

MASTERSWITCH, INC.

FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

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Policy Owner: MasterSwitch, Inc.

Applicable Regulation: 42 CFR Part 50 Subpart F

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1. INTRODUCTION

The purpose of this Policy is to ensure that research funded by the National Institutes of Health (“NIH”) and other components of the Public Health Service (“PHS”) is designed, conducted, and reported objectively and without bias resulting from Investigator financial conflicts of interest (“FCOIs”).

This Policy implements the applicable requirements of 42 CFR Part 50 Subpart F, Promoting Objectivity in Research, for PHS/NIH grants and cooperative agreements.

MasterSwitch, Inc. (“MasterSwitch” or the “Institution”) adopts this Policy for Investigators who are planning to participate in or participate in applicable PHS/NIH-funded research.

Consistent with 42 CFR Part 50 Subpart F, these requirements do not apply to Phase I Small Business Innovation Research (“SBIR”) or Small Business Technology Transfer (“STTR”) applications or awards.

2. APPLICABILITY

This Policy applies to any individual who meets the regulatory definition of “Investigator” and who is planning to participate in or participates in PHS/NIH-funded research subject to 42 CFR Part 50 Subpart F.

3. DEFINITIONS

Financial Conflict of Interest (FCOI)

A Significant Financial Interest that MasterSwitch determines is related to PHS/NIH-funded research and could directly and significantly affect the design, conduct, or reporting of that research.

Financial Interest

Anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities

An Investigator’s professional responsibilities performed on behalf of MasterSwitch, Inc., which may include, as applicable, research, research consultation, product development, scientific, medical, or technical activities, management or oversight of research, service on institutional committees or review panels, and other professional activities undertaken on behalf of MasterSwitch.

Designated Official

The individual designated by MasterSwitch to solicit and review Investigator SFI disclosures and carry out MasterSwitch’s responsibilities under this Policy. MasterSwitch has appointed Christina Galbraith, Chief Operating Officer (COO), as the Designated Official under this Policy. In the event that the COO is unable to serve as Designated Official, Christopher Brooke, Chief

Executive Officer (CEO) of Masterswitch, Inc., shall serve as the Designated Official or shall appoint an appropriate Designated Official for Masterswitch.

Investigator

The Project Director/Principal Investigator (“PD/PI”) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research or research proposed for such funding, which may include collaborators or consultants.

MasterSwitch will determine who qualifies as an Investigator based upon the individual’s responsibilities rather than title.

Management

Taking action to address an FCOI, which may include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research are free from bias.

Research

A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including basic and applied research and product development.

Senior/Key Personnel

The PD/PI and any other individual identified as senior/key personnel by MasterSwitch in an application, progress report, or other report submitted to PHS/NIH.

Significant Financial Interest (SFI)

A Significant Financial Interest is a financial interest consisting of one or more of the following interests of the Investigator, the Investigator’s spouse, or dependent children that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

Publicly Traded Entity: An SFI exists when the aggregate value of remuneration received from an entity during the 12 months preceding disclosure and the value of any equity interest in the entity as of the date of disclosure exceeds \$5,000.

Remuneration includes salary and payments for services not otherwise identified as salary, including consulting fees, honoraria, and paid authorship. Equity includes stock, stock options, or other ownership interests.

Non-Publicly Traded Entity: An SFI exists when remuneration received from an entity during the 12 months preceding disclosure exceeds \$5,000, or when the Investigator, spouse, or dependent children hold any equity interest in the entity.

Intellectual Property Rights and Interests: Intellectual property rights and interests, including patents and copyrights, constitute an SFI upon receipt of income related to those rights and interests.

Reimbursed or Sponsored Travel: Investigators must disclose applicable reimbursed or sponsored travel related to their Institutional Responsibilities. The disclosure must include, at minimum:

- purpose of the trip;
- identity of the sponsor or organizer;
- destination; and
- duration.

MasterSwitch may request additional information, including the monetary value of the travel, as necessary to determine whether the travel constitutes an FCOI.

