



BRIO POLICY ON PROMOTING OBJECTIVITY IN RESEARCH

Purpose and Scope of Policy:

Through adopting this policy, Brio Device, LLC (Brio) seeks to implement Financial Conflicts of Interests (FCOI) disclosure requirements found in 42 CFR Part 50, Subpart F (“Code”, “Subpart F”, “Regulation”) and applicable to Research funded under the Public Health Service (PHS) grants. As a requirement for receiving PHS funding, Brio must maintain a written policy on financial conflicts of interest disclosure. Subpart F requirements applies to all research for which Brio applies and receives funding from PHS. Research funded under SBIR Phase I is exempt. The regulations apply to each Investigator who is planning to participate in or is participating in such Research as well as subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the above regulations.

The FCOI regulations and this policy is intended to ensure objectivity in which Research projects are designed, conducted, or reported by managing FCOI that occur between an Investigator’s personal financial interests and his/her professional Research interests. It establishes a process of disclosure and independent review when an Investigator has a Significant Financial Interest (SFI). If Brio determines that such an interest might reasonably appear to affect the Research directly and significantly, it will develop a mitigation plan to manage or eliminate the conflict.

Definitions

1. **Financial conflict of interest** (FCOI) means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
2. **FCOI report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
3. **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
4. **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
5. **Institutional Official (IO)** means a Brio designated official assigned to solicit and review disclosure forms from each Investigator who is planning to participate in, or who is participating in, PHS funded Research and to determine whether any reported SFI is a FCOI.
6. **Institutional responsibilities** means an Investigator's professional responsibilities performed on behalf of Brio, 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.
7. **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 PHS and includes Principal Investigator (PI), Co-Investigators, consultants or collaborators.
8. **PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to this subpart.
9. **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, drug, or medical device).
10. **Senior/key personnel** means the PD/PI and any other person identified as senior/key personnel by Brio in the grant application, progress report, or any other report submitted to the PHS Awarding Component.

11. **Significant financial interest** (SFI) means the following:

1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's responsibilities at Brio:

(i) With regard to any publicly traded entity, a *SFI* 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;

(ii) With regard to any non-publicly traded entity, a *SFI* exists if the value of any remuneration received from the entity in the twelve (12) 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

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose 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.

Travel 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 is exempt.

The disclosure should include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with Brio's FCOI policy, the Brio's designated 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.

(3) **NOTE:** The term *significant financial interest* (SFI) **does not** include the following types of financial interests:

- salary, royalties, or other remuneration paid by Brio to the Investigator if the Investigator is currently employed or otherwise appointed by Brio, including intellectual property rights assigned to Brio and agreements to share in royalties related to such rights;
- any ownership interest in Brio held by the Investigator, if Brio 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; or

- income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Brio's Responsibilities – Review Disclosures, Provide Training, and Manage Financial Conflicts of Interests

Brio's Review requirement:

1. Brio has designated its CEO as the IO. Prior to expenditure of any funds under a PHS funded Research project, Brio's IO will solicit and review Investigator's disclosures (or Disclosure Forms) containing SFIs to determine whether the SFI relates to the PHS funded Research and whether a FCOI exists.
2. If a FCOI exists, Brio's IO will develop and implement a management plan that specifies the actions that have been and will be taken to manage such FCOI.

Disclosure and identifying SFI:

1. Brio will inform each Investigator of:
 - Brio's policy on Promoting Objectivity in Research,
 - the Investigator's responsibilities regarding disclosure of SFI,
 - Subpart F regulations as summarized here, and
 - require Investigator(s) to complete training provided by NIH prior to engaging in research related to PHS-funded grant.
2. Training provided via: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html and must be completed:
 - Prior to engaging in research related to any PHS-funded grant,
 - at least every four years, and
 - immediately when any of the following apply:
 - 1) Brio revises this policy;
 - 2) an Investigator is new to Brio; or
 - 3) Brio finds a SFI:
 - that was not disclosed timely by an Investigator, or
 - was not previously reviewed by Brio during an ongoing PHS funded Research project, or
 - finds noncompliance with this policy or management plan,
 - Brio's IO within 60 days of the disclosure will review the SFI to determine whether it is related to PHS funded Research and whether a FCOI exists.
3. Posting requirement if IO determines FCOI exists: Prior to Brio's expenditure of PHS funds and within sixty (60) days of Brio's receipt or identification of any additional SFI held by Senior/Key personnel performing services for the Research, related to the PHS funded Research and that is determined by Brio's IO to be a FCOI, Brio shall post to its publicly accessible Website, www.briodevice.com, the following information concerning such SFI:
 - Investigator's name, 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; and
- approximate dollar value of the 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 interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Brio will update this information at least annually as well as within sixty (60) days of the following events:

- a) Brio's receipt or identification of information concerning any additional SFI of the Senior/Key personnel for the PHS funded Research project that was not previously disclosed or
- b) Upon disclosure of any SFI of Senior/Key personnel new to the PHS funded Research.
- c) The Website shall note that the information is current as of the date shown and subject to required updates. Such postings to the website shall remain available for at least three (3) years from the date that the information was most recently updated by Brio.

Management of FCOIs: Examples of conditions or restrictions to include in management plans can be:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of FCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to project 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); or
- Severance of relationships that create financial conflicts.

