



# Financial Conflict of Interest Related to Research

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## POLICY STATEMENT

Cornell University is committed to overseeing the conduct of research in a manner that ensures the integrity of the research process and maintains the public trust and that of sponsors in the integrity and credibility of its faculty, its staff, and its research programs. This commitment requires the university to ensure that there is no reasonable expectation that research results are biased by the external commitments and financial interests of persons who are responsible for the design, conduct, reporting, or direct administration of university research. Such individuals are, for the purposes of this policy, referred to as "research personnel." Research, for the purpose of this policy, includes all sponsored projects, including research and extension, and all non-sponsored university research.

This policy identifies and addresses the real or apparent financial conflicts of interest presented by the intersection of research activities and personal financial interests, and defines the requirements of all research personnel to ensure that those activities are conducted objectively and without consideration of personal financial gain.

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## REASON FOR POLICY

The integrity of Cornell University's research is of the utmost importance. The principles and procedures of this policy assure that university research personnel will report their external commitments and financial interests in a timely manner and that the real and apparent financial conflicts of interests of research personnel will be identified and responsibly managed. This policy complements the university's policy on Conflicts of Interest and Commitment and establishes the Financial Conflicts of Interest Committee, and for Weill Cornell Medicine units, the Conflicts Advisory Panel as review bodies for real and apparent conflicts of interest related to research. This policy promotes compliance with all applicable federal and state laws, regulations, and policies regarding financial conflicts of interest.

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## ENTITIES AFFECTED BY THIS POLICY

- All units of the university

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## WHO SHOULD READ THIS POLICY

- All members of the university academic staff, and research personnel
- Deans and unit heads
- Administrative managers
- All members of the Weill Cornell Medicine community

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## MOST CURRENT VERSION OF THIS POLICY

[www.dfa.cornell.edu/policy/policies/financial-conflict-interest](http://www.dfa.cornell.edu/policy/policies/financial-conflict-interest)

## POLICY 1.7

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## RELATED RESOURCES

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### University Policies and Documents Applicable to All Units

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[University Policy 1.5, Inventions and Related Property Rights](#)  
[University Policy 3.6, Financial Irregularities, Reporting and Investigation](#)  
[University Policy 4.6, Standards of Ethical Conduct](#)  
[University Policy 4.7, Retention of University Records](#)  
[University Policy 4.14, Conflicts of Interest and Commitment \(Excluding Financial Conflict of Interest Related to Research\)](#)

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### University Policies and Documents Applicable to Only Ithaca Campus Units

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[University Policy 1.4, Care and Use of Live Vertebrate Animals in Research and Teaching](#)  
[Code of Academic Integrity](#)  
[Dismissal/Suspension Policy for Faculty Members](#)  
[Faculty Appeals Procedures](#)  
[Faculty Handbook, Chapter 5: Academic Policies and Responsibilities, page 78](#)  
[Guidance related to Financial Conflicts of Interest Related to Research maintained by the Office of Research Integrity and Assurance](#)

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### University Policies and Documents Applicable to Only Weill Cornell Campus Units

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[New York Presbyterian Code of Conduct \(PDF\)](#)  
[Study Specific Report: Quick Reference Guide \(PDF\)](#)  
[Weill Cornell Medicine Academic Handbook, \(including Dismissal/Suspension Policy for Faculty Members\)](#)  
[Weill Cornell Medicine Conflicts Management Program website, maintained by the Office of Research Integrity.](#)

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### External Documentation

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[Bayh-Dole Act of 1980](#)  
[National Institutes of Health: Financial Conflicts of Interest and Research Objectivity: Issues for Investigators And Institutional Review Boards](#)  
[National Institutes of Health Tutorial on Financial Conflict of Interest](#)  
[National Science Foundation Grant Policy Manual, Chapter V, section 510, Conflict of Interest Policies \(PDF\)](#)  
[Recognizing and Managing Personal Financial Conflicts of Interest, Council on Governmental Relations, Winter 2002 \(PDF\)](#)  
[U.S. Food and Drug Administration, Financial Disclosure by Clinical Investigators](#)

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### University Forms and Systems

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[Conflicts of Interest Reporting System \(WCM\)](#)  
[Cornell Hotline](#)

Cornell Policy Library  
Volume: 1, Academic/Research  
Responsible Executive: Senior  
Vice Provost for Research/  
Provost for Medical Affairs and  
Dean of the Medical College  
Responsible Offices: Offices of  
Research Integrity and  
Assurance  
Originally Issued: April 12, 2011  
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January 22, 2010  
Last Updated: May 3, 2018

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## CONTACTS

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Direct any general questions about this policy to your college or unit administrative office. If you have questions about specific issues, contact the following offices.

#### *Ithaca Campus Units*

<b>Subject</b>	<b>Contact</b>	<b>Telephone</b>	<b>E-mail/Web Address</b>
<b>Policy Clarification, Ithaca Campus Units</b>	Office of Research Integrity and Assurance	(607) 255-2214	<a href="mailto:coi@cornell.edu">coi@cornell.edu</a> <a href="http://www.oria.cornell.edu">www.oria.cornell.edu</a>
<b>Federal and State Laws and Regulations on Conflicts of Interest, Ithaca Campus Units</b>	Office of Research Integrity and Assurance	(607) 255-2214	<a href="mailto:coi@cornell.edu">coi@cornell.edu</a> <a href="http://www.oria.cornell.edu">www.oria.cornell.edu</a>

#### *Weill Cornell Campus Units*

<b>Subject</b>	<b>Contact</b>	<b>Telephone</b>	<b>E-mail/Web Address</b>
<b>Policy Clarification, Weill Cornell Campus Units</b>	Office of Research Integrity, Weill Cornell Medicine	(646) 962-8200	<a href="mailto:conflicts@med.cornell.edu">conflicts@med.cornell.edu</a> <a href="http://researchintegrity.weill.cornell.edu/">researchintegrity.weill.cornell.edu/</a>
<b>Federal and State Laws and Regulations on Conflicts of Interest, Weill Cornell Campus Units</b>	Office of Research Integrity, Weill Cornell Medicine	(646) 962-8200	<a href="mailto:conflicts@med.cornell.edu">conflicts@med.cornell.edu</a> <a href="http://researchintegrity.weill.cornell.edu/">researchintegrity.weill.cornell.edu/</a>

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## DEFINITIONS

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These definitions apply to terms as they are used in this policy.

<b>Academic Staff Member</b>	Any instructional or research staff member listed in Article XVII, Section 1 of the Cornell University Bylaws (see <i>Related Resources</i> ).
<b>Conflict Management</b>	Measures taken to address the risk of bias or the appearance of bias, protect research subjects, and maintain public trust in the institution's research and its personnel when research personnel may have a real or apparent financial conflict of interest (fCOI).
<b>Conflict of Commitment</b>	When an employee of the university engages in an outside activity that burdens or interferes with their fulfillment of primary commitments and obligations to the university, even if the outside activity is valuable to the university or contributes to their professional development and competence.
<b>Design, Conduct, or Reporting of Research</b>	Oversight, decision-making, or participation in research that includes creating the structure, roles, and/or protocol of a research project; participating in the execution of the research roles and protocol; participating in the publishing, presentation, or discussion of the research results.
<b>Direct Administration of Research</b>	Oversight or decision-making impacting research that includes, selection of vendors, determining the allocation of funds, sponsor negotiations for the research project, protocol review and approval, or managing resulting intellectual property and licensing opportunities.
<b>Disclose/Disclosure</b>	To provide relevant information about research personnel's financial interests related to a research project to parties inside and outside the institution to assure full awareness of potential conflicts and institutional efforts to address them. Compare with <i>Report</i> .
<b>Domestic Partner</b>	A person who meets the Cornell-Ithaca definition of domestic partner and whose partner has registered that relationship with the university in order to obtain benefits.
<b>External Commitment</b>	An obligation or activity (e.g., management, employment, advisory, or consulting role) that is not related to primary commitments or obligations to the university.
<b>External Entity</b>	An entity other than the university.
<b>Financial Conflict of Interest – Real, Apparent</b>	A <i>real fCOI</i> arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research. An <i>apparent fCOI</i> arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual's opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research.
<b>Financial Interest</b>	Anything of monetary value, whether or not the value is readily ascertainable.
<b>Human Participant Research</b>	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, involving a living individual about whom an investigator (whether professional or student) conducting the research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

## POLICY 1.7

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#### DEFINITIONS, continued

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<b>Institutional/Cornell Responsibilities</b>	Activities that contribute to, arise out of, or are impacted by research, teaching, service, outreach, publications, professional/clinical practice, other scholarly pursuits or Cornell administrative duties, such as service on panels or committees. This includes consulting, lectureships, service on external panels or committees, expert witness testimonies, book promotions, etc. that are related to or arise from an area of Cornell expertise and activities.
<b>Key Personnel</b>	Individuals responsible for the design, conduct, or reporting of a research study.  <i>For sponsored research:</i> (1) principal investigators, co-investigators, and any other individual named in a sponsored project key personnel list; (2) anyone else who is independently responsible for the design, conduct and reporting of research, as determined by the principle investigator and any of the co-investigators on the research project; and (3) anyone who during the course of a sponsored project assumes a role synonymous with the roles above.  <i>For non-sponsored research:</i> Those whose role on the research project is synonymous with the roles described above.  <i>For Institutional Review Board protocols:</i> Principal investigators and co-investigators consistent with the procedures of each campus.
<b>Management Plan</b>	See <i>Conflict Management</i> .
<b>Non-Sponsored University Research</b>	The pursuit of professional interests through research that is supported by university funds including, but not limited to, internal allocations, gifts, endowment income, fellowships, licensing income, and cost sharing.
<b>Public Health Service (PHS) Agencies</b>	Within the Department of Health and Human Services (DHHS), the following eight agencies are designated components of the U.S. Public Health Service (PHS): <ol style="list-style-type: none"> <li>1. The Agency for Healthcare Research and Quality (AHRQ).</li> <li>2. The Agency for Toxic Substances and Disease Registry (ATSDR).</li> <li>3. The Centers for Disease Control and Prevention (CDC).</li> <li>4. The Food and Drug Administration (FDA).</li> <li>5. The Health Resources and Services Administration (HRSA).</li> <li>6. The Indian Health Service (IHS).</li> <li>7. The National Institutes of Health (NIH).</li> <li>8. The Substance Abuse and Mental Health Services Administration (SAMHSA).</li> </ol>
<b>Report [Ithaca] / Conflicts Survey [WCMC]</b>	To provide information to the university concerning one's external commitments and financial interests. Compare with <i>Disclose</i> .
<b>Report File</b>	Information submitted on a report, and any pertinent information gathered in relation to a report required for a complete review of external commitments and financial interests.
<b>Research</b>	Research, for the purpose of this policy, includes all sponsored projects, including research and extension, and all non-sponsored university research.
<b>Research Personnel</b>	Any individual independently responsible for the design, conduct, or reporting of research, including key personnel, as well as those independently responsible for the direct administration of research.

