

Effective June 7, 2018

Investigator Financial Conflict of Interest Policy

Background: The Allen Institute is committed to promoting objectivity in **Research** and compliance with the Public Health Services (PHS) and National Science Foundation (NSF) regulations regarding the disclosure of Significant Financial Interests and the management of Financial Conflicts of Interests (**FCOIs**) affecting covered Research activities. We are implementing this policy to provide a reasonable expectation that the design, conduct and reporting of Research will be free from bias resulting from FCOIs as defined in the regulations. This *Investigator Financial Conflict of Interest Policy* describes circumstances that may lead to an Investigator FCOI and outlines how to disclose and manage these conflicts. This policy is intended to supplement existing Allen Institute policies relating to Conflicts of Interest (COI). All capitalized terms are defined in the [Definitions section](#).

Policy Statement: We are committed to conducting our Research with the highest level of integrity and complying with applicable laws and regulations. We promote the disclosure and management of FCOIs to minimize the possibility of bias and preserve the objectivity of Research. All **Investigators** must comply with this policy as a condition for submitting proposals and accepting awards for federal financial support and for being an Investigator for any Research activities at the Allen Institute.

Brief Summary for Investigators. As an Investigator, you have an obligation to be familiar with and abide by the provisions of this policy, which include:

- Timely completion of required FCOI training;
- Timely disclosure of Significant Financial Interests (“**SFIs**”); and
- Cooperating with the Institutional Official (“**IO**”) and **COI Committee** when you perform your duties under this policy.

Each of these requirements is described in further detail in the [Definitions section](#).

IO Responsibilities. The IO is responsible for soliciting and reviewing SFIs, creating **Management Plans** or other reports, resolving disputes, and managing policy violations. The IO may delegate responsibilities to a COI Committee, legal department member, or others as appropriate. The IO serves as the Chair of the COI Committee.

Investigator Training Requirements. You must complete the FCOI training offered by the Allen Institute prior to engaging in Research and retake it at least every 4 years. In addition, you must complete training within 30 days when this policy changes in a manner that affects your requirements as an Investigator or if you are not

in compliance with this policy or a Management Plan. The legal department will provide you with information regarding how to complete the required training, notify you when you are due to take training.

Required Disclosures by Investigators. Each Investigator is required to have an up-to-date disclosure on file prior to engaging in Research at the Allen Institute.

First Disclosure. Each Investigator must identify and disclose SFIs upon being hired or upon becoming an Investigator. When a proposal is being prepared for funded Research with the PHS (which includes NIH) or NSF, the individual serving as Principal Investigator must alert any other individuals who may meet the definition of Investigator of the need to comply with these procedures. New Investigators will then be prompted to complete training and to file this initial disclosure before the funded Research application is submitted.

Annual Disclosure. Each Investigator must re-verify and update the previously filed disclosure annually. This disclosure needs to include SFIs that were not disclosed previously and any updated information regarding previously disclosed SFIs. The legal department will prompt you to file this disclosure on an annual basis.

Updated Disclosure. To ensure that the disclosure on file is up-to-date, there are circumstances where you will need to proactively identify and disclose SFIs, rather than waiting to receive a prompt from the legal department to disclose. If you discover or acquire a new SFI during the course of the year (e.g., through purchase, sale, marriage, inheritance, or travel), or there has been a change to an SFI you have already submitted (e.g. in the value of the SFI, your **Institutional Responsibilities**, or the Research that may impact or relate to the SFI), you must update your disclosure within 30 days.

To file a new or updated disclosure go to the [Legal Intranet Page](#) to be linked to Convercent, our COI management software.

Disclosure Review and Management of FCOIs. The IO is responsible for reviewing disclosures, and may delegate such responsibilities to a COI Committee, legal department member, or others as appropriate. The purpose of the review is to determine whether a disclosed SFI is related to Research and, if so related, whether the SFI is an FCOI. If an FCOI does exist, then the IO will work with the Investigator(s) to develop a Management Plan. An SFI is related to Research when the IO determines that the SFI could be affected by the Research or is in an **Entity** whose financial interest could be affected by the Research. As the Investigator, you may be involved in this determination. An FCOI exists when the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Research. The IO may consult with or rely upon the determination of the COI Committee for review of disclosures.

COI Committee. If requested by the IO, the COI Committee may review disclosures in person, via email, or through other means. Decisions by the COI Committee will be by majority vote of COI members who are available to participate. Any COI Committee member who has a conflict related to the disclosure under review must disclose the conflict and excuse themselves from the discussion and vote.

