



Roswell Park Cancer Institute Policy and Procedure	Date Issued: 11/01/95	Number: 1102.1
Title: Managing Conflicts of Interest in Research	Revision: 13	Effective Date: 6/22/15
Prepared by: VP, Corporate Ethics	Approved by: Michael B. Sexton, General Counsel	Page: 1 of 11

A. GENERAL STATEMENT OF POLICY

To comply with federal and state requirements pertaining to the maintenance of ethical standards, particularly regarding the design, conduct and reporting of research, RPCI/HRI ("RPCI") provides education, receives and evaluates employee disclosures of financial interests, manages associated conflicts of interest and, where appropriate, provides associated reports to the federal government.

Compliance with the regulations is to assure a reasonable expectation that the design, conduct and reporting of the research will be free from bias resulting from conflicts of interest.

B. SCOPE

This policy and procedure applies to all RPCI and HRI staff and students involved in the design, conduct or reporting of research funded by the Public Health Service of DHHS (PHS) as well as RPCI employees subject to Joint Commission On Public Ethics reporting requirements under NY Public Officers Law section 73(a).

C. ADMINISTRATION

This policy and procedure will be administered by the Vice President for Clinical Operations, Corporate Ethics and Research Subject Protection and RPCI's Conflicts of Interest Committee (COIC).

D. CROSS-REFERENCE TO RELATED RPCI POLICIES

1. "Outside Activity" Policy (Policy #218.1) and "Standards for Vendor Relationships and Interactions (Policy 812.1) All RPCI and HRI employees are encouraged to review RPCI Policy 218.1 and RPCI Policy 812.1 prior to engaging in any activity which may interfere or be in conflict with the proper and effective performance of the employee's duties and responsibilities at RPCI or HRI or assumes or usurps an opportunity that should rightly belong to RPCI. RPCI and HRI employees interested in engaging in outside activities or seeking outside employment should submit Outside Employment Applications under Policy 218.1.
2. "Roswell Park Cancer Institute Corporate Code of Conduct" Policy (Policy #125.1) Under RPCI Policy #125.1, Principle 2 – "Legal Compliance," "All members of the RPCI workforce are required to comply with all applicable laws, whether or not specifically addressed in these policies." RPCI Policy #125.1, Principle 5 – "Conflicts of Interest" addresses certain Conflict of Interest

considerations in Sections 5.1 (Outside Financial Interests), 5.2 (Services for Competitors/Vendors), 5.3 (Participation on Boards of Directors/Trustees) and 5.4 (Academic Honoraria and Outside Honoraria).

E. POLICY / PROCEDURE

1. Definitions

- a. "Financial Interest" means anything of monetary value, whether or not the value is readily ascertainable.
- b. "Reportable Non-SFI Interest" or "RNFI" means any interest that is not a SFI but may reasonably be expected to bias the design, conduct or reporting of RPCI/HRI research, such as, for example, where an Investigator or their spouse or child serves as an uncompensated board member for an entity that funds or advocates for the treatment related to the Investigator's research.
- c. "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 (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.
- d. "Key Personnel" means the project director or principal Investigator of a PHS-funded research project and any other person identified as senior/key personnel by RPCI in the grant application, progress report, or any other report submitted to the PHS by RPCI.
- e. "Significant Financial Interest" or ("SFI") means
 - i. 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 institutional responsibilities:
 - 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 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;
 - 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 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
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
 - ii. 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.

- iii. Significant Financial Interest **Does NOT** include the following types of financial interests: salary, royalties, or other remuneration paid by RPCI to the Investigator if the Investigator is currently employed or otherwise appointed by RPCI, including intellectual property rights assigned to RPCI and agreements to share in royalties related to such rights; any ownership interest in the Institution 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; 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.
- f. "Financial Conflict of Interest" or FCOI" means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- g. "Conflict of Interest" or "COI" means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research or other significant interest of an RPCI employee that could be reasonably perceived as biasing such employee's discharge of their responsibilities at RPCI.

2. Disclosure to RPCI of SFIs and RNFI s

RPCI employees must disclose potential RNFI s and Financial Interests that may be SFIs to RPCI in a number of situations. Instances also arise where RPCI identifies employee potential RNFI s or Financial Interests that may be SFIs.

