

## **Conflict of Interest in Research**

### **Purpose and Policy**

The Rogosin Institute (referred to as Rogosin or the Institute) expects all research community Members to conduct affairs consistent with their ethical, employment, and contractual commitments to the Institute free from conflicts of interest or commitment. This Conflict of Interest in Research Policy (referred to as Policy) establishes principles and requirements to ensure that research, scholarship, and other professional responsibilities are not unduly influenced by competing external commitments or financial interests.

Bias is defined as any tendency that may improperly influence a situation. A Conflict of Interest (COI) can arise when a Rogosin Member has a financial interest (e.g., in a startup company) relevant to their Rogosin responsibilities that could lead to real, potential, or apparent bias. An external observer may perceive a COI even if no real opportunity for benefit exists. Such situations require assessment, management and/or elimination to avoid research bias as this can damage Rogosin's reputation and reduce public trust in its teaching, research, and clinical activities.

This Policy defines the responsibilities of research personnel to ensure activities are conducted without bias or the appearance of bias, particularly due to a COI. Federal Financial Conflict of Interest (FCOI) regulations govern research funded by public entities, including the Public Health Service (PHS) agencies such as the National Institutes of Health (NIH) under the PHS in the Department of Health and Human Services (DHHS or HHS), and other independent agencies such as the National Science Foundation (NSF). These regulations require an Investigator to disclose financial interests related to institutional responsibilities, and the Institute to identify, manage, reduce, or eliminate conflicts that are related to the research that create a FCOI.

### **Applicability**

Rogosin Members are expected to adhere to the principles outlined herein.

If a Subrecipient (e.g., subcontractors or consortium members) is involved with any Rogosin research, Rogosin will take reasonable steps to ensure that a Subrecipient Investigator comply with FCOI regulations by incorporating as part of a written agreement with the Subrecipient terms that establish whether Rogosin or Subrecipient's FCOI policy will apply.

Under the situation where a Subrecipient's Investigator needs to rely on the Rogosin's Policy as the prime award recipient, Rogosin's written agreement with the Subrecipient will specify time period(s) within which Subrecipient Investigator will submit a disclosure to Rogosin. Such time period(s) shall be sufficient to enable Rogosin to comply timely with its review, management, and reporting obligations under federal regulations. However, if a Subrecipient's Investigator will comply with the Subrecipient's own FCOI policy, the written agreement with the Subrecipient will include that indication along with time period(s) for the Subrecipient to report all identified FCOI issues to Rogosin for subsequent reporting to the sponsoring federal agency.

## **Principles**

Rogosin's Members conduct research, scholarship, and other professional activities governed by principles of academic freedom, individual and Institute responsibility, and codes of academic integrity and ethical conduct. These principles protect academic freedoms, ensure open publication of research results, and encourage entrepreneurial activity, while also requiring certain responsibilities. Institute personnel must maintain primary loyalty and service to Rogosin and observe legal and ethical requirements.

### **A. The Conduct of Research**

- **Academic Freedom and Open Research:** Rogosin protects freedom in academic and research pursuits and the open publication, presentation, and discourse of scholarship and research results.
- **Ethics and Integrity:** Rogosin safeguards the integrity of public research and scholarly records and the ethical conduct of all academic and research pursuits. (Refer to Policy RI C143).
- **Nepotism:** Rogosin prohibits family ties and personal relationships to influence judgments on work quality or decisions regarding hiring, promotion, termination, or other employment terms. (Refer to Policy RI C144).
- **Human Subjects Research:** Rogosin ensures the rights and welfare of human research subjects.
- **Confidentiality:** Rogosin balances the confidentiality of personal information related to a potential conflict disclosure or resolution with the needs to ensure the public trust.
- **Entrepreneurship:** Rogosin encourages and supports its Members in enhancing the impact of their research through relationships with existing businesses or by starting their own, within limitations required to protect against real and perceived conflicts, academic freedom, open research, integrity, and ethics.