Exclusions from SFI

SFI does not include:

1. Salary, royalties, or other remuneration paid by MasterSwitch to an Investigator who is currently employed or otherwise appointed by MasterSwitch, including intellectual property rights assigned to MasterSwitch and agreements to share royalties related to those rights;
2. Any ownership interest in MasterSwitch held by an Investigator, because MasterSwitch is a commercial, for-profit organization;
3. Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control investment decisions made in those vehicles;
4. Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with a U.S. institution of higher education;
5. Income from service on advisory committees or review panels for the U.S. governmental or U.S. academic entities described above; and
6. Travel reimbursed or sponsored by the U.S. government or U.S. academic entities described above.

Applicable financial interests received from foreign institutions and entities, including foreign institutions of higher education and foreign governmental entities, must be disclosed when they otherwise meet the SFI disclosure requirements.

4. SIGNIFICANT FINANCIAL INTEREST (SFI) DISCLOSURE REQUIREMENTS

Investigators must disclose all applicable foreign and domestic SFIs related to their Institutional Responsibilities to MasterSwitch's Designated Official.

Required disclosures include applicable SFIs of the Investigator's spouse and dependent children.

Investigators must disclose SFIs:

A. At the Time of Application

No later than the time of application for PHS/NIH-funded research.

B. Annually During the Award

At least annually during the period of the award.

C. Newly Acquired or Discovered SFIs

Within 30 days of discovering or acquiring a new SFI.

Applicable reimbursed or sponsored travel must also be disclosed within 30 days of each occurrence.

5. REVIEW OF SFI DISCLOSURES

MasterSwitch's Designated Official will solicit and review Investigator SFI disclosures.

Prior to expenditure of funds under an applicable PHS/NIH award, MasterSwitch will:

1. Review applicable Investigator SFI disclosures;
2. Determine whether an SFI is related to the PHS/NIH-funded research;
3. Determine whether any related SFI constitutes an FCOI; and
4. If an FCOI exists, develop and implement an appropriate management plan.

When an Investigator newly participates in an ongoing project or an existing Investigator discloses a new SFI, MasterSwitch will, within 60 days, review the disclosure, determine whether it is related to the PHS/NIH-funded research, determine whether an FCOI exists, and, if an FCOI exists, implement, at least on an interim basis, a management plan specifying the actions that have been and will be taken to manage the FCOI.

6. RELATEDNESS OF SFIs TO PHS/NIH-FUNDED RESEARCH AND FCOI

An SFI is related to PHS/NIH-funded research when MasterSwitch reasonably determines that:

- the SFI could be affected by the PHS/NIH-funded research; or
- the SFI is in an entity whose financial interest could be affected by the research.

MasterSwitch may involve the Investigator in determining whether an SFI is related to the research.

An FCOI exists when MasterSwitch reasonably determines that a related SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

For purposes of this determination, "significantly" means that the financial interest would have a material effect on the research.

7. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

If MasterSwitch determines that an FCOI exists, MasterSwitch will develop a management plan specifying the actions that have been and will be taken to manage the FCOI, obtain the Investigator's agreement to comply with the management plan, and implement the plan.

Depending upon the circumstances, management may include:

- public disclosure of the FCOI;

- disclosure in publications or presentations;
- disclosure to participants in human-subjects research;
- appointment of an independent monitor;
- modification of the research plan;
- change in personnel or personnel responsibilities;
- disqualification from all or a portion of the research;
- reduction or elimination of the financial interest; or
- severance of relationships creating the conflict.

8. MONITORING INVESTIGATOR COMPLIANCE

MasterSwitch will take such actions as necessary to manage FCOIs, including any FCOI of a subrecipient Investigator, if applicable, and will monitor Investigator compliance with applicable management plans on an ongoing basis until completion of the PHS/NIH-funded research project.

9. PUBLIC ACCESSIBILITY

FCOI Policy

MasterSwitch will post this FCOI Policy on its publicly accessible website, www.masterswitchbio.com, and will maintain it there in accordance with 42 CFR Part 50 Subpart F.