Brio and Subrecipient Obligations: If Brio carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Brio (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with Subpart F. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to Brio's FCOI policy as the awardee Institution for disclosing SFI that are directly related to the subrecipient's work for Brio;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to Brio in a sufficient manner to enable Brio to provide timely FCOI reports, as necessary, to the PHS as required by this Subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with Brio's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

Retrospective Reviews: If a FCOI is not identified or managed in a timely manner including:

1. failure by the Investigator to disclose a SFI that is determined by Brio to constitute FCOI;
2. failure by Brio to review or manage such a FCOI; or
3. failure by the Investigator to comply with a FCOI management plan,
4. Brio will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and determine whether any PHS funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of sch Research.

Brio is required to document the retrospective review with the following key elements:

- Project number, title, PI or co-PI;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a 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, document reviewed);
- Findings of the review and Conclusions of the review.

Based on the results of the retrospective review:

- Brio will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
- If bias is found, Brio will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. Mitigation report must include:
 - the key elements documented in the retrospective review,
 - a description of the impact of the bias on the Research project, and
 - Brio's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research project; 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).

Thereafter, Brio will submit FCOI reports annually. Depending on the nature of the FCOI, Brio may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of Brio's retrospective review.

Ongoing Monitoring: When implementing a management plan, Brio will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded Research project.

Reporting of Financial Conflicts of Interests

FCOI Report: Prior to Brio's expenditure of any funds under a PHS funded Research project, Brio will provide to the PHS Awarding Component a FCOI report regarding any Investigator's SFI found by Brio to be a FCOI. Brio will implement a management plan, in the absence of a subrecipient's plan in circumstances where subrecipient exists and such is the



agreement between the parties. In situations in which Brio identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, Brio is not required to submit a FCOI report to the PHS Awarding Component.

Subsequent FCOI Reports: For any SFI that Brio identifies as a FCOI after Brio's initial report during an ongoing PHS funded Research project, (such as participation of an Investigator who is new to the research project), Brio will provide to the PHS Awarding Component a FCOI report regarding the FCOI within sixty (60) days of identification of the FCOI.

If FCOI is found, Brio will implement a management plan in accordance with this policy and if required, complete a retrospective review and a mitigation report according to this policy. This requirement applies to instances when an SFI was not disclosed timely by an Investigator or was not previously reviewed or management by Brio (e.g., was not timely reviewed or reported by a subrecipient).

FCOI report shall contain: FCOI report described above should include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI and to assess the appropriateness of Brio's management plan. In accordance with the Code, the FCOI report shall include, but is not limited to, the following elements:

- Project number;
- PI or Contact PI if multiple PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (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 interest 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 financial interest relates to the PHS-funded research and the basis for Brio's determination that the financial interest conflicts with such research; and
- A description of the key elements of Brio's (or subrecipient's) management plan including the following minimum information:
 1. Role and principal duties of the conflicted Investigator in the Research project;
 2. Conditions of the management plan;
 3. Explanation of how the management plan is designed to safeguard objectivity in the Research project;
 4. Confirmation of the Investigator's agreement to the management plan; and
 5. Explanation of how the management plan will be monitored to ensure Investigator compliance.

Annual obligations for FCOI Reporting: For any FCOI previously reported by Brio regarding an ongoing PHS-funded research project, Brio shall:

1. Provide to the PHS Awarding Component an annual FCOI report that addresses:
 - the status of the FCOI, and
 - any changes to the management plan for the duration of the PHS funded Research project.
2. The annual FCOI report shall specify:
 - whether the financial conflict is still being managed or
 - explain why the FCOI no longer exists.



3. Brio shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

Brio's Investigator's Responsibilities:

Investigators responsible for the design, conduct, or reporting of research must do the following:

1. Read and acknowledge Brio's Policy on Promoting Objectivity in Research
2. Complete Brio's designated training relating to Subpart F,
3. Disclose SFI - Complete and submit Brio's financial disclosure form to IO; and
4. Update financial disclosure annually and within thirty (30) days of acquiring a new SFI.

Remedies and Enforcement

If the failure of an Investigator to comply with this policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, Brio is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken by Brio.

The PHS Awarding Component will consider the situation and, as necessary, 1) take appropriate action, or 2) refer the matter to Brio's for further action, which may include directions to Brio on how to maintain appropriate objectivity in the PHS-funded Research.

The PHS Awarding Component and/or HHS may inquire at any time before, during, or after into any Investigator disclosure of financial interests and the Institution's review, including retrospective reviews, of and response to such disclosure regardless of whether disclosure resulted in Brio's determination of a FCOI. Brio is required to submit, or permit onsite review of, all records pertinent to compliance with this Subpart. HHS will maintain confidentiality of records of financial interests.

On the basis of this review PHS may decide that the FCOI reviewed will bias the objectivity of the Research to such an extent that, 1) further corrective action is needed, or 2) Brio has not managed the FCOI in accordance with this regulation.

Special award conditions may be imposed or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of SFI related to federally funded research.

Retention of Records

Brio must retain all disclosures, determinations, and actions taken regarding the management of FCOI for three years beyond the date of the final expenditure report submitted to NIH under the award or other applicable dates. 45 CFR 74.53

Subcontractors/Consultants

Also worthy of note is that subcontractors and consultants who perform services within the definition of an Investigator as defined under Subpart F may also be subject to its regulatory requirements. Such subcontracts/consulting agreements shall include appropriate clauses requiring compliance with the applicable federal regulations through policy maintained by the subcontract/consultant or this policy.