## POLICY 1.7

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#### DEFINITIONS, continued

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<b>Research-Related</b>	An external commitment or financial interest that is likely to bias the outcome of research.
<b>Significant Financial Interest (SFI)</b>	<p>A financial interest consisting of one or more of an individual's family's interests that reasonably appears to be related to an individual's Cornell responsibilities:</p> <ol style="list-style-type: none"><li>1. With regard to any publicly traded entity, a significant financial interest (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.</li><li>2. With regard to any non-publicly traded entity, an 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 an individual or his or her family holds any equity interest (e.g., stock, stock option, or other ownership interest).</li><li>3. Related to intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.</li><li>4. As required by the federal regulations and only for research personnel on PHS funded awards or cooperative agreements issued on or after August 24, 2012, any travel that is reimbursed or paid on the individual's behalf, related to the individual's Cornell responsibilities, <b>and</b> determined by Cornell to constitute or contribute to an SFI. This excludes any travel that is reimbursed or sponsored by Cornell University, a federal, state, or local government agency; a U.S., non-profit 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.</li></ol> <p>The term significant financial interest (SFI) <b>does not include</b> the following types of financial interests:</p> <ul style="list-style-type: none"><li>• Salaries, royalties, or other remuneration paid by Cornell to an individual, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.</li><li>• Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles.</li><li>• Income from seminars, lectures, or teaching engagements sponsored by, or income from service on advisory committees or review panels for a federal, state, or local government agency, a non-profit U.S. institution of higher education as defined at 20 U.S.C. 1001(a), an academic</li></ul>

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## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### DEFINITIONS, continued

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	<p>teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.</p> <ul style="list-style-type: none"> <li>Any paid for or reimbursed travel determined by the Cornell not to constitute an SFI.</li> </ul>
<b>Sponsor</b>	An external entity that funds or supports research. Sponsors include federal, state, and local governments and private entities, both non-profit and for profit.
<b>Sponsored Research</b>	Research funded by a sponsor through a grant, contract, or agreement.
<b>Travel Disclosure</b>	<p>PHS Regulations, effective August 24, 2012, requires the disclosure of all reimbursed or sponsored travel related to a PHS-funded Investigator's Institutional Responsibilities within 30 days of completing travel.</p> <p>Sponsored travel means (a) travel expenses paid to an Investigator or travel paid on an Investigator's behalf, by a single entity in any twelve-month period, and (b) travel reimbursed to or paid on behalf of an Investigator's spouse, domestic partner, or dependent child by a single entity in any 12-month period ONLY if such travel reasonably appears to be related to the Investigator's Cornell responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by Cornell University, a federal, state, or local government agency, a U.S., non-profit 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 details of the disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.</p>
<b>Unit</b>	A department, research center, institute, program, business service center, office, or other operating entity of the university.
<b>Unit Head</b>	A chair, director, or administrative lead in an operating unit of the university.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## RESPONSIBILITIES, ITHACA CAMPUS UNITS

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The major responsibilities each party has in connection with this policy are as follows:

<b>Center for Technology Licensing (CTL)</b>	<p>Appoint a representative to serve as a non-voting member of the Financial Conflicts of Interest Committee (fCOIC) and provide subject-matter expertise.</p> <p>Inform fCOIC and research personnel of required financial conflict of interest (fCOI) reporting related to licensing activity.</p>
<b>Financial Conflicts of Interest (fCOI) Administrator</b>	<p>Provide regulatory, policy, and procedural expertise and administrative support to the fCOIC.</p> <p>Manage the fCOI reporting process.</p> <p>Assist in review of fCOI reports, determination of whether a real or apparent fCOI exists, and development of management plans.</p> <p>Assist and advise research personnel, units, university management, and others, as appropriate, on fCOI management, regulations, policy, and procedures.</p> <p>Make available to unit heads the information related to a real or potential conflict of commitment, and any non-research conflict of interest disclosed in an fCOI report.</p>
<b>Financial Conflicts of Interest Committee (fCOIC)</b>	<p>Ensure that all real or apparent fCOIs related to research are identified and managed.</p> <p>Review fCOI reports and determine whether a real or apparent fCOI exists.</p> <p>Determine and promulgate management plans required to reduce or eliminate real or apparent fCOI.</p> <p>Monitor compliance with management plans.</p> <p>Review management plan appeals and appeal recommendations from the senior vice provost for research.</p> <p>Issue binding decisions on management plan appeals.</p> <p>Participate in investigation of cases of potential non-compliance.</p> <p>Report findings in accordance with policies and regulations.</p>
<b>Institutional Official</b>	<p>Establish and oversee the implementation of policies and procedures for solicitation and review of disclosures of significant financial interests from all research personnel, in accordance with the applicable federal regulations and university policies.</p> <p>Ensure that university policies and procedures comply with the fCOI policy in 42 CFR 50 Subpart F and 45CFR Part 94 (Contracts) in the design, conduct, and reporting of research funded under the Public Health Service (PHS) grants or cooperative agreements, or PHS contracts.</p>
<b>Institutional Review Board for Human Participants (IRB)</b>	<p>Ensure the protection of human participants as subjects of research.</p> <p>Ensure that all required fCOI review and management requirements are met prior to approving protocols.</p> <p>May add human participant protection measures to a management plan, but may not delete plan requirements.</p>
<b>Key Personnel</b>	<p>See <i>Research Personnel</i> responsibilities.</p>

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### RESPONSIBILITIES, ITHACA CAMPUS UNITS, continued

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<b>Office of Research Integrity and Assurance (ORIA)</b>	<p>Appoint a representative to serve as a non-voting member of the fCOIC and provide subject-matter expertise.</p> <p>Provide fCOI administrators to support the fCOIC and other functions necessary to the execution of this policy (see <i>fCOI Administrator</i> responsibilities).</p> <p>Investigate situations of potential fCOI non-compliance and report to the fCOIC, university executives, and external agencies as necessary.</p> <p>Report to federal agencies, sponsors, and other regulatory bodies as necessary.</p>
<b>Office of Sponsored Programs (OSP)</b>	<p>Appoint a representative to serve as a non-voting member of the fCOIC and provide subject-matter expertise.</p> <p>Ensure that all required fCOI review and management requirements are met prior to submitting proposals and executing awards and other institutional agreements.</p>
<b>Principal Investigator (PI)</b>	<p>Identify all key research personnel on proposals and research, inform them of related fCOI reporting requirements, and ensure that they submit fCOI reports prior to proposal or protocol submission.</p>
<b>Research Personnel</b>	<p>Report external commitments and financial interests fully, accurately, timely, in accordance with the requirements set forth by this policy.</p> <p>Follow the terms of required management plans.</p> <p>May submit a written request for reconsideration of a management plan.</p> <p>Subject to sanctions for non-compliance with management plan requirements.</p>
<b>Senior Vice Provost for Research (SVPR)</b>	<p>Appoint the members of the fCOIC.</p> <p>Provide input on management plans at the request of the fCOIC.</p> <p>Review appeals of fCOIC decisions and may make recommendations to delete requirements of a management plan, but may not alter or remove requirements. May add requirements to a management plan.</p> <p>Implement sanctions for non-compliance with timely filing of reports or non-compliance with an approved management plan.</p>
<b>Unit/Unit Head</b>	<p>Identify and manage all conflicts of commitment and all non-research-related conflicts of interest.</p> <p>Determine if new employees or employees assuming new responsibilities are research personnel and if so, ensure that they complete an fCOI report within the required timeframe.</p> <p>If required by the fCOIC, assist in development and implementation of management plans for fCOIs related to research.</p> <p>As required by the fCOIC, implement aspects of management plans and report on plan compliance.</p> <p>Confer as requested with the senior vice provost for research regarding sanctions for non-compliance.</p>
<b>University Counsel</b>	<p>Appoint a representative to serve as a non-voting member of the fCOIC and provide subject-matter expertise.</p>

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## RESPONSIBILITIES, WEILL CORNELL CAMPUS UNITS

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The major responsibilities each party has in connection with this policy are as follows:

<b>Center for Technology Licensing (CTL)</b>	<p>Appoint a representative to serve as a non-voting member of the CAP and provide subject-matter expertise.</p> <p>Inform CAP and research personnel of required fCOI reporting related to licensing activity.</p>
<b>Conflicts Advisory Panel (CAP)</b>	<p>Ensure that all real or apparent financial conflicts of interest (fCOI) related to research are identified and managed.</p> <p>Review fCOI reports and determine whether a real or apparent fCOI exists.</p> <p>Determine and promulgate management plans required to reduce or eliminate real or apparent fCOI.</p> <p>Monitor compliance with management plans.</p> <p>Review management plan appeals and appeal recommendations from the provost for medical affairs.</p> <p>Issue binding decisions on management plan appeals.</p> <p>Participate in investigation of cases of potential non-compliance.</p> <p>Report findings in accordance with policies and regulations.</p>
<b>Conflicts Office Administrator / Conflicts Specialist(s) [WCMC]</b>	<p>Provide regulatory, policy, and procedural expertise and administrative support to the Conflicts Advisory Panel (CAP).</p> <p>Manage the fCOI reporting process.</p> <p>Assist in review of fCOI reports, determination of whether a real or apparent fCOI exists, and development of management plans.</p> <p>Assist and advise research personnel, units, university management, and others, as appropriate, on fCOI management, regulations, policy, and procedures.</p> <p>Make available to unit heads the information related to a real or potential conflict of commitment, and any non-research conflict of interest disclosed in an fCOI report.</p>
<b>Director, Research Integrity</b>	<p>Investigate situations of potential fCOI non-compliance and report to the CAP, university executives, and external agencies as necessary.</p> <p>Report to federal agencies, sponsors, and other regulatory bodies as necessary.</p>
<b>Institutional Review Board for Human Participants (IRB)</b>	<p>Ensure the protection of human participants as subjects of research.</p> <p>Ensure that all required fCOI review and management requirements are met prior to approving protocols.</p> <p>May add human participant protection measures to a management plan, but may not delete plan requirements.</p>
<b>Key Personnel</b>	<p>See <i>Research Personnel</i> responsibilities.</p>
<b>Office of Research Integrity (ORI), Weill Cornell Medicine</b>	<p>Appoint a representative to serve as a non-voting member of the CAP and provide subject-matter expertise.</p> <p>Provide fCOI administrators to support the CAP and other functions necessary to the execution of this policy (see <i>Conflicts Office Administrator</i> responsibilities).</p>

