

I. INTRODUCTION

The U.S. Department of Health and Human Services (**HHS**) requires that an institution receiving Public Health Service (**PHS**) research funds has a written financial conflict of interest (**FCOI**) policy. The aim of this requirement is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. For full FCOI requirements, see Section 4.1.10, Financial Conflict of Interest and 42 CFR 50 Subpart F.

II. POLICY

A. The RTOG Foundation (**RTOGF**) is committed to maintaining objectivity in the research it conducts. RTOGF promotes standards and maintains processes that are designed to create a reasonable expectation that the design, conduct, and reporting of research funded under RTOGF's PHS grants, cooperative agreements, contracts, and other funding sources will be free from bias resulting from investigator or senior/key personnel financial conflicts of interest. RTOGF requires all Covered Individuals (*as defined below*) and participants in its activities to disclose any FCOIs that may compromise, or appear to compromise, that individual's independence and objectivity in the discharge of their RTOGF responsibilities in the design, conduct, or reporting of RTOGF-related Research (*as that term defined below*).

B. The goal of this FCOI Policy is transparency through the disclosure of financial relationships with third parties and for-profit health care companies that could have a special interest in an RTOGF protocol. Additionally, this FCOI Policy serves to collect data for both the purposes of promoting objectivity in research regarding the requirements of 42 CFR Part 50 and 45 CFR 94, and to meet the requirements of the Accreditation Council for Continuing Medical Education (**ACCME**). To promote bias-free educational presentations, RTOGF requires full disclosure of all financial interests from educational planning committee members, moderators, and presenters of programs.

III. DEFINITIONS

"Conflict of Interest" (COI) means a professional, proprietary, and or significant financial interest on the part of the individual or their spouse, which may directly and significantly affect the design, conduct, or reporting of research.

"Continuing Medical Education" (CME) consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, professional performance, and relationships that a physician, researcher, or other health care professionals use to provide services for patients, the public, or the profession.

/"Covered Individuals" (CI) means Investigators, Protocol Study Chairs/Co-Chairs, Senior/Key personnel, including RTOGF Committee Chairs/Vice-Chairs, Board of Directors, and other persons and their immediate family members, regardless of title or position, who are responsible for the design, conduct, or reporting of research studies.

“Financial Conflict of Interest” (FCOI) exists when RTOGF’s designated official(s) reasonably determines that an Investigator’s significant financial interest (**SFI**) (*as defined below*) could directly and significantly affect the design, conduct, or reporting of RTOGF-funded Research (*as that term is defined below*). RTOGF is required to review each Investigator SFI disclosure to determine if an SFI:

- (i) is related to the RTOGF-supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research); and
- (ii) could directly and significantly affect the design, conduct, or reporting of the RTOGF-funded research.

“Investigator” includes all RTOGF scientists, clinicians, statisticians, nurses, clinical research associates, and patient advocates whose participation in RTOGF Research is not limited to registering patients.

Participation includes having an active role in the development and conduct of the protocol, as well as the reporting of study results.

This definition also includes those situations where there is more than one investigator, such as the potential with multidisciplinary or intergroup trials. In such cases, the investigator who leads the research for RTOGF or is considered a co-investigator will be required to comply with this Policy.

“Invited Guest Speakers” are those individuals who participate in presentations at RTOGF coordinated scientific meetings and symposia. This definition includes committee members, moderators, and presenters of programs.

RTOGF **“Immediate Family”** means a covered individual’s spouse, domestic partner, and dependent children.

“Research” means a systematic investigation, study, or examination designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.

“Significant Financial Interest” (SFI) is defined below in Section IV, subsection (B). SFI applies to the CI (and those of the CI’s Immediate Family) that reasonably appear to be related to the CI’s RTOGF responsibilities.

“Sponsor” is often, but not exclusively, the entity providing funding, drug, materials, etc., in support of or for use during, the Research in which the Investigator is involved.

IV. POTENTIAL CONFLICT OF INTEREST

A. Professional Interest

The CI has contributed significantly to the prior development of the technology or product being used in RTOGF Research. A *“professional interest”* may exist where an entity’s products or services are subject to RTOGF Research and where an entity’s products or services are in

competition with those under consideration by RTOGF. Professional interests might include consulting or advisory roles, employment, and leadership positions.

B. Significant Financial Interest

A “significant financial interest” (SFI) means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (*and those of the Investigator’s Immediate Family*) that reasonably appears to be related to the Investigator’s RTOGF-related Research responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, **exceeds USD\$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 significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, **exceeds USD\$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 must also disclose the occurrence of 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 RTOGF-related Research responsibilities; *provided, however*, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by (i) a Federal, state, or local government agency, (ii) an Institution of higher education as defined at 20 U.S.C. 1001(a), (iii) an academic teaching hospital, (iv) a medical center, (v) a research institute that is affiliated with an Institution of higher education, or (vi) ASCO, ASTRO, AACR, ESMO, or a similar professional association, charity, society, or trade organization. *In such case*, the Institution’s FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. *In accordance with the Institution’s FCOI policy*, the Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes a FCOI with the RTOGF-funded Research.