### **B. Primary Employment Obligations**

All Rogosin Members, including those with academic appointments, must evaluate and arrange their external interests and commitments to avoid compromising their ability to fulfill their primary duties to Rogosin. The opportunity to conduct scholarship and research in a free and open environment is a privilege. To maintain this environment's integrity, all employees have the following obligations:

- Maintain public and sponsor trust in the integrity of Rogosin research and scholarship;
- Refrain from actions that may compromise Rogosin's not-for-profit status;
- Not exert undue or improper influence over supervised staff;
- Comply with primary employment obligations to Rogosin, principles and rules surrounding research conduct, and applicable federal rules, regulations, and laws (e.g., conflicts, foreign influence disclosures, export controls, anti-bribery, and anti-corruption prohibitions);
- Use Rogosin facilities and resources in accordance with policy, law, and applicable regulations; and
- Maintain the integrity of U.S. government intellectual property rights and Rogosin-assigned or developed intellectual property (IP), consistent with Rogosin policies governing inventions and copyrighted content

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Rogosin employees may not supervise or assess individuals in an external enterprise in which the supervisor has a financial interest, unless authorized by Rogosin.

Part-time employees may have concurrent obligations to Rogosin and external entities, which can lead to significant potential for conflicts of interest or commitment (e.g., divided loyalties, federal award disclosure obligations, intellectual property conflicts, and the like). Therefore, part-time employees are expected to exercise particular care in immediately reporting concurrent obligations for appropriate review, assessment, and management.

All Rogosin employees, full-time or part-time, are prohibited from participating in any Malign Foreign Government Talent Recruitment Program. In addition, Rogosin's Policy requires that Rogosin Investigators with federal award proposals or awards disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure.

### Definitions

Clinical Research means any research or procedure involving human subjects in vivo or the use of human samples for the development and evaluation of patient therapies such as diagnostic tests, drug therapies, or medical devices. It includes early clinical studies, evaluative research, epidemiological studies and clinical trials. It excludes research using commercially obtained deidentified human cell lines as well as commercially obtained de-identified human tissue. It also excludes research that uses human tissue obtained from institutional tissue banks where the individual identifiers are unknown to the researcher. In general, the term includes all research required to be reviewed by an Institutional Review Board.

Conflict Management Plan (CMP) means a written plan instituted by Rogosin for the management, reduction, or elimination of a Financial FCOI.

Conflict of Interest (COI) means a situation in which a Rogosin Member or a Rogosin Family Member has a Significant Financial Interest or non-financial interest that may compromise, or provide the incentive to compromise, the Member's behavior in the conduct of his or her activities at Rogosin, the Member's influence on decisions that Rogosin may make, or the Member's influence in external entities. A COI may be real, potential or apparent. In accordance with federal regulations applicable to federally funded research, Rogosin makes determinations regarding Investigator FCOIs.

Conflict Review Officer (CRO) is a Rogosin-appointed position with the authority and responsibility for managing this Policy, including but not limited to review and assessment of financial disclosures, and management of COI situations in accordance with the Procedures defined in this Policy.

Disclosure means the reporting of a SFI related to Institutional Responsibilities, or other personal financial interests, on Rogosin's Financial Interest Disclosure Form.

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Family Member means within their household, a person's spouse, domestic partner, parent, grandparent, grandchild, sibling, dependent child, or anyone who qualifies as the person's dependent under the US Internal Revenue Code.

Federal Funding Agency means any federal agency that provides public funding to Rogosin in the form of grant awards or cooperative agreements.

Financial Conflict of Interest (FCOI) means a financial interest of an Investigator that could directly and significantly affect the design, conduct, or reporting of research.