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## RESPONSIBILITIES, WEILL CORNELL MEDICINE CAMPUS UNITS, continued

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<b>Office of Sponsored Research Administration (OSRA); Joint Clinical Trials Office (JCTO); Office of BioPharma Alliances and Research Collaborations [WCM]</b>	Appoint a representative to serve as a non-voting member of the CAP and provide subject-matter expertise. Coordinate with CAP to ensure that all required fCOI review and management requirements are met prior to submitting proposals and executing awards and other institutional agreements.
<b>Principal Investigator (PI)</b>	Identify all research personnel on proposals and research projects and co-investigators on Institutional Review Board protocols, inform them of related fCOI reporting requirements, and ensure that they submit fCOI reports prior to proposal or protocol submission.
<b>Provost for Medical Affairs and Dean of the Medical College</b>	Appoint the members of the CAP. Provide input on management plans at the request of the CAP. Review appeals of CAP decisions and may make recommendations to delete requirements of a management plan, but may not alter or remove requirements. May add requirements to a management plan. Implement sanctions for non-compliance with timely filing of reports or non-compliance with an approved management plan.
<b>Research Personnel</b>	Report external commitments and financial interests fully, accurately, timely, in accordance with the requirements set forth by this policy. Follow the terms of required management plans. May submit a written request for reconsideration of a management plan. Subject to sanctions for non-compliance with management plan requirements.
<b>Unit/Unit Head</b>	Determine if new employees or employees assuming new responsibilities are research personnel and if so, ensure that they complete an fCOI report within the required timeframe. If required by the CAP, assist in development and implementation of management plans for fCOI related to research. As required by the CAP, implement aspects of management plans and report on plan compliance. Confer as requested with the dean regarding sanctions for non-compliance.
<b>University Counsel</b>	Appoint a representative to serve as a non-voting member of the CAP and provide subject-matter expertise.

## POLICY 1.7

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## PRINCIPLES

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### Overview

The research, scholarship, and other professional activities of the university's faculty, students, and staff are governed both by principles of academic freedom with responsibility and codes of academic integrity and ethical conduct. The principles outlined below protect academic freedoms, assure open publication of research results, and encourage a spirit of entrepreneurship. At the same time, university research personnel must exercise these ideals within the bounds of legal and ethical restraints. The conduct of research in compliance with applicable regulations and free from any reasonable expectation that the research results are biased by the financial self-interest of research personnel ensures the integrity of the research process, protects the public's investment, and engenders and maintains the public trust in the integrity of the university's research and education mission.

### Principle 1: External Relationships and Research

The university recognizes the value of engagement in external organizations and activities. Such activities and relationships enable the transfer of knowledge and skills that enhance teaching, research, service, and the administration of university programs, as well as inspire solutions to benefit the world. Entrepreneurial endeavors and productive relationships with businesses can stimulate inquiry and provide opportunities to further academic research. However, the financial interests that accompany such relationships may lead to real or apparent financial conflicts of interest (fCOI).

### Principle 2: Legal Compliance

This policy promotes compliance with all applicable federal and state laws and regulations regarding fCOI, including the National Institutes of Health (NIH), the National Science Foundation, the Food and Drug Administration (FDA), and other agencies that are part of the Public Health Service (PHS). It incorporates these requirements and, where appropriate and applicable, extends them to all research conducted at Cornell, whether externally sponsored or not. In addition, it provides for agency- or contract-specific requirements where applicable.

### Principle 3: Academic Freedom and Responsibility

The university thrives when research and scholarship activities are pursued with vigor and unencumbered by constraint and censorship. At the same time, individuals conducting these activities have a primary responsibility to the university and are expected to perform their duties faithfully, legally, and ethically. Policies regarding academic freedom, integrity, and codes of conduct are referenced in the Related Resources section of this policy. Real or apparent fCOI will be managed appropriately to allow research personnel the latitude needed to pursue both their academic and external commitments, while ensuring that research is conducted with objectivity and integrity.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PRINCIPLES, continued

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**Principle 4: Open  
Publication of  
Research Results**

A principal mission of the university is the pursuit of knowledge for the benefit and use of society. Accordingly, the university vigorously protects the free and open publication, presentation, and discussion of research results. The university prohibits external commitments and financial interests that restrict or unduly delay the publication and dissemination of research results, and it will not accept external agreements that preclude university research personnel, including graduate students and postdoctoral associates, from publishing and communicating any portion of their research, including in meetings with members of the Cornell community.

**Principle 5:  
Entrepreneurship**

The university contributes to the economic development of New York State and the nation and brings important scientific and medical discoveries to the marketplace for the benefit of the public. Consistent with the Bayh-Dole Act of 1980, the university strongly encourages and supports the efforts of its research personnel to participate in the development and dissemination of intellectual property by entering into relationships with existing business entities or by starting their own. These relationships, however, also present situations where some degree of real or apparent fCOI is inevitable. These situations are appropriately managed, therefore, to ensure the integrity of the research process, the unbiased and effective development of university intellectual property, and the appropriate entrepreneurial participation and external engagement of its research personnel.

**Principle 6: Human  
Participant Research**

Research involving human participants is critical in developing knowledge and discoveries that will benefit society. Protecting the rights and welfare of human research participants is of the utmost importance and a requirement of all research personnel and the university. Of particular concern, therefore, are external commitments and financial interests that compromise or appear to compromise the rights and well-being of human research participants. The university scrutinizes the roles in such research of research personnel who have external commitments and financial interests with a sponsor or with an external entity that is related to, or can be affected by, the research. The university has instituted a rebuttable presumption that research personnel who are involved in the design, participant selection, informed consent process, or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. In other words, the default position is that participation in human participant research by conflicted research personnel is not allowed. However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research. In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk. All financial interests and external relationships related to human-participant research that are not eliminated must be disclosed to all participants in the related research. The

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PRINCIPLES, continued

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management plan must be implemented before research personnel can participate in the design or conduct of the research, enrollment of participants, or analysis of the results.

The Ithaca Campus, Weill Cornell New York campus, and Weill Cornell Medicine Qatar campus each operate Institutional Review Boards for Human Participants (IRB), which are charged with reviewing and monitoring human participant research conducted at the university. The IRBs have established rigorous policies and procedures for the review and approval of human participant research protocols. Those policies and procedures are followed in tandem with this policy.

#### **Principle 7: Full and Accurate Reporting**

Real and apparent fCOI may arise from any number and type of external commitments and financial interests, and particular expertise is required to determine whether they could affect, or could be perceived to affect, research activities and results. University research personnel are required to report fully and accurately all external commitments and all research-related financial interests in accordance with the procedures for each campus, in order to provide sufficient information for the identification of real and apparent fCOI. Research personnel must include the external commitments and financial interests of his/her spouse, domestic partner, or dependent child in accordance with the procedures for each campus.

#### **Principle 8: Timely Reporting**

Reports of external commitments and financial interests must be made at regular intervals, as required by university policy and federal regulation, to allow the university to identify and manage real and apparent fCOI in a timely manner. Additional reporting events are prescribed by federal regulation, agency- and award-specific terms, and human subject protocol submission requirements, subject to each campus' procedures. All research personnel must report (1) annually, (2) when external commitments and financial interests materially change, (3) when required by the sponsor or by the specific terms of an award, (4) upon appointment, (5) when newly assigned to a research personnel role, and (6) when otherwise required by the university.

#### **Principle 9: University Oversight**

Three principles are accounted for in the process of university review of reports of external commitments and financial interests: (1) respecting the confidentiality of reported information, (2) managing rigorously both real and apparent fCOI, and (3) achieving consistency across the university in the way that fCOI are identified and managed.

A central review committee on each campus develops conflict review procedures that ensure expert, confidential, and consistent review of reports across the university. Reviewers identify situations in which external commitments and financial interests



## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PRINCIPLES, continued

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may potentially compromise, or appear to compromise, the professional judgment of research personnel in conducting or reporting research, including the collection, analysis, and interpretation of data, the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.

**Principle 10:  
Management of  
Conflicts**

Real or apparent fCOI are addressed through a management plan. The plan must be designed to remove the bias, or the reasonable perception of bias, in research that the conflict raises, while allowing that degree of personal financial and professional freedom that is consistent with research integrity, the public trust, and the protection of human participants.

Real and apparent fCOI often can be managed, in whole or in part, by disclosing the implicated external commitments and financial interests to, as applicable, the university, journal publishers, granting agencies, conference organizers, audiences at presentations, colleagues, collaborators, students, or human participants. Other possible management plan measures include, but are not limited to, the monitoring by independent reviewers of the related research and/or of the student participation; modification of the research plan; and disqualification of the research personnel's participation in all or a portion of the research project.

Special attention is paid when research personnel have academic oversight responsibilities for undergraduates, graduate students, or postdoctoral associates who are working on projects that are funded by, or conducted in collaboration with, an external entity in which the research personnel have a financial interest.

**Principle 11:  
Reporting and  
Management Plan  
Compliance**

Persons subject to this policy are required to report fully and accurately their external commitments and financial interests and to comply with any plans developed to manage their real or apparent fCOI. Disciplinary measures and sanctions will be imposed when they fail to report as required or when they fail to comply with management plans.