(3) The term “significant financial interest” does not include the following types of financial interests: salary, royalties, or other remuneration paid by RTOGF to the Investigator if the Investigator is currently employed or otherwise appointed by RTOGF, including intellectual property rights assigned to RTOGF 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 does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by (i) a Federal, state, or local government agency, (ii) an Institution of higher education as defined at 20 U.S.C. 1001(a), (iii) an academic teaching hospital, (iv) a medical center, (v) a research institute that is affiliated with an

Institution of higher education, or (vi) ASCO, ASTRO, AACR, ESMO, or a similar professional association, charity, society, or trade organization; or income from service on advisory committees or review panels for (i) a Federal, state, or local government agency, (ii) an Institution of higher education as defined at 20 U.S.C. 1001(a), (iii) an academic teaching hospital, (iv) a medical center, (v) a research institute that is affiliated with an Institution of higher education, or (vi) ASCO, ASTRO, AACR, ESMO, or a similar professional association, charity, society, or trade organization.

C. Miscellaneous Relationships

There may be other instances in which an Investigator or individuals with whom they directly share income has an affiliation or relationship such that objective impartiality could be questioned. In such instances, the Investigator should disclose the nature and extent of such affiliation or relationship on the RTOGF FCOI Form.

V. COLLECTION OF COI FORMS

Covered Individuals will complete and submit their RTOGF FCOI Form within the following general timeframes:

(a) **Annual Call for RTOGF FCOI Disclosures** - RTOGF will initiate an annual submission request for FCOI disclosure forms. RTOGF FCOI Forms shall be submitted within thirty (30) days of the annual request.

(b) **Protocol Development** - Submission of an RTOGF FCOI Form is required thirty (30) days prior to RTOGF's submission of a concept or protocol to a funding agency for approval.

(c) **Enrolling Site Investigators** - RTOGF will request FCOI disclosure forms from all investigators prior to participating in RTOGF clinical trials and on an annual basis thereafter. Such RTOGF FCOI Forms will be submitted within thirty (30) of the disclosure request.

2. *For clarity and emphasis*, Covered Individuals are to submit their RTOGF FCOI Form within thirty (30) days of receiving an RTOGF FCOI request. Additionally, the RTOGF FCOI Form should be updated within thirty (30) days for any "off-cycle" changes.

3. Failure to submit an RTOGF FCOI disclosure form within thirty (30) days of an RTOGF FCOI request will result in enforcement action from the RTOGF Conflict Management Committee as outlined below in Section VI, subsection B.

VI. MANAGEMENT AND ENFORCEMENT

A. Management

1. RTOGF FCOI Forms will be reviewed by the RTOGF Governance Committee (**GC**).

2. The RTOGF GC Chair facilitates the GC FCOI review. Financial disclosures of **greater than USD\$5,000** will be assessed by the GC and referred to the GC Chair. The CG Chair will

review and make a recommendation to the RTOGF Board Chair. The GC shall be responsible for monitoring and enforcing management plans.

3. A CI who is found to have an FCOI above the maximum threshold will not be permitted to proceed in RTOGF activities until they have agreed to implement a FCOI management/mitigation plan that is acceptable to RTOGF.

B. Enforcement

1. Each person conducting research under a management plan shall comply fully and promptly with the plan, and each person identified in the management plan as having responsibility for monitoring compliance with the plan shall carefully and fully monitor that compliance. Failure to disclose a potential or existing FCOI as required or otherwise comply with the provisions of this Policy may subject a CI to disciplinary action. Enforcement actions taken will depend on the nature and degree of non-compliance and will be recommended by the GC to the RTOGF Board of Directors. Enforcement for significant FCOI that includes a change in a CI's role within RTOGF will be reviewed by the RTOGF Board Chair. Examples of appropriate actions to resolve a FCOI include but are not limited to:

- (a) public disclosure of SFIs in abstracts, publications, presentations, press releases, and applications or proposals for research funding;
- (b) monitoring of research by independent reviewers or an oversight committee;
- (c) disqualification from participation in all or a portion of the funded research;
- (d) divestiture of SFIs;
- (e) severance of relationships that create actual or potential conflicts;
- (f) refusal by RTOGF to enter into a research agreement if a FCOI cannot be managed effectively;
- (g) participation of one or more non-conflicted persons in the evaluation of future research data and/or preparation of manuscripts; or
- (h) participation in a research ethics course, seminar, or workshop.

2. An official of RTOGF, who is acting as reviewer, may require a CI to disclose all outside income related to professional responsibilities, *regardless of any threshold amount specified in the RTOGF FCOI Form*.

C. Training; Reporting; Record Keeping

1. Training

FCOI training, review of the then-current RTOGF FCOI Policy, and submission of relevant RTOGF FCOI Forms must be completed prior to research participation at least annually. Additionally, all CIs will receive notice and additional training (if necessary) if RTOGF revises this FCOI Policy.

2. Reporting

A. RTOGF will notify the relevant government agency/entity promptly if bias is found with the design, conduct, or reporting of NIH-funded research, and file a FCOI management/mitigation report in accordance with 42 CFR 50.605.

B. If RTOGF determines or is made aware that a CI has not complied with the disclosure requirements for SFIs or that an FCOI was not identified and reported in a timely manner, then

RTOGF shall review the finding and if necessary, report the finding to the relevant government agency/entity within one hundred and twenty (120) days and document the review as required by federal regulation.

C. This RTOGF FCOI Policy shall be posted on the public portion of the RTOGF website. Upon receipt of a written request for information concerning identified FCOI's held by Senior/Key Personnel (*as defined by this Policy*), RTOGF will make that information available within five (5) business days of the request, as required by 42 CFR Part 50.605.

3. Record Keeping

RTOGF will maintain all records relating to this FCOI Policy for three (3) years after the termination or completion of the Research. RTOGF will follow all applicable record retention dates as specified in 42 CFR 50.604.