FCOI in New Research. If the IO determines that there is an FCOI in new Research, the IO and/or the COI Committee will implement a Management Plan. If federal funds are involved in the Research, this review and implementation of a Management Plan, if necessary, must be done before expenditure of such funds.

FCOI in Ongoing Research. If the IO determines that there is an FCOI in ongoing Research after reviewing a disclosure from an Investigator new to a Research project or currently working on a Research project, the IO will implement, on at least an interim basis, a Management Plan that will specify the actions that we have taken or will take to manage the FCOI. Depending on the nature of the SFI, the IO may require additional interim measures with regard to your participation in the Research project between the date of disclosure and the completion of the IO's review. The review and implementation of a Management Plan, if necessary, must be done within 60 business days of the disclosure or discovery.

Federally Funded Research Specifics. While we apply this policy across all our Research, Research funded by the NSF or PHS has other specific requirements. When the Research is funded by the NSF or PHS and the IO or COI Committee determines that an FCOI exists, we will submit an **FCOI Report** to the **Awarding Agency** (or the NSF Office of the General Counsel if funded by NSF) prior to the expenditure of federal funds. The IO will implement a Management Plan and we will submit FCOI Reports annually, or as otherwise specified by the Awarding Agency. If an FCOI is identified and eliminated prior to the expenditure of funds, we do not need to submit an FCOI Report.

Reports to the Awarding Agency. If needed, we will adjust standard procedures to follow Awarding Agencies' policies or instructions on FCOI reporting. All FCOI Reports need to include sufficient information to enable the Awarding Agency to understand the nature and extent of the FCOI and to assess the appropriateness of the Management Plan. See the [definition below](#) for more information on what an FCOI Report needs to include. We will submit FCOI Reports in the manner specified by the Awarding Agency (1) prior to expenditure of any funds under a PHS-funded Research project and (2) within 60 days after any determination that you have an FCOI, whether you are an Investigator who is newly participating in a project or an existing Investigator who disclosed a new SFI during the period of award. Whenever you do not timely disclose a previously existing FCOI or the IO or COI Committee fails to timely review a previously existing SFI during an ongoing PHS-funded project, the IO must, conduct a review using the procedures detailed below in the [Retrospective Review section](#).

Updating Reported FCOIs. We will submit an annual FCOI Report to the PHS Awarding Agency for any previously-reported FCOIs for an ongoing PHS-funded Research project. The annual FCOI Report is a follow-up report to the initial FCOI Report and we must specify how we are still managing the FCOI(s) or explain why it no longer exists. This report is due to the Awarding Agency annually throughout the project period (including extensions with or without funds), even if you eliminate the FCOI during that time. It is submitted at the same time as the annual progress report, multi-year progress report (if applicable), or at the time of the extension.

Mitigation Reports. If the IO and/or COI Committee find bias during a Retrospective Review (as discussed [below](#)), we will notify the Awarding Agency promptly and submit a **Mitigation Report**. Thereafter, we will submit FCOI Reports annually as described above in *Updating Reported FCOIs*.

Awarding Agency-Requested Reports. At any time before, during, or after award, the Awarding Agency and/or **HHS** may inquire into any Investigator disclosure of SFIs and our review of, and response to, the disclosure, whether or not it was determined that an FCOI existed. We will submit, or permit an onsite review, of all pertinent records relating to the SFI review. The Awarding Agency may determine that an enforcement action is necessary until the matter is resolved.

Subrecipient FCOI Reports. FCOI Reports regarding all FCOIs of subrecipient Investigators will be submitted in the same format as ours, prior to the expenditure of funds, and within 60 days of any subsequently identified FCOI.

Failure to Disclose/Review; Retrospective Review; Mitigation Report.

Retrospective Review. Whenever the IO identifies any **Noncompliance**, the IO or its designee will complete a **Retrospective Review** within 120 days of determination of the Noncompliance and implement a Management Plan if an FCOI is found to exist (an interim plan can be used during the review). Following completion of a Retrospective Review, we will only submit a revised FCOI Report to the Awarding Agency if: (1) there is new FCOI information that results in a change to a previously submitted FCOI Report (e.g., an increase in value of a previously reported SFI, discovery of a new SFI, or changes to the management of the FCOI, etc.); or (2) the IO and/or COI Committee finds that the Research was biased by the FCOI and we need to submit a Mitigation Report. If the funder is a PHS Awarding Agency, we will update any previously submitted FCOI Report, if needed, specifying the actions that will be taken to manage the FCOI going forward based on the results of the Retrospective Review.