Financial Interest Disclosure Form entitled "Financial Disclosure Form for Funded Awards" (includes a Supplement Form) is specific for PHS grant applications and awards. Any Investigator responsible for the design, conduct, or reporting of federal funding is required to submit this form that for each grant application sent to a federal agency.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Investigator means a Program Director (PD) or Principal Investigator (PI), Co-Principal Investigator, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, or proposed for such funding. This may include collaborators or consultants. The term "Investigator" for purposes of disclosure of a Significant Financial Interest (SFI) includes the Investigator's spouse and dependent children.

Institutional Responsibilities means any professional responsibilities on behalf of Rogosin, including, but not limited to purchasing, teaching, research, administration, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

PHS means the Public Health Service, an operating division of the DHHS, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 USC 201 et seq.

Research means a systematic investigation designed to develop or contribute to knowledge which can be generalized and which relates broadly to public health. The term encompasses basic and applied research and product development and includes any such activity for which research funding is available from a PHS grant or cooperative agreement whether authorized under the PHS Act or other statutory authority.

Research Conflicts of Interest Committee (RCOIC) is the Rogosin-appointed body responsible for the review, management, and resolution of conflict-of-interest situations involving an Investigator.

Rogosin Member means an individual who meets the definition of Investigator, or is an individual separately identified by the CRO and/or the RCOIC as needing to complete a Financial Interest Disclosure Form.

Significant Financial Interest (SFI) means:

1. A financial interest consisting of one or more of the following interests of an Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - o 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.
  - o With regard to any non-publicly traded entity, a 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 the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
  - o Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. An Investigator also must 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 institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is 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. The Institute will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

The term SFI does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by Rogosin to the Investigator if the Investigator is currently employed or otherwise appointed by Rogosin, including intellectual property rights assigned to The Institute and agreements to share in royalties related to such rights.
- Any ownership interest in Rogosin held by the Investigator, if the Institution 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.

- 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.

## **Responsibilities**

**Rogosin's CRO** or designee (both identified hereafter as CRO) has the authority and responsibility for the following procedures in accordance with this Policy:

- Ensure that an Investigator involved in research completes FCOI training;
- Require each Investigator disclose foreign and domestic SFIs and those SFIs of an Investigator's spouse and dependent children related to the Investigator's institutional responsibilities;
- Solicit and review financial interest disclosures for determining a SFI's relatedness to research, and if so, whether the SFI is a reportable FCOI;
- Devise appropriate Conflict Management Plans (CMP) including communicating the conditions or restrictions of the CMP to research personnel, and monitoring compliance, including determining consequences of non-compliance and appeal process; or eliminate the SFI; and
- Review and respond to requests from research personnel to revise CMPs.

To the extent practicable and consistent with legal obligations, Rogosin aims to ensure protecting the confidentiality of information related to conflict of interest matters and management plans. Information and materials provided to the CRO are shared to the most limited degree possible.

The CRO monitors compliance with conflict reporting and management and investigates non-compliance cases. Sanction recommendations may include, but are not limited to, written notice to supervisors, denying eligibility for research or innovation projects, and, in egregious cases, dismissal from Rogosin.

If a conflict is not identified or managed in a timely manner, the CRO will review and implement a mitigation plan and notify sponsoring agencies in accordance with their regulations.

**A Rogosin Member** is responsible for discharging their Rogosin research duties with integrity, independent of self-interest, reporting external relationships fully, accurately, and timely, and complying with all policies, procedures, and CMPs.

**A Principal Investigator** who is conducting research and supervising other researchers is responsible for identifying and reporting new Investigators as they become known, informing them of COI reporting requirements, and ensuring they submit a Financial Interest Disclosure Form prior to proposal or protocol submission.

**An Investigator** responsible for the design, conduct, or reporting of federally funded research is obligated to submit financial interest disclosures fully, accurately, and promptly as required by this Policy (also see Disclosure Obligations below) when:

- Newly appointed to a research personnel role;
- External relationships or those of their Family change;
- Required annually;
- Required by regulations of sponsor grants on which they are supported; and/or
- Family Members have disclosable SFI.