FCOIs Held by Senior/Key Personnel

Prior to expenditure of funds under an applicable PHS/NIH award, MasterSwitch will make publicly accessible, on its website, information concerning any identified FCOI held by Senior/Key Personnel that:

1. was disclosed and is still held by the Senior/Key Personnel;
2. MasterSwitch determines is related to the PHS/NIH-funded research; and
3. MasterSwitch determines constitutes an FCOI.

The information will include:

- Investigator's name;
- Investigator's title and role with respect to the research;
- name of the entity in which the SFI is held;
- nature of the SFI; and
- approximate dollar value of the SFI using the ranges below, or a statement that its value cannot readily be determined.

Value ranges:

- \$0–\$4,999;
- \$5,000–\$9,999;
- \$10,000–\$19,999;
- amounts between \$20,000 and \$100,000 in \$20,000 increments; and

- amounts above \$100,000 in \$50,000 increments.

MasterSwitch will update the posted information at least annually and within 60 days of identifying a newly disclosed or newly identified FCOI for Senior/Key Personnel.

The website will note that the information is current as of the date listed and is subject to update at least annually and within 60 days of a newly identified FCOI.

The information will remain available for at least three years from the date it was most recently updated.

10. REPORTING IDENTIFIED FINANCIAL CONFLICTS OF INTEREST

MasterSwitch will submit required FCOI reports to NIH through the eRA Commons FCOI Module for MasterSwitch Investigators and for Investigators of its subrecipients, if applicable, in accordance with 42 CFR Part 50 Subpart F.

An FCOI report is required only when an FCOI has been identified.

Prior to expenditure of funds under an NIH award, MasterSwitch will report any identified FCOI of a MasterSwitch Investigator or subrecipient Investigator, as applicable.

If an FCOI is identified during an ongoing award, including an FCOI involving a MasterSwitch Investigator or a subrecipient Investigator, MasterSwitch will submit the required report within 60 days.

An FCOI report will contain the information required by 42 CFR § 50.605(b)(3), including:

- project number;
- PD/PI or contact PD/PI;
- name of the Investigator with the FCOI;
- name of the entity with which the Investigator has the FCOI;
- nature of the financial interest;
- value of the financial interest or a statement that the value cannot readily be determined;
- description of how the financial interest relates to the research;
- basis for the determination that an FCOI exists; and
- key elements of the management plan.

For each previously reported FCOI relating to ongoing PHS/NIH-funded research, including applicable FCOIs of subrecipient Investigators, MasterSwitch will submit an annual FCOI report at the same time as the applicable annual progress report, multi-year progress report, if applicable, or at the time of an extension. The annual report will address the status of the FCOI and any changes to the management plan and will continue for the duration of the project.

MasterSwitch will submit revised or mitigation reports when required following a retrospective review.

11. INVESTIGATOR TRAINING

MasterSwitch will inform each Investigator of:

- this Policy;
- the Investigator's responsibility to disclose applicable foreign and domestic SFIs; and
- the requirements of 42 CFR Part 50 Subpart F.

Each Investigator must complete FCOI training:

1. Prior to engaging in PHS/NIH-funded research;
2. At least once every four years;
3. Immediately when MasterSwitch revises this Policy in a manner affecting Investigator requirements;
4. Immediately when an Investigator is new to MasterSwitch; or
5. Immediately when MasterSwitch determines that an Investigator has not complied with this Policy or an FCOI management plan.

NIH confirms that institutional training must address both the federal regulation and the institution's own policy/disclosure requirements.

12. NONCOMPLIANCE, RETROSPECTIVE REVIEW, AND MITIGATION

If MasterSwitch identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by MasterSwitch during an ongoing PHS/NIH-funded research project, including an SFI that was not timely reviewed or reported by a subrecipient, MasterSwitch will, within 60 days:

1. Review the SFI;
2. Determine whether it is related to PHS/NIH-funded research;
3. Determine whether it constitutes an FCOI; and
4. If an FCOI exists, implement, at least on an interim basis, a management plan specifying the actions that have been and will be taken to manage the FCOI going forward.

