

**APPENDIX B**  
**TO**  
**POLICIES ON CONFLICTS OF INTEREST, COMMITMENT AND CONSULTING**

**RESEARCH CONFLICT OF INTEREST COMMITTEE**  
**OPERATING GUIDELINES**

(Capitalized terms are defined in the *Policy on Conflicts of Interest in Research and Sponsored Programs* or the *Policy on Institutional Conflicts of Interest in Human Subjects Research*.)

I. **Research Conflict of Interest Committee (or RCOIC) Governance**—The RCOIC’s members, including the Chair, are nominated by the Senior Vice President and Vice Dean for Science of the Medical Center and are appointed by the Dean and CEO of the Medical Center. The Chair of the RCOIC and the Office of Compliance will report to the Senior Vice President and Vice Dean for Science regarding the RCOIC’s activities annually or more frequently if requested.

II. **RCOIC Members**—The RCOIC should consist of at least five (5) and no more than nine (9) members, each appointed for a three-year term. The RCOIC’s members shall be faculty members of the Medical Center, except that one (1) member of RCOIC may be from NYU but not from the Medical Center and one (1) member of RCOIC may be from outside of the NYU and Medical Center community. The RCOIC shall include (i) at least one faculty member who conducts Non-Human Subjects Research; (ii) at least one faculty member who conducts Human Subjects Research; and (iii) at least one member of the Medical Center’s IRB. Recusal is required whenever any member has a conflict of interest (personal or due to Medical Center responsibilities) regarding any matter under review.

III. **RCOIC Meetings**

A. Meetings of the RCOIC shall be scheduled monthly and held as needed.

B. The following Medical Center individuals shall be invited to attend all non-executive meetings of the RCOIC: (i) representative(s) from the Office of Compliance; (ii) representative(s) from the Office of Science & Research, (iii) a representative of the Office of Industrial Liaison, (iv) a representative from the IRB’s staff; and (v) a representative from the Office of Legal Counsel. The RCOIC and the Office of Compliance may also invite individuals to attend meetings as situations warrant. Non-RCOIC members are not entitled to a vote on RCOIC matters.

C. Executive meetings of the RCOIC may be called by the Chair of the RCOIC or the Office of Compliance for investigations and other special matters. Only members of the RCOIC and representatives from the Office of Compliance and the Office of Legal Counsel shall be invited to attend executive meetings of the RCOIC.

D. Each RCOIC member shall have one vote. Actions of the RCOIC shall require a majority of the votes cast at any meeting in which a quorum is present. The presence of an actual majority of the members of the RCOIC shall constitute a quorum and shall be necessary to conduct the business of the RCOIC. RCOIC meetings may be held in person or by teleconference. Minutes shall be kept of all meetings of the RCOIC and approved at subsequent meetings of the RCOIC.

E. The RCOIC may also act by unanimous consent electronically, including via e-mail correspondence, without a scheduled meeting. Any such actions shall be entered into the minutes at the next scheduled meeting of the RCOIC.

F. The Chair of the RCOIC may act for the RCOIC on behalf of the full RCOIC, provided that such act is conditional pending ratification by the RCOIC at the next scheduled meeting. The Chair of the RCOIC may take this temporary action only in the event a project will lapse or otherwise be materially compromised if a delay is required until the next scheduled meeting of the RCOIC.

G. To the limited extent permitted by the *Policy on Conflicts of Interest in Research and Sponsored Programs*, the Office of Compliance may make determinations on behalf of the RCOIC. When the Office of Compliance makes any such determination, the Office of Compliance shall report such action to the RCOIC and the RCOIC shall enter such act into the minutes at the next scheduled meeting.

H. All information disclosed at or in connection with any RCOIC meeting will be kept confidential by all RCOIC members and invitees and used only as contemplated in these Operating Guidelines.

#### IV. **Responsibilities**

A. The RCOIC shall review any initial disclosure of a Significant Financial Interest under the *Policy on Conflicts of Interest in Research and Sponsored Programs* or Institutional Financial Interest under the *Policy on Institutional Conflicts of Interest in Human Subjects Research*, and any other matter referred to it by the Office of Compliance.

B. The RCOIC's primary responsibility is to make a determination on any matter submitted to it by the Office of Compliance on whether Compelling Circumstances exist that justify (i) an Investigator's participation in the Sponsored Project notwithstanding a disclosed Financial Interest or (ii) the Medical Center's participation in a Human Subjects Research project notwithstanding an Institutional Financial Interest. The RCOIC shall make and document its determinations.

C. The RCOIC shall make a determination that Compelling Circumstances exist to justify participation only if the RCOIC adopts a conflict management plan (the "Plan") which maintains research integrity and serves the best interests of subjects. The Plan shall describe the nature of the financial interest, the conditions under which the activity may proceed and the individuals, including the principal investigator, subject to the Plan (the "Interested Parties"). A Plan permitting an activity notwithstanding a Significant Financial Interest/Institutional Conflict of Interest should contain an additional paragraph describing the depth and frequency of any compliance audits that are required by the Plan. The RCOIC shall use its best efforts to develop a standard approach to managing those types of interests for which a standard approach is reasonable and appropriate. Any changes in the Plan (other than by the Senior Vice President and Vice Dean for Science under Section VII below) require the approval of the RCOIC.