- a. Every Investigator must disclose to RPCI their potential RNFI s and Financial Interests that may be SFIs as follows:
 - i. At least annually (prior to April 15 of each year within [Conflicts of Interests Form A](#) submitted to the Office of Research Subject Protection (ORSP)) [*Note: Individuals subject to reporting obligations under NY Public Officer's Law section 73(a) who are not Investigators also have Conflicts of Interests Form A reporting obligations*];
 - ii. Prior to applying for human subject research ([Supplemental Disclosure Form](#) submitted through Clinical Research Services (CRS));
 - iii. Prior to submitting an application for research funding ([Form DOH-3995](#) submitted to the Director of HRI); and
 - iv. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new potential SFI (File an updated version of the above noted forms).
- b. Instances where potential RNFI s and Financial Interests that may be SFIs are identified by RPCI, other than via disclosures made under section E.2.a., comprise:
 - i. [Outside Employment Application](#) (OEA) review by RPCI's Outside Employment Committee (OEC);

- ii. Review of Human Studies "Attachment B" information by RPCI;
 - iii. Review of Privately funded human studies information by RPCI;
 - iv. Company interactions with RPCI's General Counsel's Office or Tech Transfer Office;
 - v. RPCI grant administration review of grant related information (e.g., SBIR/STTR sub-award enters Phase II); and
 - vi. RPCI Corporate Compliance Office or other compliance function receives a confidential report of a Financial Interest. *(Recognizing the importance of preserving the confidentiality of the identity of individuals submitting reports to the Corporate Compliance Office or other compliance functions, ORSP staff will coordinate with the Corporate Compliance Office and carry out its efforts under the applicable COI Process Categories in a manner that as fully as practically possible preserves the confidentiality of the individual who submitted the report.)*
- c. Financial Interests that may be SFIs and potential RNFI's identified by RPCI other than under section E.2.a. shall be treated similarly to those identified under section E.2.a.

3. RPCI's Review and identification of Potential SFIs, RNFI's FCOI's and other COI's

Review Process. RPCI's Vice President for Clinical Operations, Corporate Ethics and Research Subject Protection (VP for Ethics), or designee(s), in conjunction with RPCI's Conflicts of Interest Committee (COIC) shall promptly review submitted or identified potential RNFI's and Financial Interests that may be a SFI to determine (i) whether a SFI exists, and, if so, whether a FCOI exists, and (ii) whether a RNFI exists and, if so, whether a COI other than a FCOI exists.

- a. RPCI's VP for Ethics, or designee(s), shall promptly evaluate
 - i. Whether there is a reasonable likelihood that a Financial Interest is a SFI, and, if so, whether there is a reasonable likelihood that such potential SFI may constitute a FCOI.
 - ii. Whether there is a reasonable likelihood that a Financial Interest or potential RNFI is a RNFI, and, if so, whether there is a reasonable likelihood that such potential RNFI may constitute a COI.
- b. When a Financial Interest is determined to have a reasonable likelihood of being a SFI constituting a FCOI, such potential SFI and FCOI shall be submitted to RPCI's COIC. Such submission to the COIC may be accompanied by a proposed FCOI management plan for consideration by the COIC.
- c. When a Financial Interest or potential RNFI is determined to have a reasonable likelihood of being a RNFI and constituting a COI (other than a FCOI), such potential RNFI and COI shall be submitted to RPCI's COIC. Such submission to the COIC may be accompanied by a proposed COI management plan for consideration by the COIC.
- d. When a potential SFI and FCOI or potential RNFI and COI is submitted to the COIC, the COIC shall promptly determine whether a SFI, FCOI, RNFI, or COI exists and, if a FCOI or COI is determined to exist, develop and approve a management plan to address such FCOI or COI.
- e. The COIC, VP for Ethics and/or individual(s) designated in this section 3 may involve the researcher/employee in determining whether a potential SFI is related to PHS funded research; whether the potential SFI could be affected by the PHS funded research, or is in an entity whose financial interests could be affected by the research.