**Principle 12:  
Confidentiality and  
Sharing of Financial  
Information**

The university is committed to maintaining the confidentiality of reported information as far as is practicable and consistent with legal obligations. All information and written materials provided to the campus review committees are shared only with committee members and staff who are involved in the processing and review of the information, as well as those who create and implement management plans. Other individuals, including unit heads and IRB members and staff, receive this information on a need-to-know basis. Individuals with access to confidential personal information are required to sign a confidentiality agreement.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, ITHACA CAMPUS UNITS

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### Administrative Structures

#### Financial Conflicts of Interest Committee (fCOIC)

- a. **Authority:** The fCOIC has authority for reviewing external commitments and financial interests reported under this policy, in order to identify real or apparent financial conflicts of interest (fCOI) related to research, and address them in accordance with this policy and federal regulations. The fCOIC has the authority to promulgate binding fCOI management plans.
- b. **Scope of Responsibility:** The fCOIC is responsible for ensuring that all real or apparent fCOI are identified and managed. The fCOIC reviews reported information, requests additional material as needed, identifies real or apparent fCOI, devises an appropriate plan to manage the conflict, communicates the plan to the research personnel, and monitors compliance with the plan.
- c. **Committee Membership:** The fCOIC is appointed by the senior vice provost for research (SVPR) and includes as voting members no fewer than seven members of the Ithaca faculty chosen from both the endowed and contract colleges. The committee also includes, in a non-voting status, university administrators, including representatives from the Office of Research Integrity and Assurance (ORIA), Office of Sponsored Programs (OSP), Center for Technology Licensing (CTL), and the Office of University Counsel. The SVPR appoints one of the voting members to serve as chair of the fCOIC.
- d. **Financial Conflicts of Interest Committee (fCOIC) Training:** fCOIC members receive appropriate training and continuing education in the identification and management of fCOI, including related university policies and procedures and federal regulations.
- e. **Confidentiality:** As far as is practicable and consistent with legal obligations, Cornell protects the confidentiality of fCOI information. Information and written materials provided to the fCOIC and its administrators are shared to the most limited degree possible with those committee and staff members who are involved in the processing and review of reported information and the creation and implementation of management plans, and others on a need-to-know basis.

#### Office of Research Integrity and Assurance

**Financial Conflict of Interest (fCOI) Administration:** ORIA includes staff members responsible for providing administrative support to the fCOIC (“fCOI administrators”) and other key functions necessary to the execution of this policy and procedures. fCOI administrators (1) coordinate the reporting and collection of annual and event-based reports of external commitments and financial interests, (2) provide

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, ITHACA CAMPUS UNITS, continued

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administrative support to the fCOIC, (3) conduct preliminary reviews of reports to assess completeness, and consult with the reporters and others as required to obtain clarifications and additional information required for making an fCOI determination, (4) are exempt from review those reports that do not present a significant fCOI related to research, (5) facilitate an expedited review of reports that present a common type of conflict that can be managed through standard measures such as disclosure to a journal, (6) assist the fCOIC in developing and monitoring management plans for more complex fCOI, and (7) assist and advise research personnel, units, university management, and others as appropriate on fCOI management, regulations, policy, and procedures.

### Reporting

#### Who Must File and When

**All Members of the Academic Staff and Research Personnel:** All members of the academic staff and university research personnel, including key personnel, are required to report their external commitments and financial interests annually and on an event-required basis for themselves, as well as for their spouses, domestic partners, and dependent children.

#### **What Must Be Reported:**

- For determination of a conflict of commitment, irrespective of dollar amount, a reporter's external commitments or financial interests with an external entity, such as employment, service or consulting; or intellectual property or licensing.
- Significant financial interest, as defined in this policy, for a reporter or his or her family with any external entity whose activities could be related to the reporter's Cornell responsibilities.
- Material changes to existing financial interests as described in "Event-Based Reports" below.

For each such external relationship or financial interest, reporters must provide all of the information required in the reporting form.

#### Annual Reports

1. **Required Reporting:** All required personnel must update their reports of external commitments and financial interests annually ("annual report"). The unit is responsible for identifying any newly appointed individuals who are subject to this policy, and ensuring that they file annual reports.
2. **Handling of Annual Reports:** fCOI administrators coordinate the solicitation and collection of the annual reports and review reports for the purpose of identifying

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, ITHACA CAMPUS UNITS, continued

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real and apparent conflicts of interest related to research. Information relevant to conflicts of commitment and non-research-related conflict of interest is distributed to the units, which have responsibility for identifying and managing all such conflicts.

3. **Timely Reporting Requirement:** All required personnel must complete and submit their annual reports by the required deadlines.

#### Event-Based Reports

1. **New Appointments:** Upon the appointment of a new faculty member, academic staff member, or other employee, each unit head determines whether that individual is subject to this policy. Such appointees must complete the annual report within one month of his or her Cornell start date.

The unit making the appointment is responsible for ensuring that these individuals are identified and complete their reports within the required timeframe.

2. **Newly Assigned Responsibilities:** Individuals who become newly responsible for the design, conduct, reporting, or direct administration of research are required to complete annual reports within one month of their assumption of such responsibilities.

The unit making the assignment is responsible for ensuring that these individuals are identified to the fCOI administrator in ORIA and complete their reports within the required timeframe.

3. **Material Change in Circumstances:** All research personnel must amend their annual reports within 30 days of any material changes to their external financial interests related to their Cornell responsibilities.

4. **Sponsored Project-Specific Report:**

- a. **Proposals:** All key personnel for a proposal must declare if they have any proposal-specific financial interests that could impact the design, conduct, or reporting of the research, and report any sponsor-required information, at the time the principal investigator (PI) submits the proposal to the OSP. The OSP will not submit any grant proposal for which the declaration and required reporting for all key personnel have not been completed.

- b. **Awards (to be implemented in fall 2012 for PHS-funded awards):** Any resulting award may be distributed only after any SFIs related to the

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, ITHACA CAMPUS UNITS, continued

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project have been reviewed and any management plan has been implemented.

5. **Institutional Review Board (IRB) Protocol-Specific Report for Research Involving Human Participants:** Non-student PIs and co-investigators for IRB protocols are required to declare if they have any project-related, external commitments and financial interests at the time they submit a protocol to the IRB. Any financial interests related to the project must be reviewed and any required management plans implemented prior to protocol approval.
6. **For Key Personnel Funded Under PHS Awards or Cooperative Agreements Issued On or After August 24, 2012:** A report within 30 days of the completion of travel, any reimbursed or paid travel that is related to your Cornell responsibilities. This excludes any travel that is reimbursed or paid for by Cornell University, a federal, state, or local government agency, a U.S., non-profit 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 details of the disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

#### **Report Review and Conflict Management**

#### Unit-Level Review of Annual Reports, and Unit-Level Involvement in Identification and Management of a Financial Conflict of Interest (fCOI)

The unit head, per University Policy 4.14, Conflicts of Interest and Commitment, is responsible for addressing issues involving conflicts of commitment and non-research-related conflicts of interest.

In addition, the fCOIC and its administrators may call on units to supply additional information about reported external commitments and financial interests, and to assist in the development and implementation of management plans.

#### Financial Conflicts of Interest Committee (fCOIC) Review

The fCOIC and its administrators in ORIA are responsible for reviewing reports, collecting additional required information, identifying fCOI, and determining required management plans. Under the guidance of the fCOIC, fCOI administrators review all report files to make the preliminary determination as to whether the report file shall be processed as follows:

- **Exemption from Review:** No significant financial interest (SFI) exists and hence the report does not require further consideration.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, ITHACA CAMPUS UNITS, continued

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- Expedited Review: External commitments and financial interests constitute an SFI and either present no real or apparent fCOI, or pose real or apparent fCOI that can be easily addressed by standard management plan measures (e.g., disclosure of the interest to journal publishers).
- Full Committee Review: External commitments and financial interests exist that pose real or apparent fCOI that require full fCOIC review to develop an appropriate management plan.

#### Management Plan Development and Monitoring

1. **Management Plan Development:** The fCOIC subcommittees review the fCOIC administrators' preliminary determinations of SFI and real or apparent fCOI and oversee development of proposed management plans. Where full committee review is advised, the fCOIC votes on whether a real or apparent fCOI exists, and, if so, whether to approve the recommended management plan as presented by the subcommittee or with modifications. Based on the fCOIC decisions, the fCOI administrator will finalize the management plan. Management measures may, as appropriate, include, but are not limited to, the following:
  - Disclosure of the external commitment or financial interest to human participants, fellow researchers, students involved in the research activity, journal publishers, and/or others.
  - Research personnel's abstention from certain project segments or decisions.
  - Modification of the external commitment or financial interest.
  - Modification of the research plan (including the assignment of responsibilities).
  - Monitoring of the potentially affected research activity by an independent individual or subcommittee.
  - Divestiture or severance of an external commitment or financial interest.
  - Independent review of student research progress.
  - Discontinuation of advisee's or subordinate employee's participation in an external entity.

The management plan will state who is responsible for overseeing the implementation of the plan, and for reporting on compliance at stated intervals to the fCOIC. If the management plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to the fCOIC.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, ITHACA CAMPUS UNITS, continued

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2. **Additional Input on Management Plans:** In making review and management decisions, the fCOIC and fCOI administrators may consult with others on an as-needed basis only, including campus administrative offices, University Counsel, and the SVPR, as well as the research personnel (and/or spouse, domestic partner, or dependent children, if applicable) and unit heads, particularly when the management plan will likely require unit-level implementation and/or monitoring.
3. **Management Plan Notification:** The fCOIC communicates the fCOIC decision and management plan to the research personnel, and those responsible for implementation of the management plan. In addition, sponsors will be notified of the existence of a managed conflict if the regulations of that agency or award so require.
4. **Institutional Review Board (IRB) Review:** If a protocol-related external commitment or financial interest is identified in a protocol application, the IRB may not approve the protocol until the fCOIC has completed a review of the report file and any necessary management plan has been approved and implemented. The IRB has the authority to recommend, as a condition of protocol approval, adding human participant protection measures to an approved management plan, but does not have the authority to delete other items approved by the fCOIC.
5. **Appeals Process:** After receiving a notification of the fCOIC decision, research personnel must, within a time frame required by the fCOIC, acknowledge in writing agreement to comply with any required management plan or submit a written request for reconsideration to the fCOIC, which has the authority to review and affirm the previous decision or amend the management plan. The fCOIC will notify the research personnel and the responsible individual of the result of the appeal. Research personnel who do not agree with the fCOIC decision may submit a written request for reconsideration to the SVPR, who may recommend to the fCOIC that they alter or delete a requirement. The SVPR may not alter or remove a requirement. In all cases, the SVPR may add requirements to a management plan at his or her discretion. The fCOIC issues a final binding decision.