When an FCOI was not identified or managed in a timely manner, including because:

1. an Investigator failed to disclose an SFI that MasterSwitch later determines constitutes an FCOI;
2. MasterSwitch failed to review or manage an FCOI; or
3. an Investigator failed to comply with an FCOI management plan,

MasterSwitch will complete a retrospective review within 120 days of its determination of noncompliance to determine whether the PHS/NIH-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting.

The retrospective review will document:

- project number;
- project title;
- PD/PI or contact PD/PI;
- name of the Investigator with the FCOI;
- name of the entity with which the Investigator has the FCOI;
- reason or reasons for the retrospective review;

- detailed methodology used for the retrospective review, including the review process, composition of the review panel, and documents reviewed;
- findings of the review; and
- conclusions of the review.

Based on the results of the retrospective review, MasterSwitch will update any previously submitted FCOI report when required.

If bias is found, MasterSwitch will promptly notify the PHS/NIH Awarding Component and submit a mitigation report containing the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and MasterSwitch's plan of action or actions taken to eliminate or mitigate the effect of the bias.

13. CLINICAL RESEARCH REQUIREMENTS

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 was designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required, MasterSwitch will require the Investigator to:

1. disclose the FCOI in each public presentation of the results of the research; and
2. request an addendum to previously published presentations.

14. SUBRECIPIENT REQUIREMENTS

When MasterSwitch conducts PHS/NIH-funded research through a subrecipient, the written agreement with the subrecipient will establish whether the subrecipient Investigators will comply with:

1. the subrecipient institution's FCOI policy; or
2. this MasterSwitch FCOI Policy.

If the subrecipient's policy applies, the subrecipient will certify that its policy complies with 42 CFR Part 50 Subpart F, and the written agreement will establish a reporting timeframe that permits MasterSwitch to meet its NIH reporting obligations.

If the subrecipient cannot provide such certification, applicable subrecipient Investigators will comply with this Policy, and the written agreement will establish appropriate disclosure and reporting timeframes.

MasterSwitch will report identified FCOIs involving subrecipient Investigators to NIH as required by Section 10 of this Policy and 42 CFR Part 50 Subpart F.

15. MAINTENANCE OF RECORDS

MasterSwitch will maintain records relating to:

- Investigator disclosures of financial interests;
- MasterSwitch's review of and response to those disclosures, whether or not an FCOI was identified;
- actions taken to manage an FCOI; and

- retrospective reviews and mitigation actions, when applicable.

Records will be retained for at least three years from the date of submission of the Final Federal Financial Report, or for any longer period required by applicable federal record-retention requirements, including 2 CFR § 200.334.

MasterSwitch will make information concerning Investigator disclosures and MasterSwitch's review and response available promptly to HHS/NIH upon request as required by 42 CFR Part 50 Subpart F.

16. ENFORCEMENT AND INSTITUTIONAL COMPLIANCE

MasterSwitch will maintain adequate enforcement mechanisms and provide for employee sanctions or other administrative actions, as appropriate, to ensure Investigator compliance with this Policy and any FCOI management plan.

MasterSwitch will promptly notify the PHS/NIH Awarding Component if an Investigator or subrecipient Investigator, as applicable, fails to comply with the applicable FCOI policy or if noncompliance with an FCOI management plan appears to have biased the design, conduct, or reporting of PHS/NIH-funded research, and MasterSwitch will take appropriate corrective action.

17. USEFUL FCOI AND NIH RESOURCES

NIH e-mail address for FCOI-related inquiries: fcoicompliance@mail.nih.gov

FCOI Regulation 42 CFR Part 50 Subpart F - Promoting Objectivity in Research at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>

Financial Conflict of Interest at <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>

FCOI Training at <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>

18. POINT OF CONTACT

Questions concerning this Policy, disclosure of a financial interest, or requests concerning publicly accessible FCOI information should be directed to:

Christina Galbraith
Chief Operating Officer and Designated Official
MasterSwitch, Inc.
Website: www.masterswitchbio.com
Email: christina@masterswitchbio.com
Telephone: +1 (917) 825-2705