- f. Timing requirements.
 - i. For PHS funded research that has not yet commenced, the review, determination and management plan development and approval process of section E.3., as well as reporting to PHS under section 7, shall be completed prior to the expending of any PHS funds for the research.
 - ii. For PHS funded research that has already commenced, if a potential SFI is disclosed or identified after, the review, determination and management plan development and approval process of section E.3., as well as reporting to PHS under section 7, shall be completed, along with preliminary implementation of any associated FCOI management plan(s), within sixty (60) days of the disclosure or identification of such potential SFI.
- g. SBIR Phase I awards and STTR Phase I awards are exempt from the SFI and FCOI management and reporting requirements under this policy. SBIR Phase II awards and STTR Phase II awards are **NOT** exempt.

4. Determinations of Non-Compliance and Retrospective Reviews

- a. Whenever an instance is identified where there is a reasonable likelihood of non-compliance with this policy (e.g., FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a FCOI; failure by RPCI to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan) RPCI shall promptly bring the matter before the COIC for a review and determination regarding non-compliance (e.g., within 60 days).
- b. Whenever non-compliance is identified under section E.4.a. RPCI shall complete a retrospective review of the Investigator's activities and the PHS-funded research project to 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 such research.
- c. RPCI shall document the retrospective review, and such documentation shall include, but not necessarily be limited to, all of the following key elements:
 - i. Project number;
 - ii. Project title;
 - iii. Key Personnel;
 - iv. Name of the Investigator with the FCOI;
 - v. Name of the entity with which the Investigator has a financial conflict of interest;
 - vi. Reason(s) for the retrospective review;
 - vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - viii. Findings of the review; and
 - ix. Conclusions of the review.
- d. Timing Requirements. Such determination regarding non-compliance and retrospective review shall be completed by RPCI within one hundred and twenty (120) days of identification of the instance of potential non-compliance.
- e. Reporting regarding any non-compliance and retrospective review shall be in accordance with section E.7.a.iii.

5. IRB/IACUC Notifications

IRB/IACUC Notification. If review of any Financial Interest or potential RNFI identifies any information pertinent to any research or clinical studies under review or approved by an IRB or RPCI's IACUC, such information shall be promptly (e.g. within 24 hours) provided to such IRB or IACUC for appropriate action.

6. Management Plans for FCOIs and other COIs

When RPCI's evaluation of Financial Interests that may be SFIs and RNFIs results in a determination by the COIC that SFIs or RNFIs exist and constitute a FCOI or other COI, RPCI shall develop management plans to eliminate or otherwise manage the FCOI or other COI, with such management plans being reviewed and approved by the COIC.

- a. Management plans developed by RPCI and approved by the COIC (potentially in conjunction with other cognizant committee(s) or review board(s)), whether or not involving research, may include elements of the following, non-inclusive, list of approaches and/or requirements:
 - i. Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to RPCI's Institutional Review Board(s));
 - ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
 - iv. Modification of the research plan;
 - v. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
 - vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
 - vii. Severance of relationships that create financial conflicts; or
 - viii. Monitoring of involvement of students and postdoctoral appointees by independent reviewers or oversight committees.
 - ix. ** NOTE: RPCI employees having an SFI in a company must obtain prior approval from the Institute to serve as lead Principal Investigator in any pre-clinical research funded by such company. RPCI employees must submit an application via a memo to the chair of the COIC for review containing a proposed pre-clinical research plan and budget and a disclosure of the employee's interest, by percentage, and position or appointment, if any, with such company.*
- b. In all instances where RPCI institutes a management plan pertaining to a FCOI, RPCI shall monitor such management plan on an ongoing basis until the completion of the PHS funded research.
- c. In all instances where RPCI institutes a management plan pertaining to a COI, other than a FCOI, RPCI shall monitor such management plan on an ongoing basis and subject the management plan to additional COIC review at least annually.

7. PHS FCOI Reporting, Disclosure and Record Retention Requirements

- a. Reporting. SFIs that are determined by RPCI to create a FCOI relative to the conduct of research funded by the PHS shall be appropriately managed or eliminated, and any such FCOIs shall be reported to PHS through the eRA Commons Module.

i. Standard Reporting. Such reports shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of RPCI's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has a financial conflict of interest;
- 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 RPCI's determination that the financial interest conflicts with such research; and
- A description of the key elements of RPCI's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

ii. Timing Requirements.