#### Financial Conflict of Interest Reporting to Public Health Service Agencies

For research personnel funded under a Public Health Service (PHS) award or cooperative agreement awarded on or after August 24, 2012, Cornell will provide to the appropriate PHS agency an fCOI report regarding any investigator's SFI found to be an fCOI as follows:

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, ITHACA CAMPUS UNITS, continued

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- Prior to the expenditure of funds.
- During the period of award.
- Within 60 days of identifying a new fCOI.
- At the same time as when the grantee submits an annual progress report, including multiyear progress: report annually for the duration of the project period (including extensions with or without funds), addressing the status of the financial interest and any changes to the management plan and whether the fCOI is still being managed, or explain why the fCOI no longer exists.

All fCOI reports will include the following information:

- The project number.
- The program director (PD)/PI or contact PD/PI if a multiple PD/PI model is used.
- The name of the investigator with the fCOI.
- The name of the external entity with which the investigator has an SFI.
- The nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
- 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 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 why Cornell determined that the financial interest conflicts with such research.
- A description of the key elements of the institution's management plan, including the following:
  - a. The role and principal duties of the conflicted investigator in the research project.
  - b. The conditions of the management plan.
  - c. How the management plan is designed to safeguard objectivity in the research project.



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### Financial Conflict of Interest Related to Research

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#### PROCEDURES, ITHACA CAMPUS UNITS, continued

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- d. A confirmation of the investigator's agreement to the management plan.
- e. How the management plan will be monitored to ensure investigator compliance.
- f. Other information as needed.

#### **Sanctions and Mitigation Plans for Noncompliance**

##### Annual Report of External Commitments and Financial Interests

Submitting the annual report by the filing deadline is a requirement of all members of the academic staff and research personnel. During the submission timeframe, individuals will be reminded of the reporting deadline. Those who fail to submit the report will be referred to the unit head and the SVPR. At the discretion of the SVPR, if an individual does not complete the reporting requirements, one or more of the following sanctions may apply, until the report is submitted:

- The individual will be deemed ineligible to maintain PI, Co-PI, Key Personnel, or Faculty Advisor status on sponsored projects and on any research protocols (IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC)).
- The individual will be deemed ineligible to enter into technology transfer agreements.
- A letter, over the signature of the SVPR, will be placed in the individual's personnel file indicating that his or her good standing as a member of the faculty or university has been called into question.
- Future annual salary increases will not be paid based on the duration of non-compliance. For non-compliance for any duration beginning at the deadline and for 14 days thereafter, the salary increase for the first full pay period of the next fiscal year will not be paid. For non-compliance of any duration during the next 15 days, a second pay period's salary increase will not be paid, and so on. Unpaid amounts will not be reimbursed.
- The individual's research activities and associated salary will be suspended until the individual comes into compliance. Any suspension of research activities and associated salary will be undertaken in accordance with the applicable university policies and codes, including the Dismissal/Suspension Policy for Faculty Members (see the Related Resources section of this policy).
- All academic appointments that are modified by the terms acting, adjunct, courtesy, and visiting will be terminated.

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### Financial Conflict of Interest Related to Research

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#### PROCEDURES, ITHACA CAMPUS UNITS, continued

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- Salaries and stipends cannot be charged to sponsored projects for the entire pay period during which the individual is non-compliant. Appointing units will need to find unrestricted funds to pay for such salaries and stipends.

##### Sponsored Project-Specific Report

At a minimum, (1) research personnel who have not completed their proposal-specific declaration will not be able to submit the proposal or must be removed from the proposal before it is submitted, and (2) any awards for projects in which these research personnel are participating will not be distributed by OSP until any required management plans have been implemented.

##### IRB Protocol-Specific Report

IRB protocols will not be processed until all non-student PIs and co-PIs named on a protocol to the IRB have declared the existence of any project-specific, external financial interests. The IRB will not approve a protocol unless all fCOI related to the research have been resolved.

##### Reimbursed Travel Report for Senior Personnel on PHS-Funded Awards:

The OSP will not distribute any new awards or renewals until key personnel on PHS-funded awards have submitted travel-related reports within 30 days of completing travel that meets the criteria outlined above in "What Must Be Reported."

##### Other Event-Based Reports

Research personnel are required to provide other event-based reports as required by this policy, other Cornell policies, a sponsor's award or contract, or regulations. Failure to provide such reports will result in the sanctions described in "Annual Report of External Commitments and Financial Interests" above.

##### Management Plans

The fCOIC will review cases of failure by research personnel to sign off on a conflict management plan and to adhere to an approved management plan and determine whether or not they constitute non-compliance with this policy. Determination of non-compliance will be cause for one or more of the sanctions noted above in "Annual Report of External Commitments and Financial Interests," at the discretion of the SVPR. In addition, where such failure is not remedied, the non-compliance may be reported to the pertinent sponsor, if applicable, and disciplinary action may be commenced, including academic misconduct proceedings, and, in severe cases, termination. Any academic misconduct or termination proceedings will be conducted in accordance with the applicable university policies and codes, including those set forth in the Faculty Handbook, the Code of Academic Integrity, the

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## PROCEDURES, ITHACA CAMPUS UNITS, continued

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Dismissal/Suspension Policy for Faculty Members, and the Faculty Appeals Procedures (see the Related Resources section of this policy).

#### **Retrospective Review, Mitigation Plans and Reporting to PHS Agencies:**

For key personnel funded under PHS grants or cooperative agreements issued on or after August 24, 2012:

Whenever an fCOI is not identified or managed in a timely manner, including failure by the investigator to disclose an SFI, failure by the institution to review or manage an fCOI, or noncompliance with the management plan, Cornell will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research. The retrospective review will include the following:

1. The project number.
2. The project title.
3. The PD/PI or contact PD/PI if a multiple PD/PI model is used.
4. The name of the investigator with the fCOI.
5. The name of the entity with which the investigator has an fCOI.
6. The reason(s) for the retrospective review.
7. The detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
8. The findings and conclusions of the review.

When bias is found, ORIA will notify the appropriate PHS agency promptly and submit a mitigation report with the following pieces of information required under the regulations:

- The key elements documented in retrospective review.
- A description of the impact of the bias on the research project.
- A plan of action to eliminate or mitigate the effect of the bias.

#### **Training**

**For all research personnel:** Must attest, as part of the annual reporting and any event-based report, that they have reviewed this policy, and understand and agree to comply with the requirements outlined in this policy.

## POLICY 1.7

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## PROCEDURES, ITHACA CAMPUS UNITS, continued

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**For research personnel funded under PHS awards/cooperative agreements issued on or after August 24, 2012:** In addition to the above, must complete training on their responsibilities for disclosure of external interests and other aspects of the National Institutes of Health (NIH) regulations under 42 CFR 50 (Subpart F) prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances whenever:

- Institutional fCOI policies change in a manner that affects the requirements for research personnel.
- Cornell finds that the key personnel is not in compliance with Cornell's fCOI policy or management plan.

#### **Audit**

The ORIA and/or the University Audit Office may conduct investigations of potential non-compliance with reporting requirements, management plans, or other policy-related issues, when necessary. Instances of non-compliance that require reporting to federal agencies, sponsors, and/or other regulatory bodies, will be determined by ORIA, University Audit, and/or the Office of the Vice Provost for Research, and acted on as required. The fCOIC, ORIA, and/or the University Audit Office may conduct audits and process and compliance reviews to identify needed improvements to the fCOI process.

#### **Public Accessibility of a Conflict of Interest Related to Public Health Service-Funded Research**

Applicable to key personnel on PHS-funded awards or cooperative agreements with issue dates on or after August 24, 2012:

To ensure public accessibility, ORIA will provide a written response within five business days of receiving a request submitted according to the procedures outlined on ORIA's public website on fCOI, regarding information concerning any SFI disclosed to the institution that meets the following three criteria:

1. The SFI was disclosed and is still held by the key personnel for the NIH-funded research project identified by Cornell in the grant application, progress report, or any other required report submitted to the NIH.
2. Cornell determines that the SFI is related to the NIH-funded research.
3. Cornell determines that the SFI is a fCOI.

The information that Cornell will make available via a written response will include the following:

- The investigator's name.

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### Financial Conflict of Interest Related to Research

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#### PROCEDURES, ITHACA CAMPUS UNITS, continued

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- 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.
- 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.

#### **Sub-Recipients For Public Health Service-Funded Awards**

For PHS-funded research that is carried out through a sub-recipient, Cornell will take reasonable steps to ensure that any sub-recipient investigator complies with 42CFR 50 subpart F, by incorporating in the certificate of commitment and in the contract, terms that establish whether Cornell's fCOI policy or the sub-recipient's own fCOI policy will apply to its investigators, and include time periods to meet disclosure and/or fCOI reporting requirements.

Sub-recipient institutions who rely on their fCOI must report identified fCOI to Cornell in sufficient time to allow Cornell to report the fCOI to the NIH to meet its reporting obligations.

Except under special circumstances, organizations who do not have their own fCOI policy that complies with the NIH regulations, will be considered ineligible to be a sub-recipient for PHS awards until such time as they develop, adopt, and implement their policy and can demonstrate compliance with it in the conduct on the PHS-funded research.

Sub-recipient institutions that must comply with Cornell's policy must submit all investigator disclosures of SFI to Cornell in sufficient time to allow Cornell to review, manage, and report identified fCOI to the PHS agency.

Cornell will take reasonable measures to monitor the sub-recipient's compliance with the fCOI regulation, management plans, and for reporting all identified fCOI to the appropriate PHS agency. This may include periodic review of the fCOI policy, disclosures or disclosure forms, management plans, and any other information deemed relevant to assessing the effectiveness of the sub-recipient's fCOI disclosure and management process.