Mitigation Report. If the IO finds bias during a Retrospective Review, the legal department will notify the Awarding Agency promptly and submit a Mitigation Report, as described in the [Definitions section](#). After the Retrospective Review, we will update the FCOI Report, as applicable.

Subrecipient Requirements. A subrecipient is an individual or Entity that is conducting Research through an agreement with us and is paid for that Research with funds received by an Awarding Agency. We must take reasonable steps to ensure that all subrecipients that receive Awarding Agency funds from or through the Allen Institute comply with FCOI regulations. We will include any FCOI of a subrecipient in the FCOI Reports submitted prior to the expenditure of funds, and within 60 days for any subsequently identified FCOI.

Subrecipient following its own FCOI Policy. We require subrecipients who rely on their own FCOI policy to certify, as part of the subcontract with us, that their policy complies with the regulations. Subrecipients relying on their own FCOI policy must report all FCOIs to the Allen Institute within 45 days of discovery, or such other time period as specified in the subcontract. The Allen Institute, as prime recipient, must make an initial FCOI Report to the PHS Sponsor within 60 days of discovery. We will request that the subrecipient provide us with a copy of the Management Plan. The subcontract will include provisions requiring

subrecipients to comply with applicable regulations related to disclosure of SFIs and management of FCOIs consistent with federal requirements for covered awards, time periods to meet SFI disclosure to us, and/or FCOI reporting requirements, as applicable, and will set forth requirements to make any FCOI information publicly available pursuant to the [Public Accessibility](#) provision below.

Subrecipient using the Allen Institute's FCOI Policy. Our subcontracts require that if the subrecipient does not have its own FCOI policy (or it does not comply with the regulations), the Investigators are subject to this FCOI policy for disclosing SFIs that are directly related to their work on our Research project. We will send the subrecipient Investigator a copy of our policy, training information, the **Disclosure Forms**, and the disclosure summary. The subrecipient Investigator will follow the same disclosure schedule as us for the period of the subcontract.

Allen Institute as Subrecipient. We will certify that we follow our own written and enforced FCOI Policy when we are the subcontractor to another organization for an Awarding Agency's Research project. We will disclose any FCOIs to the prime awardee in accordance with the terms of the subcontract and in sufficient time for the prime awardee to report the FCOI to the Awarding Agency.

Violations of Policy.

PHS Remedies. If you fail to comply with this policy in a way that appears to bias the design, conduct, or reporting of Awarding Agency-funded Research, we must promptly notify the Awarding Agency of our completed or planned corrective action. The Awarding Agency will consider the situation and, as necessary, take appropriate action or refer the matter to us for further action, which may include directions on how to maintain appropriate objectivity in the Research project. The Awarding Agency may impose special award conditions, suspend funding, or take other enforcement actions until the matter is resolved. If HHS determines that a PHS-funded clinical Research project 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 an FCOI that was not managed or reported, the Investigator involved must disclose the FCOI in each public presentation of the results of the Research and request an addendum to previously published presentations.

Internal Remedies. In addition to any reports to or remedies required by the Awarding Agency, the IO will report an Investigator's violations of this policy or procedures to the COI Committee for appropriate action, which may include disciplinary action up to and including termination of employment, suspension of Research activities, and/or other remedies as appropriate to the violation.

Public Accessibility.

Policy on Website. This policy is available via our publicly accessible website.

Public Availability of Certain FCOI Information. Prior to the expenditure of funds for Awarding Agency-funded Research, we must ensure that information concerning any SFI disclosed to the Allen Institute that meets the following criteria is publicly accessible, via a publicly accessible website or written response within five business days of a request:

- The SFI was disclosed and is still held by the **Senior/Key Personnel**;
- The IO has determined that the SFI is related to PHS-funded Research; and
- The IO has determined that the SFI is an FCOI.

This information will remain publicly available for three (3) years from the date that we last updated the information.