- For any SFI disclosed or identified prior to the commencement of PHS funded research, which SFI creates a FCOI, the FCOI report shall be submitted to PHS prior to the expenditure of funds under the PHS award.
- For any SFI disclosed or identified after the commencement of PHS funded research, which SFI creates a FCOI, the FCOI report shall be submitted to PHS within sixty (60) days of the reporting or discovery of the SFI.

iii. Non-Compliance Reporting. If the failure of an Investigator to comply with an RPCI's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, RPCI shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

- Based on the results of any retrospective review, if appropriate, RPCI shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.
- If bias is found, RPCI is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum,
 - the key elements documented in the retrospective review above

- a description of the impact of the bias on the research project
 - RPCI '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; and analysis of whether the research project is salvageable).
 - Thereafter, the Institution will submit FCOI reports annually
- iv. Sub-awardee Reporting. If RPCI carries out the PHS-funded research through a sub-recipient, RPCI (as awardee Institution) shall provide FCOI reports to PHS regarding all FCOIs of all sub-recipient Investigators.
- b. Public Disclosure
- i. This policy shall be made available to the public via posting on RPCI's publicly accessible website.
 - ii. Publication requirements regarding Key Personnel's SFIs that are determined to be FCOIs.
 - Prior to RPCI's expenditure of any funds under a PHS-funded research project, RPCI shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any SFI disclosed to RPCI that meets the following three criteria:
 - The SFI was disclosed and is still held by the Key Personnel;
 - RPCI determines that the SFI is related to the PHS-funded research; and
 - RPCI determines that the SFI is a FCOI.
 - The information that RPCI makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following:
 - 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 (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.
 - If RPCI responds to written requests for the purposes of this subsection, RPCI will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of RPCI's identification of a new FCOI, which should be requested subsequently by the requestor.
 - RPCI shall maintain information concerning the SFI of an individual subject to this sub-section for responses to written requests or for posting via RPCI's publicly

accessible Web site for at least three years from the date that the information was most recently updated.

- v. Section E.7.a. and E.7.b. reporting and public disclosure requirements shall not apply to SBIR Phase I awards and STTR Phase I awards.
- vi. Record Retention. RPCI shall maintain records relating to all Investigator disclosures of Financial Interests and RPCI's review of, and response to, such disclosures (whether or not a disclosure resulted in RPCI's determination of a FCOI) and all actions under RPCI's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report.

8. Contractual Obligations Imposed on Other Institutions, Researchers and Personnel Involved in PHS/NIH Funded Research (e.g., Sub-awards)

- a. PHS sub-award contracts to institutions, Investigators or other personnel outside of RPCI shall specify (i) whether the COI policy of the prime awardee Institution or the sub-awardee will apply to the sub-awardee Investigators and (ii) require applicable time periods be adhered to for the transfer of information to meet disclosure and/or FCOI reporting requirements.
- b. For sub-awardee COI policy specified agreements the sub-awardee must be required to notify the prime awardee of FCIOs in sufficient time for the prime awardee to report the FCOIs to NIH in a timely manner.
- c. For prime awardee COI policy specified agreements the sub-awardee must be required to notify the prime awardee of sub-awardee Investigator disclosures of Significant Financial Interests in sufficient time for the prime awardee to review, manage and report identified FCOIs to NIH in a timely manner, and require that sub-awardee comply with the prime awardee's FCOI management plan.
- d. For prime awardee COI policy specified agreements the sub-awardee must be required to present or make available to sub-awardee Investigators education required under 42 CFR Part 50 (Subpart F) [Section 50.604] and certify to the prime awardee and provide documentation that such educational requirements have been completed by sub-awardee Investigators in a timely manner. To aide in this effort the prime awardee may provide to the sub-awardee pre-prepared presentation materials so supplement NIH's training module.
- e. In all cases the prime awardee remains responsible for FCOI reporting to NIH, and, as such, no sub-award agreement may be entered into unless the sub-awardee agrees to contractual language sufficient for RPCI/HRI to meet its obligations.

9. Enforcement and Sanctions

RPCI may take all actions within its power to ensure adequate compliance with and enforcement of this policy, including, without limitation, cancelling of PHS sub-awards, suspension of research privileges, changing employee responsibilities, progressive employee discipline and/or termination of employment.