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## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, ITHACA CAMPUS UNITS, *continued*

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##### **Record Retention**

The fCOI administrators in ORIA will maintain the records regarding the fCOI process, in accordance with university policy and sponsors' requirements.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS

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### **Administrative Structures**

#### Conflicts Management Office (CMO)

The provost for medical affairs or his/her designee will establish a Conflicts Management Office (CMO), which will be responsible for the overall management of issues related to conflicts of interest and commitment. The office will be responsible for (1) implementing the Weill Cornell Medicine (WCM) Conflicts Policy; (2) serving as a resource to the faculty and staff regarding questions relevant to issues of conflict of interest; (3) collecting an annual disclosure of conflicts-related information from faculty and staff members; (4) evaluating information submitted in the annual disclosure as well as other individual disclosures; (5) developing and implementing conflict-management plans; (6) providing staff support for the Conflicts Advisory Panel and for any conflicts oversight committees; and (7) developing educational programs for faculty and staff members regarding conflict-related issues.

The office will be under the direction of the assistant dean of human research compliance or his/her designee. The CMO will establish its own procedures to accomplish its mission as indicated above. Its procedures and actions are not to be inconsistent with the WCM Conflicts Policy.

#### Conflicts Advisory Panel (CAP)

The provost for medical affairs will appoint a Conflicts Advisory Panel (CAP) consisting of the chairman of the General Faculty Council and between four and ten members of the faculty of the medical college (at least two of whom will hold rank of professor).

The CAP will, upon request, (1) provide advice to the provost of medical affairs or his/her designee, the associate dean and the CMO, in consultation with other staff to the CAP such as the associate university counsels, with regard to conflicts of interest- and commitment-related matters; and (2) advise and make recommendations to the provost for medical affairs on the acceptability of conflicts management plans submitted to the CAP by the CMO on behalf of members of Cornell regarding potential conflicts of interest or commitment. In addition to reviewing conflicts management plans submitted by the CMO, the CAP will review possible conflicts of interest or commitment issues as referred to it by the Office of Sponsored Research Administration (OSRA), Joint Clinical Trials Office (JCTO), Office of BioPharma Alliances and Research Collaborations, Office of the University Counsel, the Center for Technology Licensing (CTL), the Institutional Review Board (IRB), and the Institutional Animal Care and Use Committee (IACUC).

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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### Reporting

#### Who Must Comply with this Policy

All university research personnel, including key personnel, voluntary faculty, off-site researchers, students and fellows are required to comply with this policy.

#### Who Must File and When

**Research Personnel:** All university research personnel, including key personnel, are required to report their external commitments and financial interests annually and on an event-required basis for themselves, as well as for their spouses, domestic partners, or dependent children.

◆ **Note:** For IRB/IACUC protocols, “research personnel” includes non-student principal investigators (PIs), and co-investigators named on protocols.

#### **What Must Be Reported**

For all research personnel:

- For determination of a conflict of commitment: Irrespective of dollar amount, a reporter’s external commitments or financial interests with an external entity, such as employment, service or consulting; or intellectual property or licensing.
- Significant financial interest, as defined in this policy (including all reimbursed or sponsored travel related to institutional responsibilities), for a reporter or his/her family with any external entity whose activities could be related to the reporter’s Cornell responsibilities.
- Material changes to existing financial interests as described in “Event-Based Disclosure Reports” below.

For each such external relationship or financial interest, reporters must provide all of the information required in the reporting form.

#### Conflicts Survey

1. **Required Reporting:** All research personnel must update their reports of external commitments and financial interests annually (“conflicts survey”). The unit is responsible for identifying WCM representatives responsible for the direct administration of research and any newly appointed representatives who participate in research, and ensuring that they file annual conflict surveys.
2. **Handling of Annual Reports:** Conflicts specialist(s) coordinate the solicitation and collection of the annual reports and review reports for the purpose of identifying real and apparent conflicts of interest related to research.



## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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3. **Timely Reporting Requirement:** All research personnel must complete and submit their annual reports by the required deadlines.

#### Event-Based Disclosure Reports

1. **New Appointments:** Upon the appointment of a new faculty member, academic/non-academic staff member, (or other employee), including any student, each unit head determines whether he or she is responsible for the design, conduct, reporting, or direct administration of research and is subject to this policy. The new appointee must complete the conflicts survey within forty-five (45) days of his or her WCM start date.

The unit making the appointment is responsible for ensuring that these WCM representatives are identified and complete their reports within the required timeframe.

2. **Newly Assigned Responsibilities:** WCM representatives who become newly responsible for the design, conduct, reporting, or direct administration of research are required to complete the conflicts survey within one month (30 days) of their assumption of such responsibilities.

The unit making the assignment is responsible for ensuring that these WCM representatives are identified to the conflicts management office in the Office of Research Integrity (ORI), and complete their conflicts survey within the required timeframe.

3. **Material Change in Circumstances:** All research personnel must amend their annual reports within 30 days of any material changes to their external commitments and financial interests related to their Cornell responsibilities. Material changes include, but are not limited to, the initiation or elimination of a reportable external commitment or financial interest for the reporter and family, a change in, or the initiation of, a sponsor, or any change that might affect a current management plan.
4. **Study Specific Report:** All research personnel, who are identified by the principal investigator (PI), for a proposal must report study-specific external commitments and financial interests, including any sponsor-required information, at the time the PI submits the proposal to OSRA/JCTO. PIs ensure that research personnel submit financial conflict of interest (fCOI) reports prior to proposal submission. OSRA/JCTO will not submit any grant proposal for which the proposal-specific reports for all research personnel have not been submitted. Any resulting award may be distributed only after the reported study specific

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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information has been reviewed and any management plan has been implemented.

5. **Study Specific Report for IRB/IACUC Submissions:** WCM representatives identified as investigators on IRB/IACUC protocols (including faculty, academic and non-academic staff members, and students) who contribute to the design, conduct, reporting, or direct administration of research are required to report their project-related external commitments and financial interests at the time they submit a protocol to the IRB/IACUC. PIs ensure that co-investigators submit fCOI reports prior to protocol submission. The study-specific reports must be reviewed and any required management plans implemented prior to protocol approval.
6. **Travel Disclosure Requirement For Individuals Applying for or Funded Under Public Health Service (PHS) Awards or Cooperative Agreements AND Other Non-Profit Agencies that Invoke PHS COI Policy:** Investigators and others involved in PHS-sponsored research must disclose their reimbursed or sponsored travel related to their institutional responsibilities over the previous twelve-month period no later than at the time of application for PHS-funded research and after that, within 30 days of completing reimbursed travel. The details of the travel disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

This includes reimbursed or sponsored travel received by the investigator's spouse, domestic partner, or dependent child that is also related to the individual's institutional responsibilities. Investigators applying for or funded by PHS sponsors should familiarize themselves with these regulations, which can be found at [www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=45:1.0.1.1.51](http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=45:1.0.1.1.51).

Sponsored travel means (a) travel expenses paid to an investigator or travel paid on an Investigator's behalf, by a single entity in any twelve-month period and/or (b) travel reimbursed to or paid on behalf of an investigator's spouse, domestic partner, or dependent child) by a single entity in any 12-month period.

The CMO will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an fCOI with PHS-funded research. This reporting excludes any travel that is reimbursed or paid for by Cornell University, a federal, state, or local government agency, a U.S., non-profit 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.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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7. **Travel Disclosure Requirements Applicable to All WCM Representatives:** Refer to University Policy 4.14, Conflicts of Interest and Commitment (Excluding Financial Conflict of Interest Related to Research).
8. **Initiating Licensing Activity:** Research personnel are required to report their external commitments and financial interest at the time the Center for Technology Licensing (CTL) begins to negotiate a license for technologies for which the research personnel is named as an inventor.

#### **Financial Conflict of Interest Reporting to the National Institutes of Health**

For research personnel funded under a PHS award or cooperative agreement awarded on or after August 24, 2012, Cornell will provide to the National Institutes of Health (NIH) an fCOI report regarding any investigator significant financial interest (SFI) found to be an fCOI as follows:

- Prior to the expenditure of funds.
- During the period of award.
- Within 60 days of identifying a new fCOI.
- At same time, as when grantee submits annual progress report, including multiyear progress: report annually for the duration of the project period (including extensions with or without funds), addressing the status of the financial interest and any changes to the management plan and whether the fCOI is still being managed or explain why the fCOI no longer exists.

All fCOI reports will include the following information:

- A project number.
- A program director (PD)/PI or contact PD/PI if a multiple PD/PI model is used.
- The name of the investigator with the fCOI.
- The name of the external entity with which the investigator has an SFI.
- The nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
- 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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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- A description of how the financial interest relates to the NIH-funded research and why Cornell determined that the financial interest conflicts with such research.
- A description of the key elements of the institution's management plan, including the following:
  - a. The role and principal duties of the conflicted investigator in the research project.
  - b. The conditions of the management plan.
  - c. How the management plan is designed to safeguard objectivity in the research project.
  - d. A confirmation of the investigator's agreement to the management plan.
  - e. How the management plan will be monitored to ensure investigator compliance.
  - f. Other information, as needed.

#### **Sanctions and Mitigation Plans for Noncompliance**

#### Annual Report of External Commitments and Financial Interests

WCM representatives determined by the Conflicts Advisory Panel (CAP) to have shown "willful disregard" for WCM Conflicts of Interest in Research policies will be subject, at the discretion of the dean, to the sanctions listed below.

- The individual will be deemed ineligible to maintain PI status on sponsored projects.
- The individual will be deemed ineligible to enter into technology transfer agreements.
- A letter, over the signature of the dean, will be placed in the representative's personnel file indicating that his or her good standing as a member of the faculty or university has been called into question.
- Any annual salary increment will be withdrawn until the representative comes into compliance.
- The representative's research activities and associated salary will be suspended until the representative comes into compliance. Any suspension of research activities and associated salary will be undertaken in accordance with the applicable university policies and codes, including the Dismissal/Suspension Policy for Faculty Members (see the Related Resources section of this policy).

Department chairs/unit heads and the department administrators will be notified if any faculty and non-faculty within their respective department/unit does not

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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comply with the completion and/or submission of the conflicts survey within forty-five (45) days of hire OR when annual re-certification of the conflicts survey are not completed by the reporting deadline. The CAP will monitor instances of non-compliance and may recommend to the department chair/unit head the enforcement of appropriate sanctions and disciplinary actions.

#### Sponsored Projects Study Specific Report

At a minimum, (1) research personnel who have not completed their proposal-specific declaration will not be able to submit the proposal or must be removed from the proposal before it is submitted, and (2) any awards for projects in which these research personnel are participating will not be distributed by OSRA/JCTO until any required management plans have been implemented.