SFI Information to Disclose. For each SFI that must be made publicly accessible, the following information will be included, either on the website or in response to a written request:

- Senior/Key Personnel’s name, title, and role with respect to the PHS-funded Research project;
- Name of Entity in which the SFI is held;
- Nature of the SFI;
- The approximate dollar value range of the SFI (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Updates to Publicly Accessible Information. Whether we provide this information through a website or through a written response, we will update the information at least annually and within 60 days of the IO’s receipt of identification of info concerning any additional Senior/Key Personnel SFIs that were not previously disclosed or are for Senior/Key Personnel new to the Research project, or in accordance with the requirements of the PHS Awarding Agency, whichever is more restrictive. When providing this information to the public, we will note that it is current as of the date listed (or the date of the correspondence in the case of a written response) and is subject to updates on at least an annual basis and within 60 days of our identification of a new FCOI, which should be requested subsequently by the requestor.

Scope: This policy applies to all Investigators at the Allen Institute, as well as applicable grant subrecipients (referred to as “you”). For non-Investigators, see the section Outside Financial Interest in the Allen Institute [Conflict of Interest Policy](#) for disclosure requirements.

Definitions:

Awarding Agency is the organization that funds a Research project with either federal or private funds, especially PHS or NSF.

COI Committee is a group of up to five (5) Allen Institute personnel, appointed by the IO, that oversees the application of this policy.

Disclosure Forms refers to the Annual FCOI Questionnaire used by the Institutional Official and the COI Committee to evaluate SFIs that may result in an FCOI

Entity is any domestic or foreign, public or private, organization (excluding a federal agency) from which an Investigator (or their spouse or dependent children) receives remuneration or has an ownership or **Equity** interest.

Equity means any interest in the ownership or profits of a business enterprise, including stock, stock options, or other Equity security.

Family Member is the spouse and dependent children of an Investigator.

Financial Conflict of Interest (FCOI) is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

FCOI Report is the Allen Institute's report of an FCOI to the PHS Awarding Agency. It must include the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the Entity with which the Investigator has an FCOI;
- Nature of the SFI (e.g., Equity, consulting fee, travel reimbursement, honorarium);
- The value of each SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the SFI relates to the PHS-funded Research and why the Allen Institute determined that the SFI conflicts with such Research; and
- A description of the key elements of the Management Plan.
- NSF only: Reports must also indicate when we are unable to satisfactorily manage an FCOI.

HHS is the United States Department of Health and Human Services.

Institutional Official (IO) is the Allen Institute individual(s) appointed by the CEO to be responsible for appointing COI Committee members, reviewing and evaluating SFI disclosures to determine if an FCOI exists, preparing Management Plans for identified FCOIs, and conducting additional activities pursuant to this policy.

Institutional Responsibilities are the Investigator's professional responsibilities on behalf of the Allen Institute, including but not limited to Research, Research consultation, teaching, professional practice, clinical activities, purchasing, institutional committee membership, and service on advisory or review panels or boards.

Investigator is anyone who is responsible for the design, conduct, or reporting of Research, regardless of funding source (internal or external), and regardless of title or position. It especially applies to project

directors and principal investigators and may include subrecipients, collaborators, or consultants. This may be different than the Allen Institute job title of “investigator.”

Management Plan is the Allen Institute’s documented plan that specifies the actions that we have taken or will take to manage, reduce, or eliminate an FCOI. Management Plans must include the following:

- The role and principal duties of the conflicted Investigator in the Research project;
- Conditions or restrictions 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; and
- How the Management Plan will be monitored to ensure Investigator compliance
- The Management Plan may also include conditions or restrictions, such as:
 - Public disclosure of SFIs or FCOIs (e.g., when presenting or publishing the Research results);
 - For Research involving human subjects, disclosure of the FCOI directly to participants;
 - 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;
 - Modification of the Research plan;
 - Change of Investigator or Investigator responsibilities, or disqualification of Investigator from participation in all or a portion of the Research;
 - Reduction or elimination of the FCOI (e.g., sale of an Equity interest);
 - Severance of relationships that create the FCOI; and
 - Any additional information needed to ensure that the Awarding Agency understands the nature and extent of the FCOI.

The IO or their designee will monitor Investigator compliance with the Management Plan on an ongoing basis until completion of the Research project. If you have an FCOI, you must remain in compliance with a Management Plan at all times during the Research project period. To implement a Management Plan, the IO and/or COI Committee will schedule a meeting with you to review and discuss all requirements. You will be required to sign the Management Plan to indicate your understanding and agreement to comply.

Mitigation Report is a report prepared by the IO and/or COI Committee for submission to the Awarding Agency after the IO and/or COI Committee has found bias during a Retrospective Review. It must include:

- The key elements documented in the Retrospective Review;
- A description of the impact of the bias on the Research project (i.e., 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); and
- Our plan of action or actions taken to eliminate or mitigate the effect of the bias.

