been managed, reduced or eliminated. NSF requires that only conflicts that have not been managed, reduced or eliminated prior to the expenditure of funds under an award be reported to NSF. In addition, there is federally mandated public accessibility to some information as described in this policy under *Public Accessibility*.

Employee Forms. Attached to this FCOI policy are four forms to be used by Employees to meet their Employee obligations: 1) FCOI POLICY ACKNOWLEDGEMENT; 2) FCOI TRAINING ACKNOWLEDGEMENT; 3) FCOI COMPLIANCE CERTIFICATION; 4) SFI DISCLOSURE FORM.

COMPANY'S OBLIGATIONS

Policy Creation

Federal Regulations require that Company develop, maintain, and enforce a financial conflicts of interest policy in order to discover and manage any financial conflicts of interest in ongoing research programs. Company is required to inform all Employees of this policy and appropriately train and enforce this foregoing FCOI policy for all Employees.

Company FCOI Policy and FCOI Training

Every new Employee must be provided a copy of this policy and training materials within 5 business days of start date. The Employee must complete training and submit the training certificate to the designated Company official within 10 business days. The Employee must also sign that they have received, read and understood the Company FCOI policy within 10 business days of start date. These certificates must be filed in the Employee's record until updated certificates are received.

Training must be completed and a new training certificate must be filed at the following times:

- 1) Within 10 days of start date.
- 2) At least every two years;
- 3) If the Employee is ever not in compliance with the policy or management plan.

A training presentation prepared by the NIH that covers the basics of the federal regulations pertaining to financial conflict of interest and federal grants can be found at

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Review of this presentation and completion of the certificate will serve as the Company training.

The Employee must recertify that that have received, read and understood the Company FCOI policy, whenever Employees are notified of a revision that affects employee responsibilities.

Disclosures, Review, Management and Monitoring SFI

Company must collect FCOI compliance certification and any corresponding SFI disclosure form(s) from every Employee after completion of training and within 30 days of employment commencement. A separate SFI disclosure form (attached) is required for each entity in/with which the Employee holds an SFI. It is the responsibility of the designated Company official to ensure he/she receives the disclosure forms from each Employee upon the respective due dates as designated above.

The disclosure forms should be collected by the designated Company official and reviewed for potential conflict of interest within ten (10) business days of receipt. The designated official must sign the original SFI disclosure form to signify his/her review. If the designated Company official is made aware of a potential FCOI, he/she will bring it to the attention of the President. At that time, a review committee will be selected by the designated official and President to consist of at least 2 additional unbiased personnel (such as Employees at the VP or Director level) to review the SFI. The review committee (designated official and/or President and 2 additional committee members) will meet to discuss and determine whether or not the SFI represents a FCOI within fifteen (15) business days from the submission of the disclosure form.

If it is determined that an FCOI exists, a management plan must be developed by the review committee to report, manage and/or eliminate the conflict of interest within sixty (60) days. This management plan must be shared with the Employee, Investigator or Subrecipient along with a list of tasks and/or sanctions to resolve the conflict of interest. The review committee must meet at least monthly to ensure the management plan has been appropriately executed until the conflict is being managed or resolved according to the management plan. The Company may consult outside legal counsel with FCOI expertise for the evaluation of potential FCOI and FCOI management plans. Management plans may include public disclosures of FCOI at each public presentation of the results or research, in conformance with requirements of the organizers of the public presentation.

Company will comply with federal agency requests to make information available about any conflicts of interest and how they have been managed, reduced, and/or eliminated.