#### IRB/IACUC Protocol Study Specific Report

IRB/IACUC Protocols will not be processed until all non-student principal investigators (PIs) and co-PIs named on a protocol to the IRB/IACUC have declared the existence of any project-specific external financial interests. The IRB/IACUC will not approve a protocol unless all fCOI related to the research have been reported, managed and/or resolved.

#### **Reimbursed Travel Report for Senior Personnel on NIH-Funded Awards:**

OSRA/JCTO will not distribute any new awards or renewals, until key personnel on NIH-funded awards have submitted travel disclosures within 30 days of completing travel that meets the criteria outlined above in "What Must Be Reported."

#### Other Event-Based Reports

Research personnel are required to provide other event-based reports as required by this policy, other Cornell policies, a sponsor's award or contract, or regulations. Failure to provide such reports will result in the sanctions described in "Annual Report of External Commitments and Financial Interests" section above.

#### Management Plans

The CAP and institutional official will review cases of failure by research personnel to adhere to an approved management plan and determine whether or not they constitute non-compliance with this university policy. Determination of noncompliance will be cause for one or more of the sanctions noted above in "Annual Report of External Commitments and Financial Interests," at the discretion of the dean. In addition, where such failure is not remedied, the noncompliance may be reported to the pertinent sponsor, if applicable, and disciplinary action may be commenced, including academic misconduct proceedings, and, in severe cases,

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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termination. Any academic misconduct or termination proceedings will be conducted in accordance with the applicable university and Medical College policies and codes, including those set forth in the Faculty Handbook, the Code of Academic Integrity, the Dismissal/Suspension Policy for Faculty Members, and the Faculty Appeals Procedures (see the Related Resources section of this policy).

#### **Retrospective Review, Mitigation Plans, and Reporting to NIH:**

For key personnel funded under Public Health Service (PHS) grants or cooperative agreements issued on or after August 24, 2012:

Whenever an fCOI is not identified or managed in a timely manner, including failure by the investigator to disclose an SFI, failure by the institution to review or manage an fCOI, or noncompliance with the management plan, Cornell will, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator's activities and the project to determine bias in the design, conduct, or reporting of such research. The retrospective review will include the following:

1. A project number.
2. A project title.
3. The PD/PI or contact PD/PI if a multiple PD/PI model is used.
4. The name of the investigator with the fCOI.
5. The name of the entity with which the investigator has an fCOI.
6. The reason(s) for the retrospective review.
7. The detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
8. The findings and conclusions of the review.

When bias is found, the ORI will notify NIH promptly and submit a mitigation report with the following pieces of information required under the regulations:

- The key elements documented in retrospective review.
- A description of the impact of the bias on the research project.
- A plan of action to eliminate or mitigate the effect of the bias.

#### **Conflict Management**

##### **1. Submission of Disclosures**

All research personnel are required to complete and submit a financial disclosure survey on an annual basis ("conflicts survey") through the web-based conflicts of

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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interest system at <https://wrg.weill.cornell.edu>. Amendments to surveys must be submitted whenever there is a change in what has been previously reported.

Study Specific Reports must be completed through the web-based conflicts of interest system at <https://wrg.weill.cornell.edu> and submitted with sponsored research proposals as required by OSRA/JCTO and ORI.

#### 2. Review of Disclosures

The CMO will review all conflicts disclosures, including the required conflicts survey and Study Specific Reports.

#### Training

**Research personnel 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 aspects of the NIH regulations under 42 CFR 50 (Subpart F) prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional fCOI policies change in a manner that affects the requirements for research personnel.
- Cornell finds that the key personnel is not in compliance with Cornell's fCOI policy or management plan.

#### Right to Appeal

Faculty and staff members have the right to appeal all sanctions proposed by the dean.

If the member disagrees with the dean's determination, the member may request further consideration of the matter and may then examine the recommendations of the CAP, including supporting evidence, and offer other relevant information or explanations.

The university counsel shall serve as advisor to the dean. Following such consideration, the dean shall make a final and binding determination in writing.

#### Public Accessibility of a Conflict of Interest Related to Public Health Service-Funded Research

Applicable to key personnel on PHS-funded awards or cooperative agreements with issue dates on or after August 24, 2012:

To ensure public accessibility, the ORI will provide a written response within five business days of receiving a request submitted according to the procedures outlined on the ORI's public website on fCOI, regarding information concerning any SFI disclosed to the institution that meets the following three criteria:

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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## PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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1. The SFI was disclosed and is still held by the key personnel for the NIH-funded research project identified by Cornell in the grant application, progress report, or any other required report submitted to the NIH.
2. Cornell determines that the SFI is related to the NIH-funded research.
3. Cornell determines that the SFI is an fCOI.

The information that Cornell will make available via a written response will include 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.
- 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.

#### **Sub-Recipients for Public Health Service-Funded Awards**

For PHS-funded research that is carried out through a sub-recipient, Cornell will take reasonable steps to ensure that any sub-recipient investigator complies with 42 CFR 50 subpart F, by incorporating in the certificate of commitment and in the contract, terms that establish whether Cornell's fCOI policy or the sub-recipient's own fCOI policy will apply to its investigators, and include time periods to meet disclosure and/or fCOI reporting requirements.

Sub-recipient institutions that rely on their fCOI must report identified fCOI to Cornell in sufficient time to allow Cornell to report the fCOI to the NIH to meet its reporting obligations.

Except under special circumstances, organizations that do not have their own fCOI policy that complies with the NIH regulations, will be considered ineligible to be a sub-recipient for NIH awards until such time as they develop, adopt, and implement their policy and can demonstrate compliance with it in the conduct on the NIH-funded research.



## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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Sub-recipient institutions that must comply with Cornell's policy must submit all investigator disclosures of SFIs to Cornell in sufficient time to allow Cornell to review, manage, and report identified fCOI to the NIH.

Cornell will take reasonable measures to monitor sub-recipient's compliance with the fCOI regulation, management plans, and for reporting all identified fCOI to the NIH. This may include periodic review of the fCOI policy, disclosures or disclosure forms, management plans, and any other information deemed relevant to assessing the effectiveness of the sub-recipient's fCOI disclosure and management process.

#### **Audit**

The ORI and/or the University Audit Office may conduct investigations of potential non-compliance with reporting requirements, management plans, or other policy-related issues, when necessary. Instances of non-compliance that require reporting to federal agencies, sponsors, and/or other regulatory bodies will be determined by the ORI, University Audit, and/or the dean, and acted on as required. The CAP the ORI, and/or the University Audit Office may conduct audits and process and compliance reviews to identify needed improvements to the fCOI process.

#### **Record Retention**

The fCOI administrators in ORI will maintain the records regarding the fCOI process, in accordance with university policy and sponsors' requirements.

#### **Industry Relationships**

##### **Equity and Stock Holdings in External Entities Based on Faculty Technologies**

Equity and stock holdings are defined as monetary investments, held by a WCM representative or his/her family tied to the financial standing of an external entity. This policy refers specifically to entities that have licensed technology developed at WCM through agreement with the CTL. Refer to the "Equity and Stock Holdings in External Entities Not Based on Faculty Technologies" below for specific information regarding these types of relationships. WCM representatives holding equity/stock with an entity that also supports his/her research are strongly encouraged to speak with the CAP prior to entering into any research agreements with such an entity.

Agreements made between the WCM representative conducting clinical research and the entity related to his/her research, specifically those in which the WCM representative or his/her family is expected to receive \$5,000 (or the active de minimis threshold required for disclosure by the NIH included in 42 CFR Part 50 Subpart F) or more annually, may be subject to increased scrutiny from the ORI and/or CAP. In such cases, additional and/or supplemental information may be required by the CAP in order to determine the appropriateness of such relationships and whether or not the arrangement should be allowed, monitored, or modified.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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Final determination on the permissiveness of consulting arrangements in these circumstances will be made at the discretion of the CAP in consultation with the appropriate WCM representative(s). While the holding of equity/stock options by WCM representatives in such cases may be permissible, these types of relationships may be subject to increased scrutiny by the CAP and will require the implementation of a comprehensive conflicts management plan.

Research involving human participants is critical in developing knowledge and discoveries that will benefit society. Protecting the rights and welfare of human research participants is of the utmost importance and a requirement of all research personnel and the university. Of particular concern, therefore, are external commitments and financial interests that compromise or appear to compromise the rights and well-being of human research participants. The university scrutinizes the roles in such research of research personnel who have external commitments and financial interests with a sponsor or with an external entity that is related to, or can be affected by, the research. The university has instituted a rebuttable presumption that research personnel who are involved in the design, participant selection, informed consent process, or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. In other words, the default position is that participation in human participant research by conflicted research personnel is not allowed. However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research. In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk. All financial interests and external relationships related to human-participant research that are not eliminated must be disclosed to all participants in the related research. The management plan must be implemented before research personnel can participate in the design or conduct of the research, enrollment of participants, or analysis of the results.

#### **Equity and Stock Holdings in External Entities Not Based on Faculty Technology**

Equity and stock holdings are defined as monetary investments, held by a WCM representative or his/her family tied to the financial standing of an external entity. This policy refers specifically to entities that have not licensed technology developed at WCM through agreement with the CTL. Please refer to “Equity and Stock Holdings in External Entities Based on Faculty Technologies” above for specific information regarding these types of relationships. This policy does not refer to diversified mutual funds not under the control of the WCM representative. WCM representatives holding equity/stock with an entity that also supports his/her

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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research are strongly encouraged to speak with the CAP prior to entering into any research agreements with such an entity.

Agreements made between the WCM representative conducting research and the entity related to his/her research, specifically those in which the WCM representative or his/her family is expected to receive \$5,000 (or the active *de minimis* threshold required for disclosure by the NIH included in 42 CFR Part 50 Subpart F) or more annually, may be subject to increased scrutiny from the ORI and/or CAP. In such cases, additional and/or supplemental information may be required by the CAP in order to determine the appropriateness of such relationships and whether or not the arrangement should be allowed, monitored, or modified. Final determination on the permissiveness of consulting arrangements in these circumstances will be made at the discretion of the CAP in consultation with the appropriate WCM representative(s).

