

Financial Conflicts of Interest Policy

Revised February 25, 2021

Next Scheduled Review: January 15, 2023

Policy Statement

Birkeland Current is committed to conducting Research and Research Activities in a manner consistent with the highest standards of integrity and ethics. This policy promotes objectivity in Research and ensures that Research Activities are conducted in a manner free from bias resulting from Financial Conflict of Interest.

Reason for Policy

This policy implements the requirements of 42 CFR 50.604 *Responsibilities of Institutions regarding Investigator financial conflict of interest.*

Procedures and Responsibilities

1. APPOINTMENT OF CONFLICT OF INTEREST OFFICIAL

The President appoints the Director of Operations or his or her designee(s) as the Conflict of Interest Official (COI Official) for Birkeland Current. The COI Official shall perform the duties established in 42 CFR 50.604 relating to the review of Disclosures of Significant Financial Interest and the management and reporting of Financial Conflicts of Interest.

2. TRAINING AND CERTIFICATION

All Birkeland Current employees who are Investigators as defined in 42 CFR 50.603 must complete training as required in 42 CFR 50.604 or associated with changes in this policy. In addition, each Investigator must certify that the Investigator is aware of and has read 42 CFR 50.604 and this policy and is aware of the Investigator's responsibilities regarding disclosure of SFIs and applicable federal regulations. All investigators will certify prior to undertaking any PHS funded grants, annually, upon initial employment, or if determined to be out of compliance.

3. DISCLOSURE AND REVIEW

All Birkeland Current employees who are Investigators as defined in *42 CFR 50.603* must disclose Significant Financial Interests (SFI) and submit Financial Disclosure Statements to Birkeland Current's COI Official in accordance with this policy. In accordance with *42 CFR 50.604*, the COI Official will review all Financial Disclosure Statements by Investigators and determine whether any disclosed SFI is related to the Investigator's Research or Research Activities or PHS funded research and whether a Financial Conflict of Interest (FCOI) exists. If a FCOI exists, the COI Official will develop a Management Plan, as described in *42 CFR 50.604*, specifying the actions that must be taken to manage, reduce or eliminate the FCOI. All FCOIs identified by the COI Official must be satisfactorily managed, reduced or eliminated prior to the expenditure of any sponsored research funds. All investigators will complete disclosures prior to undertaking any PHS funded grants, annually, and within 30 days of discovering or acquiring a new SFI, or when new investigators are identified. Management plans shall be established within 60 days of identifying an SFI that was not previously disclosed or previously reviewed.

4. MONITORING

Each Investigator conducting Research or Research Activities under a Management Plan must comply fully and promptly with the Management Plan and each person identified in the Management Plan as having responsibility for monitoring compliance shall carefully and fully monitor that compliance. Additionally, the COI Official shall be responsible for conducting periodic reviews of Financial Disclosure Statements and Management Plans to determine individual and institutional compliance. The COI Official shall report instances of noncompliance as required in *42 CFR 50.604*.

5. REPORTING REQUIREMENTS TO THE NIH

The COI Official shall provide initial, annual, and revised FCOI reports as required by *42 CFR 50.604 (h)* and *42 CFR 50.605 (b)* to the NIH prior to expenditure of funds, within 60 days of identification of new investigators, within 60 days of newly identified FCOIs for existing investigators, or with the annual progress reports to provide status and any changes to management plans. Each FCOI management plan will include independent procedures for identifying and reporting bias or failure to comply.

6. MAINTENANCE OF RECORDS

The COI Official or his or her designee(s) shall maintain all FCOI-related records in accordance with *42 CFR 50.604(i)* for at least 3 years from the date of final expenditures report submitted to PHS(NIH) or from other dates where applicable in *45 CFR 75.361*.

7. ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE

All Birkeland Current employees who are Investigators will have compliance with this policy and any FCOI management plans as part of their annual review process. The COI Official will conduct an annual review for compliance and document within 120 days of

determining a non-compliance. Any investigator with an unreported FCOI will be required to disclose the FCOI in each future public presentation and be required to request an addendum to previously published presentations.

8. SUBRECIPIENT REQUIREMENTS

All subrecipients of PHS funded research will be required to maintain a FCOI Policy compliant with 42 CFR 50.604 and where required provide certification of the policy to include the subrecipient disclosures, reporting and management of FCOIs to the NIH.

9. PUBLIC ACCESSIBILITY

9.1 The COI Official shall ensure that this policy is available through a publicly accessible website.

9.2 Public Health Service (PHS) funded Research

If the COI Official determines that a FCOI exists that is related to PHS-funded research, the COI Official shall maintain records for 3 years and make the following information available in writing to any requestor within five business days after receipt of a request, so long as the Investigator still holds the SFI:

- (a) The name of the Investigator;
- (b) The title and role of the Investigator in relation to the affected Research or Research Activities;
- (c) The name of the entity in which the SFI is held;
- (d) A description of the SFI that was determined to be an FCOI; and
- (e) The approximate dollar value of the SFI.

10. OTHER CONSIDERATIONS

In addition to the issues addressed in 42 CFR 50.604 and this policy, there may be other considerations that are separate from FCOI questions, including but not limited to external employment or conflict of commitment. The primary responsibility of each employee of Birkeland Current is the accomplishment of the duties and responsibilities assigned to the employee's position. Other outside employment should not interfere with those duties and responsibilities as set forth in system policies and regulations.

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Birkeland Current Managing Member

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Birkeland Current COI Official