Reporting

Company is willing to certify in each application for research funding from federal agencies the existence of this policy and to identify any existing conflicts of interest and assure that they have been managed, reduced and/or eliminated upon request of the Grantor. Company also agrees to report any conflicting interests (FCOIs) to the appropriate federal agency through its required procedure at the following time points:

- 1) prior to expenditure of any grant funds;
- 2) within sixty (60) days of any new conflicts of interest that become apparent after the initial report to the relevant federal agency;
- 3) within sixty (60) days of the identification of a new Employee or Investigator participating in the research project;
- 4) at any additional time point requested by the Grantor.
- 5) following a retrospective review to make appropriate changes to the previously submitted report. If applicable, a mitigation report must be filed when bias is found as a result of a retrospective review.

Company is required to submit all FCOI reports to the Grantor through the Grantor's required procedure. For the NIH, this is through the eRA Commons FCOI Module.

Maintenance of Records

Company shall keep all FCOI-related documents including the review and response to each SFI disclosure on file for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53 (b) and 92.42 (b) for different situations.

Enforcement Mechanisms and Remedies and Noncompliance

Federal regulations require Company to impose sanctions where appropriate. Company maintains the right to impose sanctions on Employee for failure to disclose SFIs within the time frames specified in this policy and for failure to abide by this policy. Sanctions may include restrictions on future submission of research proposals, change of work responsibilities while delinquent SFI and/or FCOIs are evaluated, and other disciplinary actions up to and including dismissal.

If it has been determined that an Employee, Investigator or the Company is in noncompliance with this policy (e.g., SFIs not disclosed, reviewed or managed in a timely or appropriate manner), then Company must complete and document a retrospective review within 120 days. The retrospective review should be conducted by the SFI disclosure review committee as designated by the President and designated Company official. The results of the retrospective review shall be documented and attached to the disclosure documents. If bias is found, Company must immediately notify the Grantor by submitting a mitigation report.

Company must enforce any sanctions or actions required by the Department of Health and Human Services pertaining to a PHS-funded research project involving clinical research. If an FCOI was not reported or managed according to regulations for a project whose purpose is to evaluate safety or effectiveness of a drug, medical device, or treatment, then Company must require the Employee or Investigator to disclose the FCOI in each public presentation of the results or research and request an addendum to previously published results or presentations.

Subrecipient Requirements

If a Subrecipient is not employed by Company then they may comply with their institution's FCOI policy provided that their institution has a suitable policy in place and that they supply Company with the necessary disclosure information to meet all reporting obligations and deadlines. Prior to the Subrecipient's participation in the research project, they must certify that their institutional FCOI policy complies with regulations. If the Subrecipient's institution does not have a suitable FCOI policy in place, then they shall adhere to this policy set forth for Investigators of this Company. The Subrecipient must agree in writing to comply with the Company FCOI policy and to provide the required information to Company.

Public Accessibility

This FCOI policy is publicly available on our website at www.ginerinc.com. Information regarding FCOIs must be accessible upon written request within five (5) business days. Requests can be made by mail to “FCOI Administrator, Giner Inc., 89 Rumford Ave, Newton MA 02466” or by email information@ginerinc.com with the subject line “FCOI information request”. Requests for information that meet these three criteria in federal regulations will be processed:

- 1) The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the government grant funded research project identified by the Company in the grant application, progress report, or any other required report submitted to the Grantor;
- 2) The Company has determined that the Significant Financial Interest is related to Grantor-funded research; and
- 3) The Company has determined that the Significant Financial Interest is a Financial Conflict of Interest.

The Company is required to submit to Grantor upon request all records pertinent to compliance with the public accessibility regulations.

RESOURCES

- 1) Designated Company Official
- 2) http://grants.nih.gov/grants/policy/coi/coi_faqs.htm (frequently asked questions)
- 3) <http://grants.nih.gov/grants/policy/coi/index.htm> (policy and guidance)
- 4) FCOICompliance@mail.nih.gov

Designated Company Official (as of 7/5/2016):

*Theresa Scavone
Controller
information@ginerinc.com
781-529-0500*

Company Administrator for submittal of forms (as of 7/5/2016):

Sage Wicinski

**FCOI POLICY ACKNOWLEDGEMENT
(MANDATORY FOR ALL EMPLOYEES)**

I acknowledge that:

- Giner, Inc. has provided me access to the Company FCOI policy.
- I have read, understood and had an opportunity to ask questions concerning this FCOI policy.