## **Compliance**

A Rogosin Member must attest to awareness of and compliance with this Policy and procedures, submitting financial interest disclosures when requested by the CRO, and complete all training requirements of sponsors for grants on which they are supported.

If a Rogosin Member violates this Policy, the CRO will report the violation to the Research Director, and sanctions may be imposed in consultation with Rogosin's President. Rogosin will also follow federal regulations as described in Procedures below regarding notification of the sponsoring agency if an Investigator fails to comply which may lead to the sponsor suspending funding. An Investigator has the right to appeal decisions made by the CRO or Research Conflict of Interest Committee (RCOIC) to the Rogosin President.

## **Training**

An Investigator funded under PHS awards/cooperative agreements issued on or after August 24, 2012, must complete training on their responsibilities for disclosure of external interests and other regulations under 42 CFR Part 50:

- Prior to engaging in research related to any PHS-funded project;
- At least every four years; and/or
- Immediately, if:
  - Rogosin revises this Policy that affects Investigator requirements
  - An Investigator is new
  - Rogosin finds that an Investigator is not in compliance with this Policy or a CMP.

Training requirements include familiarity with this policy and each Investigator must undergo required training prior to engaging in federally funded research. A Certificate of Training must be provided to Rogosin's CRO or designee.

## **Procedures**

**Investigator Disclosure Obligation:** Each Investigator has an ongoing obligation to disclose SFIs to Rogosin, through its CRO, on Rogosin's Financial Interest Disclosure Form.

An Investigator may submit an updated disclosure at any time, but must submit one:

- Upon initiation of employment;
- Annually, as instructed by Rogosin;

- Prior to the date of submitting a proposal/application for federally funded research, e.g., PHS-funded research;
- Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and/or
- If added as a new Investigator to an ongoing federally funded research project; and/upon request of Rogosin.

In addition, an Investigator must submit a Financial Interest Disclosure Form for PHS Awards specific to each grant application prior to its submission, as the required financial disclosure under 42 CFR Part 50.

The Principal Investigator for a federal grant application is responsible for determining who meets the definition of Investigator who is responsible for the design, conduct, or reporting of the award. The Principal Investigator is responsible for ensuring and certifying that each Investigator or other person identified as being responsible for the design, conduct, or reporting of research provides a completed Financial Interest Disclosure Form for PHS Awards with the proposal. These forms must be completed and submitted to the Clinical Research Manager before a proposal is endorsed by Rogosin and forwarded to the federal funding agency. All disclosures must be updated annually or as new reportable SFIs are obtained during the award period.

**Conflict of Interest Review of SFIs:** Rogosin's CRO reviews all disclosures of SFIs within sixty (60) days of disclosure. The review criteria will determine whether a SFI related to institutional responsibilities is disclosed. If yes, the review determination then is whether the SFI is related to federally funded research, and if so, whether or not the related SFI constitutes a reportable FCOI.

A SFI is *related* to the federally funded research when Rogosin, through its CRO, reasonably determines that the SFI is one that: 1) could be affected by the federally funded research, or 2) is in an entity whose financial interests could be affected by the research. The Investigator who submitted the disclosure may be involved in helping make the determination of whether the SFI is related to the federally funded research.

A *reportable FCOI* exists when, Rogosin, through its CRO, reasonably determines that the related SFI could directly and significantly affect the design, conduct, or reporting of the federally funded research. If yes, Rogosin, through its CRO, develops, implements, and documents a Conflict Management Plan (CMP) that specifies the conditions and actions necessary to manage the FCOI (see below), and obtain the approval by the Investigator. The FCOI and CMP together are timely reported to the relevant federal agency prior to the expenditure of federal funds.