Research involving human participants is critical in developing knowledge and discoveries that will benefit society. Protecting the rights and welfare of human research participants is of the utmost importance and a requirement of all research personnel and the university. Of particular concern, therefore, are external commitments and financial interests that compromise or appear to compromise the rights and well-being of human research participants. The university scrutinizes the roles in such research of research personnel who have external commitments and financial interests with a sponsor or with an external entity that is related to, or can be affected by, the research. The university has instituted a rebuttable presumption that research personnel who are involved in the design, participant selection, informed consent process, or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. In other words, the default position is that participation in human participant research by conflicted research personnel is not allowed. However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research. In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk. All financial interests and external relationships related to human-participant research that are not eliminated must be disclosed to all participants in the related research. The management plan must be implemented before research personnel can participate in the design or conduct of the research, enrollment of participants, or analysis of the results.

#### **Executive Positions**

For purposes of this policy, executive positions are defined as those that imply managerial or supervisory roles within an external entity (commercial or non-profit)

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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including external entities based on faculty technologies. These titles may include, but are not limited to, president, vice president, chief executive officer, chief technical officer, chief operations officer, scientific director, and medical director. This policy does not refer to members of scientific advisory boards. While executive positions in external entities may be permissible, these types of relationships may be subject to increased scrutiny by the CAP for potential conflicts of interest and conflicts of commitment and will require the implementation of a Comprehensive Conflicts Management Plan (cCMP).

#### **Ghostwriting**

WCM representatives are prohibited from engaging in the practice commonly referred to as ghostwriting, or honorary authorship. This refers to the practice in which a manuscript is developed principally by a for-profit business directly or through a third-party vendor such as a medical education company and then attributed to an academic researcher who did not contribute meaningfully. This policy does not refer to attribution determination. Further, this policy does not prohibit instances in which an author's own work is shared with an outside entity for purely editorial assistance. WCM representatives are expected to follow the rules of authorship as defined by the International Committee of Medical Journal Editors.

#### **Gifts**

WCM representatives are prohibited from accepting gifts, of any variety or value, from external entities whose interests may represent an actual or perceived conflict of interest to the individual and/or institution. Gifts are defined as any remuneration not made in exchange for services rendered. WCM representatives are, however, permitted to accept educational materials if the material does not include the logo or brand of the external entity. Educational material, including academic journals, intended to promote the product(s) of the external entity are not permitted.

#### **Industry or Vendor Representatives in WCM Controlled Spaces**

Industry or vendor representation refers to the physical presence of individuals or groups, representing for-profit, non-WCM entities, including but not limited to, employees, officers and consultants of pharmaceutical manufacturers, in any WCMC-controlled space for the purpose of product marketing and/or promotion. This policy does not refer to industry or vendor representatives on campus for previously scheduled and faculty-approved educational purposes including, but not limited to, product and/or device demonstrations.

Industry or vendor representatives visiting the WCM campus must have a scheduled appointment with a WCM representative. Any literature provided by the

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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industry or vendor representative, particularly those including a company or logo or brand and intended to market a particular drug or company, must be given directly to a WCM representative and not left by the industry or vendor representative in patient areas. Materials provided by the industry or vendor representative must be reviewed by senior practice leadership before being left in patient areas. Facilities are expected to develop and enact procedures that minimize patient exposure to industry or vendor representatives. Industry or vendor representatives are prohibited from entering any patient care areas or at meetings and/or functions in which patient-specific information is discussed.

#### **Industry-Sponsored Meals in Non-WCM-Controlled Spaces**

WCM representatives are prohibited from accepting meals from external entities whose interests may represent an actual or perceived conflict of interest to the individual and/or institution. This does not include off-campus continuing medical education (CME) events in which it would not be reasonable to attribute individual consumption, e.g. large conferences featuring buffet-style meals. Please refer to "Industry-sponsored Meals in WCM-Controlled Spaces" below for additional regulations regarding industry interactions.

#### **Industry-Sponsored Meals in WCM-Controlled Spaces**

Meals or drinks directly funded by industry are not permitted at non-CME events in WCM-controlled space. Please refer to the "Industry Sponsored Meals in Non-WCM-Controlled Spaces" and "Industry or Vendor Representatives in WCM-Controlled Spaces" above for additional regulations regarding industry interactions.

#### **Private Consulting Agreements**

For purposes of this policy, a consulting agreement is defined as a financial relationship between a WCM representative and an external entity in which the faculty member is compensated for providing his/her expert advice and/or opinion for the benefit of that entity.

- Private consulting may be undertaken if it enhances the value of the individual to the university and does not interfere with university duties.
- Private consulting duties of WCM representatives cannot include services that are otherwise provided by WCM or the WCM representative in the course of his/her usual duties.
- WCM representatives are required to notify their department chairpersons of private consulting agreements and permission will be given at the discretion of department chairpersons, or their designees.

## POLICY 1.7

### Financial Conflict of Interest Related to Research

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#### PROCEDURES, WEILL CORNELL CAMPUS UNITS, continued

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- WCM representatives are expected to include the “Addendum to Consulting Agreement” document, available through the institution website, as part of all private consulting agreements.
- The private consulting agreement policy does not apply to arrangements commonly referred to as speakers’ bureaus. Please refer to the “Speakers’ Bureaus” section below for specific information on these types of relationships.
- Agreements covered by this policy include, but are not limited to, participation on advisory boards, scientific advisory boards, and data safety monitoring boards. Please refer to the WCM policy above regarding agreements that involve “Executive Positions” for specific information and guidelines on leadership positions including, but not limited to, president, vice president, chief executive officer, chief technical officer, chief operations officer, scientific director and medical director.
- Because consulting arrangements represent agreements entered into between a WCM representative, individually, and an external entity, this policy does not refer to sponsored research agreements made between the external entity and WCM.
- WCM representatives seeking to engage in a consulting agreement with an entity that also supports his/her research are strongly encouraged to speak with the ORI prior to entering into any arrangement. Consulting agreements made between the representative conducting research and the entity related to his/her research, specifically those in which the WCM representative is expected to receive \$5,000 (or the active *de minimis* threshold required for disclosure by the NIH included in 42 CFR Part 50 Subpart F) or more annually, may be subject to increased scrutiny from the CAP. In such cases, additional and/or supplemental information may be required by the CAP in order to determine the appropriateness of such relationships and whether or not the arrangement should be allowed, monitored, or modified. Final determination on the permissiveness of consulting arrangements in these circumstances will be made at the discretion of the CAP in consultation with the appropriate WCM representative(s).
- WCM representatives must refer to University Policy 4.10, Use of Cornell’s Name, Logos, Trademarks and Insignias for specific guidelines on allowable use and required disclaimers related to their appointment with WCM.
- The reasonable use of WCM resources as part of consulting agreements may be permitted only after the approval of the department chairperson or

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his/her designee. Use of WCM space, equipment or other resources will be subject to service charges.

- WCM faculty members are not permitted to use WCM employees or students to promote, advance, assist, or participate in private consulting.

#### **Purchasing Authority of Conflicted WCM Representatives**

WCM representatives must disclose relevant relationships and refrain from participating in procurement decisions in which they have a conflict of interest with the potential entity, or a competing entity. The disclosure of potential conflicts of interest in purchasing are required as part of annual survey of external relationships and as part of conflicts management plans.

#### **Speaker's Bureau**

WCM representatives are prohibited from participating in external relationships commonly referred to as speakers' bureaus. This includes any arrangement in which the outside entity has the contractual right to dictate or control the content of a presentation or talk, and/or the company creates the slides or presentation material and has final approval of the content and edits, and/or the WCM representative is expected to act as a company's agent or spokesperson for the purpose of disseminating company or product information. WCM representatives have the right to appeal to the CAP if he/she feels that their relationship does not meet this definition.

#### **Frequently Asked Questions (FAQ) Regarding WCM Study-Specific Disclosures**

For all study-specific disclosures

#### **Q1: What is the Study Specific Report? Do I need to fill that out?**

A1: A Study Specific Report (SSR) is a form that is applicable to individuals involved in the design, conduct, and reporting of research. An SSR must be filled out with each new grant proposal and/or research protocol (both human and animal subjects) application for which a discloser has related financial interests. Information provided in the SSR is used by the Conflicts Management Office (CMO) to determine whether there is a financial interest that needs to be managed. If disclosers do not have a study-specific interest to report, they do not need to submit an SSR.

#### **Q2: Who should use the Travel Disclosure form? What does the Conflicts Management Office (CMO) do with this information?**

A2: The form should be used by WCM employees to disclose sponsored travel that is not reimbursed or paid by Cornell University. You also do not have to report self-funded travel. Please note there are different reporting requirements for travel that is

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sponsored by *for-profit* and *non-profit* entities. Details can be found on the CMO website on the Travel Disclosure page.

Sponsored travel may be considered a significant financial interest. It will be reviewed in the context of one's Conflicts Survey and may be managed based on value and relatedness to your WCM job responsibilities. For researchers, it may be managed based on the value, your WCM responsibilities, and relatedness to your research activities.

#### **Q3: What if my financial interests changed since I last disclosed my interests? When do I report these new interests?**

A3: You should disclose new entities as follows:

- If the interest is significant, or involves intellectual property or licensing, contact the Conflicts Management Office directly before engaging the interest. In addition, please note that university policy requires that any compensated consulting must be reported to, and approved by, your department chairperson prior to being undertaken.
- If you are an investigator on a grant that [follows the Public Health Service Financial Conflict of Interest regulation](#), you must disclose new significant financial interests by the time an application is submitted to the agency for funding, within thirty (30) days of discovering or acquiring a new significant financial interest and on an annual basis.
- If the entity is for-profit and related to your ongoing research or research grant(s), you must disclose within 30 days of acquiring the conflict. Do this by updating your Conflicts Survey in the Weill Research Gateway (WRG). You should then submit an updated Study Specific Report.
- Whenever you complete a Study Specific Report. Before completing the Study Specific Report, you should update your Conflicts Survey in the WRG with the new entity. Since the Study Specific Report process requires certification of your entire Conflicts Survey, this will reset your annual disclosure date to 12 months hence.

#### **Q4: What should I do if I am unsure about how to answer a question on the study-specific report?**

A4: If in doubt, please disclose and the Conflicts Management Office staff will determine if you have a conflict. Please use the comments sections where you can provide clear and accurate description of your relationship with a disclosed entity. The comments sections do not have word count limitations. If you have any



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questions, you may always call the Conflicts Management Office at (646) 962-8200 or email at [conflicts@med.cornell.edu](mailto:conflicts@med.cornell.edu).

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