Check one:

- First reading of FCOI Policy as new employee
- First reading of FCOI Policy as Policy is introduced
- Repeated reading of FCOI Policy as Policy is updated

Print Name: _____

Signed: _____ Date: _____

**FCOI TRAINING ACKNOWLEDGEMENT
(MANDATORY FOR ALL EMPLOYEES)**

I acknowledge that:

- I have undergone the required FCOI training mandated in the current FCOI policy
- I have attached the appropriate training certificate(s)

Check one:

- First training as new employee
- First training as FCOI Policy is introduced
- Repeated training every two years
- Repeat training due to return to compliance with FCOI policy or an FCOI management plan

Print Name: _____

Signed: _____ Date: _____

FCOI COMPLIANCE CERTIFICATION

SCREENING QUESTIONNAIRE FOR SFIs		
Please check YES or NO for each of the following:	Yes	No
During the past twelve months , did you, your spouse, registered domestic partner, or your dependent children receive aggregated compensation – monetary or otherwise (e.g., consulting fees, honoraria, speaking fees, stipends, dividends, ownership interest, equity interest, stock, stock options and gifts)—exceeding \$5,000 in value from an external entity operating in areas relating to your responsibilities ?		
During the past twelve months did you, your spouse, registered domestic partner or your dependent children own any equity interest including any stock, stock option, or other ownership interest, that when aggregated, exceeds \$5,000 as of the date of the disclosure as determined through reference to public prices or other reasonable measures of fair market value related to your Company responsibilities		
During the past twelve months , did you, your spouse, registered domestic partner, or your dependent children receive income exceeding \$5,000 related to any interests or rights in intellectual property from an external entity related to your Company responsibilities ?		
During the past twelve months or in the next twelve months , did you participate in/do you plan to participate in any travel that was reimbursed or sponsored by an external entity operating in areas relating to your responsibilities ? Do not report travel reimbursed or sponsored by 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.		

Check one:

Based on the Company FCOI policy and the questionnaire above:

I **DO NOT** have new SFIs to report or existing SFIs to update

I **DO** have SFI(s) to report or update which are attached

Check one:

Occasion for recertifying my SFI disclosures are up to date:

Initial (start of FCOI policy)

Initial (new employee)

Submittal of grant application as Key Personnel: proposal # _____

New grant award or assignment to new project: grant # _____

Annual

New SFI to report

I hereby affirm that the above information (and the information contained in the attached statements, if any) is true to the best of my knowledge and that I will update promptly if my circumstances change.

Print Name: _____

Signed: _____ Date: _____

SFI DISCLOSURE FORM (one ENTITY per form)

Entity _____

Entity type _____
(e.g., energy, biomedical, service provider, or other)

Check one:

- List an SFI
- Update/edit an SFI
- Delist an SFI

1) Employee Significant Financial Interest as defined in FCOI policy
Include type of interest (renumeration, equity, intellectual property, travel), dollar amount, dates, and other details:

2) ALL open Federal Grants where employee is an investigator:

3) Explain any potential relationship between Employee, Entity and any Federal Grant for which employee is an Investigator: (e.g., vendor, subcontractor, potential investor)

4) If delisting an SFI, state reason: (e.g., equity sold)

I hereby affirm that the above information (and the information contained in the attached statements, if any) is true to the best of my knowledge and that I will update promptly if my circumstances change.

Print Name: _____

Signed: _____ Date: _____

SFI Review (Designated Company Official)

Check one:

- SFI is not deemed a FCOI with respect to any applicable grants
- SFI may be an FCOI with respect to grant(s) _____
and has been referred to FCOI committee for review on or before _____

Print Name: _____

Signed: _____ Date: _____