D. The review and evaluation of any submission to the RCOIC must be completed prior to the expenditure of any awarded funds for the applicable Sponsored Project or its commencement (including any enrollment of research subjects).

V. **Compelling Circumstances Test**— A finding of Compelling Circumstances will be exceptional, made only after a review of the totality of the circumstances, and made only where the RCOIC is satisfied that a Plan to mitigate any effects of the Significant Financial Interest/Institutional Conflict of Interest can and will be implemented. The following list of factors to consider may (or may not) be used by the RCOIC, at its discretion, in evaluating whether Compelling Circumstances are present:

- A. whether basic academic values are upheld, an open academic environment is maintained, the research is appropriate to the mission of the Medical Center, and the research is of a fundamental or basic nature;

- B. the nature and amount of the disclosed interest, how closely the interest is related to the research, the control or influence such relationship or interest might have over the Research Sponsor's or Financially-Interested Company's decisions, and the extent to which the research results could be influenced by the financial interest;
- C. whether the research is essential to maintain the continuity of a research effort related to NYU's rights in intellectual property covering a product or process to be used in the research;
- D. the potential gains to patients and the community in the immediate and long-term future in the event the research is successful;
- E. any unique expertise of the Investigator (e.g. inventorship, experience, special insights, knowledge, perseverance, laboratory resources or a need for a special patient population) that may make his or her involvement essential, including the degree to which the safety or effectiveness of the research might be compromised without that individual;
- F. restrictions, if any, on publications, presentations or other disseminations related to or referencing the research or the research results;
- G. whether the risks to Human Subjects Research are sufficiently low and disposition may be similar to or identical with disposition for a Non-Human Subjects Research project;
- H. the steps proposed by the Investigator for effective oversight and management of the financial interests;
- I. what role students, trainees, and junior faculty and staff will play and whether such role is appropriate and free from exploitation; and
- J. (for Institutional Financial Interests in Human Subjects Research only) whether the Medical Center is uniquely qualified (by special facilities or equipment, unique patient population, qualifications of its investigators, etc.) to conduct the research and safeguard the human subjects in the Research.

Compelling Circumstances will not normally be found to justify participation in a clinical trial if participation gives rise to a Conflict of Interest or Institutional Conflict of Interest.

VI. **Management Strategies**—In its deliberations, the RCOIC shall consider the following management strategies for inclusion in the Plan for both individual and institutional conflicts of interest:

- A. Restriction from holding the Outside Position;
- B. Reduction, divestiture or elimination of the Financial Interest;
- C. Disclosure of the interests: to others working on the research; to the Research Sponsor; to federal or state government officials as required by law; in any substantive public communication related to or referencing the research or the research results (including publications, presentations and other disseminations, whether oral or written); and to research subjects in the informed consent documents in an IRB-agreed form.

Generally, disclosures should be sufficiently specific to indicate whether the financial interest giving rise to the potential conflict is one of the following arrangements, if applicable: (a) consulting income, (b) royalties (including an institutionally-defined inventor's share), (c) equity

interests, or (d) an outside, fiduciary position. Such disclosure should also indicate that the conflict has been disclosed and evaluated and is being managed by the Medical Center.

Disclosures to subjects will include (a) a clear reference to the presence of the conflicting interest, (b) an explanation of the fact that the financial interest has been reviewed by the RCOIC and approved subject to management and oversight, (c) a statement by both the Committee and the IRB that there is little increased risk to the welfare of the subject or to scientific quality of the research, and (d) an explanation that additional information would be provided to the research subjects upon request.

- D. Disqualification or restriction of the conflicted Investigator's participation in all or relevant portions of the research activity;
- E. Revision of study design to address potential bias from interests;
- F. Periodic or annual reports to the RCOIC certifying compliance with the applicable Plan;
- G. Appointment of a review committee to receive periodic reports regarding implementation of the Plan, or of individual(s) with sufficient independence and expertise to evaluate the research and its progress to oversee and monitor the entire project or of the research data. The review committee or the individuals may be from within or outside the Medical Center; and
- H. [for institutional conflicts only] Limitation of research to a non-primary research site and/or not serving as the coordinating site.

The RCOIC shall be mindful that the data integrity risks of Non-Human Subjects Research are the same as those in Human Subjects Research.

VII. **Appeals**—Determinations of the RCOIC may be appealed to the Senior Vice President and Vice Dean for Science. Appeal must be in writing and be submitted to the Office of Compliance. Appeals may be made by the Office of Compliance, the RCOIC, Vice Dean for Science, the Investigator with the Financial Interest, or any other Interested Parties. The Office of Compliance will provide copies to the Vice Dean for Science and the RCOIC Chair. Decisions of the Vice Dean for Science are final and shall be submitted in writing by the Office of Compliance to the RCOIC or the IRB (if applicable), and the Investigator's Department Chair. If the Vice Dean for Science modifies the RCOIC's determination, the Office of Compliance shall modify and reissue the Plan.

VIII. **Comparative Authority of RCOIC and IRB / IACUC** —Neither the IRB nor IACUC may approve research protocols referred to the RCOIC that have not been recommended for approval by the RCOIC or approve monitoring procedures or other conditions that are less restrictive than those imposed by the RCOIC. No authorization granted by the RCOIC may supersede the authority of the IRB or the IACUC and both the IRB and the IACUC may modify the Plan to impose more stringent restrictions than those imposed by the RCOIC.