When an Investigator discloses a new SFI, Rogosin, through its CRO, within sixty (60) days, reviews disclosures of a SFI, determines relatedness as described above to the Investigator's federally funded research; determines whether an FCOI exists; and, if so, implements, on at least an interim basis, a CMP that specifies the conditions and actions that have been, and will be, taken to manage the FCOI.

**Review of a SFI not Timely Disclosed or Reviewed:** For an ongoing federally funded award, if a new Investigator discloses a SFI, or an existing Investigator updates a disclosure with a new SFI, or if Rogosin identifies that a SFI was not timely disclosed by an Investigator, or, for whatever reason, was not previously

reviewed by Rogosin during an ongoing federally funded research project (e.g., was not timely reviewed or reported by a subrecipient), Rogosin, through its CRO, within sixty (60) days, will review the new SFI disclosure, determine whether it is related to the Investigator's federally funded research under the criteria above; determine whether an FCOI exists also as defined above, and if so, implement, at least on an interim basis, a CMP that specifies the conditions and actions that have been taken, and will be taken, to manage the FCOI going forward.

**Retrospective Review for Undetermined or Untimely FCOI:** Retrospective reviews to determine if federally funded research was biased in the design, conduct, or reporting of a FCOI are required: 1) when a FCOI for a federally funded award is not identified or managed in a timely manner, including failure by an Investigator to disclose a SFI that is determined to be a FCOI; 2) when the CRO does not timely review or manage a FCOI; or 3) when an Investigator fails to comply with a FCOI CMP. The retrospective review must occur within one-hundred-twenty (120) days of discovery.

The CRO will document the retrospective review. Such documentation includes the following key elements:

- Project number and title;
- Program Director/Principal Investigator (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);
- Findings of the review; and
- Conclusions of the review.

If bias is found, the CRO will:

- Ensure that the RCOIC has implemented a CMP;
- Notify the relevant federal agency promptly;
- Submit an updated FCOI report to relevant federal agency; and
- Submit a mitigation report to the relevant federal agency which includes the key factors documented in the retrospective review, the description of the impact on the research project, and the plan of action to eliminate or mitigate the effect of the bias.

**Management of an Identified FCOI:** If a FCOI is determined from a disclosed SFI that has been determined to be related to federally funded research, the CRO will present it to RCOIC. The disclosure must be reviewed to determine if further action is required before Rogosin expends awarded funds, e.g., issues a purchase order or subcontracts for goods and services related to any award resulting from the proposal, pays salaries, funds subrecipients, and the like expenditures.

When an FCOI is identified, the RCOIC will determine conditions or restrictions that are described in a written CMP to manage, reduce, or eliminate the conflict designed to safeguard objectivity in the funded research. Examples of possible conditions or restrictions include, but are not limited to:

- Confirmation of the Investigator's agreement to the CMP;
- Public disclosure of the FCOI (e.g., when presenting or publishing the research);
- For research projects 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 personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction, severance, or elimination of the FCOI (e.g., sale of an equity interest);
- Severance of relationships that create actual or potential conflicts;
- Refusal of the proposed sponsored project;
- How the management plan will be monitored to ensure Investigator compliance; and
- Any other restrictions that the CRO and/or RCOIC determines to be appropriate.

If an Investigator is dissatisfied with the determinations and the conditions imposed by a particular CMP, the Investigator may submit a written appeal to the Rogosin President within ten (10) calendar days of the recommendation. The President will make the final decision regarding whether a conflict exists and what actions should be taken.

For collaborators/subrecipients/subcontractors from outside institutions involved in externally sponsored projects, Rogosin will take reasonable steps to ensure compliance with federal conflict of interest regulations, e.g., 42 CFR 50 subpart F and the like. This is accomplished in a written agreement with specific terms and conditions establishing which FCOI policy will apply, Rogosin's or their own compliant policy, and including time periods for disclosure and reporting requirements. Subrecipient institutions relying on their FCOI policy must report identified FCOI to Rogosin in sufficient time for reporting the FCOI to the responsible federal agency.