Noncompliance is whenever an FCOI has not been identified or managed in a timely manner. Examples of this include when an Investigator fails to disclose an SFI that constitutes an FCOI, the IO or COI Committee fail to review or manage an FCOI, or an Investigator fails to follow the Management Plan

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), including any such activity for which Research funding is available from the NSF or a PHS funding agency 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. Per NSF requirements, this also pertains to educational activities.

Retrospective Review is the documented process where the IO and/or COI Committee determine whether there was any bias in the design, conduct or reporting of Research during a time of Noncompliance (whenever an FCOI is not identified or managed in a timely manner). It must be conducted within 120 days of the determination of Noncompliance. The Retrospective Review must include the following:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the Entity with which the Investigator has an FCOI;
- Reason(s) for the Retrospective Review;
- Detailed methodology used for the Retrospective Review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings of the Retrospective Review; and
- Conclusions of the Retrospective Review.

Senior/Key Personnel means the project director, principal investigator, and any other person identified as Senior/Key Personnel by the Allen Institute in the grant application, progress report or any other report submitted to PHS.

Significant Financial Interest (SFI) is:

- A financial interest consisting of one or more of the following interests of an Investigator or Investigator's **Family Member**, when considered in aggregate, that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - With regard to any publicly traded Entity, an SFI exists if the value of any remuneration received from the Entity in the twelve months preceding the disclosure and the value of any compensation and/or 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, an SFI 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 Family Member holds any Equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights, royalties), upon receipt of income related to such rights and interests.
- Reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities where the aggregate value of such reimbursed or sponsored travel received from a single outside organization exceeds \$5,000 in the twelve months preceding the disclosure. (Sponsored travel is travel that is paid on behalf of the Investigator and not reimbursed to the Investigator.) Reimbursed or sponsored travel does not include travel expenses reimbursed by or sponsored by a U.S. federal, state, or local government agency, an accredited, domestic 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 applying for or receiving NSF Funding only:* SFI includes salary, royalties or other payments related to the Investigator's Institutional Responsibilities that, when aggregated for the Investigator and the Investigator's Family Member, are expected to exceed \$5,000 during the next twelve-month period (prospectively).

Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties or other remuneration from the Allen Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the Allen Institute, including intellectual property rights assigned to the Allen Institute and agreements to share in royalties related to such rights.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator (or Family Member, as applicable) does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, an accredited, domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- Income from services on advisory committees or review panels for a U.S. federal, state, or local government agency, an accredited, domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- Equity interest that does not exceed \$10,000 and does not represent more than a 5% ownership interest in any single Entity when the values of the Investigator and Investigator's Family Member are considered in aggregate.
- Salary, royalties, or other remuneration that are not expected to exceed \$10,000 during the twelve-month period when the Investigator or Investigator's Family Member are considered in aggregate.

References:

- [42 CFR 50 Subpart F and 45 CFR Part 94](#)
- [NIH FAQs on FCOI Regulation](#)
- [NSF Conflict of Interest Policy](#)

Records Retention: All records relating to SFI disclosures and the Allen Institute review of or response to such disclosures (whether or not an SFI is determined to be an FCOI) and all action taken under this policy will be maintained for at least three (3) years from the date of the final expenditures report, the termination or completion of the related grant, the resolution of any action involving those records, or as otherwise required by law, whichever is longer. The legal department will maintain these records and those associated with FCOI training completion.

Frequently Asked Questions (FAQs)

1. [Does the existence of an FCOI mean that I've done something wrong?](#)
2. [Who submits the reports to the Awarding Agencies?](#)
3. [Who is our IO?](#)
4. [Who is on the COI Committee?](#)

Does the existence of an FCOI mean that I've done something wrong?

SFIs often exist and can create FCOIs in the absence of any wrongdoing. The important thing is to disclose them so they can be reviewed and managed. Please refer to this NIH [slide deck](#) for examples of various FCOIs.

Who submits the reports to the Awarding Agencies?

The research funding team is responsible for submitting reports to the Awarding Agencies.

Who is our IO?

The Allen Institute IO is our General Counsel (GC).

Who is on the COI Committee?

We don't have a standing COI Committee, but if the IO were to delegate authority to a COI Committee, the members could include the CEO, CAO, leader(s) of your business unit or others knowledgeable about the Research, and additional members as deemed appropriate for the circumstance by the IO.