In any case where the department of U.S. Health and Human Services (HHS) determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by RPCI as

required by this subpart, RPCI shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

10. NIH and JCOPE COI Education and Training Requirements

Federal and State laws require that certain employees receive periodic training relating to conflicts of interests and associated compliance and reporting requirements. PHS related training is required under federal law and pertains to financial conflicts of interest (FCOIs) relating to research funded by PHS. JCOPE related training is required under New York State law and pertains to certain employees' individual obligation to submit financial and other information directly to NY's Joint Commission On Public Ethics (JCOPE). JCOPE education and training will be offered by the ORSP at RPCI. PHS related training is secured by employees through online providers identified by RPCI (e.g., CITI (<https://www.citiprogram.org>) or NIH (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) and personnel completing such online courses must print the certificate of completion and provide it to RPCI's Grants Office.

- a. PHS education and training is required for Investigators (individuals responsible for the design, conduct or reporting of research) and must be undertaken prior to engaging in PHS funded research, at least every four years, and immediately when:
 - i. RPCI's Financial Conflicts of Interest policies change in a manner that affects Investigator requirements;
 - ii. An investigator is new to RPCI; or
 - iii. RPCI finds that an Investigator is not in compliance with RPCI's Financial Conflicts of Interest policy or management plan.
- b. JCOPE – Under NY Executive Law section 94(10) a two hour education and training program is required for individuals subject to the reporting requirements of NY Public Officers Law section 73(a), with an additional 90 minute education and training program to be completed at least every three years thereafter. Section 73(a) of the NY Public officers law applies to RPCI employees holding positions designated by RPCI as policy-making or making in excess of \$88,256 per year as of April 1, 2010.
- c. Employees' JCOPE reporting is separate and distinct from RPCI's reporting requirements pertaining to Significant Financial Interest(s) under this Policy 1102.1. Questions about NIH and JCOPE education and training requirements may be directed to RPCI's Office of Research Subject Protection (ORSP).

11. Conflicts of Interest Committee Structure

- a. Roswell's President/CEO shall appoint an Institutional Conflicts of Interest Committee (COIC) to oversee and administer this policy and to support adherence to ethical principles in the design, conduct, reporting and funding of research and other activities at RPCI/HRI. The COIC shall be composed of not less than ten (10) individuals. At least four (4) COIC members shall be faculty members chosen from the Ph.D. faculty at RPCI/HRI, one (1) of whom shall be from the Department of Prevention and Population Sciences, and at least (3) COIC members shall be physician members of the faculty. One (1) COIC member shall be an attorney licensed to practice law in the State of New York. A Chairman shall be appointed by and shall serve at the pleasure of RPCI's President/CEO.
- b. Each COIC member shall serve a two (2) year term, which can be renewed. Membership terms shall be staggered so that in any year not more than three (3) COIC seats shall

become vacant. For meetings, a quorum of not less than six (6) members is required, and actions may be taken by vote of a majority of those members present at a meeting where a quorum of members is present. At least one (1) staff member from the Office of Research Subject Protection will be present at each COIC meeting, where practicable, to record the actions of the COIC, and to facilitate communications between the COIC and the Internal Review Board (IRB). In addition to regular meetings, at the discretion of the COIC Chairman matters may be brought before the COIC electronically (e.g., via e-mail or web access) and voted upon and resolved electronically provided that the number of members' electronic votes constitute a quorum and the actions taken are by a majority vote of those members voting.

12. Additional Reference Materials

- a. New York Public Officers Law section 73
- b. New York Public Officers Law section 73 (a)
- c. New York Public Officers Law section 74
- d. New York Executive Law section 94
- e. www.jcope.ny.gov
- f. 42 CFR Part 50 (including Subpart F)
- g. 45 CFR Part 94
- h. 45 CFR Parts 74.61, 74.62 and 92.43
- i. [RPCI Policy 218.1](#) "Outside Activity"
- j. [RPCI Policy 812.1](#) "Standards for Vendor Relationships and Interactions"
- k. [RPCI Policy 125.1](#) "Roswell Park Cancer Institute Corporate Code of Conduct"
- l. [RPCI Policy 122.1](#) "A+ Time and Academic Honoraria"
- m. [RPCI Policy 709.1](#) Technology Transfer Commercialization Fund and Usage Criteria
- n. [RPCI Policy 119.1](#) Employee Affiliated Companies (Startups)

F. DISTRIBUTION

This Policy and Procedure will be distributed to all Institute Managers via the RPCI internal web page and to holders of backup hard copies of the manual. Managers are responsible for communicating policy content to pertinent staff.