**Reporting and Compliance Obligations:** Rogosin will submit reports for the following situations:

FCOI: For an Investigator funded under a PHS award or cooperative agreement awarded on or after August 24, 2012, Rogosin will provide a FCOI report to PHS (e.g., NIH) regarding an SFI that Rogosin determined to be a FCOI:

- Prior to the expenditure of funds;
- Within sixty (60) days of identifying a FCOI for an Investigator who is newly participating in the research;
- Within sixty (60) days for a FCOI, new or newly identified, for an existing Investigator; and/or

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- At least annually for the duration of the project period at required reporting periods (annual progress report, multi-year progress report, or at time of extension) addressing the financial interest's status and any changes to the CMP, and whether the FCOI is still managed or explaining why it no longer exists.

All initial FCOI reports will include:

- Project number and 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;
- The nature of the FCOI (equity, consulting fees, travel reimbursement, honoraria, etc.);
- The 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 a value cannot be readily determined;
- A description of how the financial interest relates to PHS-funded research and the basis for Rogosin's determination of the FCOI; and
- A description of the key elements of the Institute's CMP (see above section).

Annual Reports: For any FCOI previously reported by Rogosin, the CRO will provide to the PHS Awarding Component an annual FCOI report that addresses:

- The status of the FCOI; and
- Any changes to the CMP.

Mitigation Reports: If Rogosin identifies that bias is found in the design, conduct, or reporting of federally funded research, Rogosin will promptly notify the agency through a mitigation report. This can result from a FCOI that was not timely disclosed by an Investigator, a FCOI that was not timely reviewed by Rogosin, when an Investigator is determined to not be complying with the terms and conditions of a FCOI CMP, as described above for retrospective review. Rogosin, through its CRO, will submit an updated FCOI report as well as a mitigation report that includes, at a minimum:

- The key elements set forth in the retrospective review;
- A description of the impact of the bias on the research project; and
- Rogosin'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).

Clinical Research: In any case in which a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of drug, medical device, or treatment has been designed, conducted, or reported by a Investigator with a FCOI that was not managed or reported by Rogosin as required by this policy, Rogosin will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

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Violations/Sanctions: Failure to comply with the provisions of this Policy, including any failure to make proper disclosure or comply with a CMP, may result in disciplinary action consistent with Rogosin's employment policies and procedures.

**Records, Public Accessibility:** The required Financial Interest Disclosure Form(s) must be updated if new reportable information is obtained during the federal award period. Records of Investigator Financial Conflict of Interest Disclosure Form(s) and actions taken to manage actual, potential or apparent COIs will be retained by Rogosin, e.g., the Clinical Research Manager and the Rogosin's Corporate Compliance Officer, or designee, in accordance with standard Institute policies and procedures governing record retention. The retention period will be no less than three years after the termination or completion of the award or the resolution of any government action involving those records, whichever is later.

To ensure public accessibility, Rogosin ensures this Policy is available via a publicly accessible website. In addition, prior to the expenditure of any funds under a federally funded research project, Rogosin will make information available concerning identified FCOIs held by an Investigator either via Rogosin's publicly accessible web site or by a written response to any requestor within five (5) business days of a request regarding any SFI disclosed to the Institute that meets the following criteria:

- The SFI was disclosed and is still held by the Investigator for the federally funded research project as identified by Rogosin in the grant application, progress report, or any other required report submitted to the funding agency;
- Rogosin determines that the SFI is related to the federally funded research; and
- Rogosin determines that the SFI is an FCOI.

This information will include at a minimum:

- The Investigator's name;
- The Investigator's 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
- The approximate dollar value of the SFI, or a statement that the interest's value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The information will be updated as required.

**Policy Review:** Rogosin will review this Policy as needed and will update the Policy in accordance with changes in federal, state, and local regulations. Questions regarding the implementation of this Policy should be directed to Rogosin's CRO.