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# UNIVERSITY SENATE AD HOC CONFLICT OF INTEREST REVIEW COMMITTEE

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NOVEMBER 30, 2011

## EXECUTIVE SUMMARY

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The University Policy on Financial Conflicts of Interest and Research requires faculty to disclose to peers and members of the public outside financial interests that relate to any of their research including unfunded research. The 2009 revisions required that the Policy be reviewed in two years' time. In March 2011, the University Senate Ad Hoc Conflict of Interest Review Committee was convened with a mandate to:

- Evaluate whether the current Policy, enacted in 2009, is working as intended;
- Assess the impact that proposed changes to NIH rules and regulations will have on the University and the Policy; and
- Evaluate whether the Policy is sufficiently robust to manage evident and potential risks to the University.

The committee met with representatives of all parts of the University, working in coordination with Business, Law, SIPA, and the Arts and Sciences, as they developed their own school-specific implementation plans. Through these deliberations, the committee arrived at the following conclusions: 1) although the 2009 policy is functioning as intended in screening and managing potential conflicts, gaps in disclosure requirements that may create a perception of bias are a concern; 2) the 2009 policy anticipated many of the new NIH guidelines; however, these additional regulations will result in an increased caseload and necessitate additional staff; and 3) implementation of the disclosure requirements and faculty awareness of these obligations must be strengthened at both the school and university level.

The committee recommends the following to enhance the implementation of the 2009 policy and manage potential conflicts of interest. The University should:

- Broaden the transparency clause to include white papers, policy briefs and similar publications available to the public;
- Require disclosure of paid consultancy in any resulting publication as well as unpaid activities if they create perceived bias;
- Utilize a single centralized disclosure mechanism to fulfill all disclosure requirements, where possible;
- Prohibit information collected through these mechanisms from being used for salary determinations or other purposes; and
- Enhance University and school-level communication regarding conflict of interest disclosure requirements, including an annual letter from the Provost, follow-up communications by deans, and information sessions.

## INTRODUCTION

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As set forth in the 2009 Policy, Columbia University recognizes the importance of relationships between faculty and commercial organizations, and seeks to encourage such relationships.<sup>1</sup> These relationships can give rise to significant discoveries and to the translation of those discoveries into useful products. Productive relationships with commercial organizations also inspire new avenues of inquiry and provide opportunities to test academic research. In addition, the University recognizes that outside professional activities by faculty members enhance their professional development, deepen their expertise, inform their teaching and research, and enable their ideas to have greater social impact.

However, the financial incentives that accompany such relationships may lead to conflicts of interest. Such conflicts of interest have the potential to create real or apparent bias that may affect research integrity and may place human research subjects at additional risk. Conflicts of interest, and even the appearance of conflict of interest, may reduce public confidence in the research enterprise.

Over the years, the University has developed guidelines and standards around the management and disclosure of potential financial conflicts of interest. In 2009, in response to the need to promote interdisciplinary research with consistent University-wide policies, the University adopted new conflict of interest in research rules with the intent to harmonize policies across the campuses and provide clearer standards for review and management of potential conflicts. Since the 2009 revisions, the University now has one conflict of interest committee that comprises two subcommittees, one for CUMC and one for Morningside.

Under the Policy, the researcher is permitted a limited personal financial interest in the companies that fund the research, own the product or technology under study, or otherwise qualify as an “interested businesses,” unless a review committee determines that there are countervailing circumstances. In every case, the researcher is required to disclose such financial interest to peers and the public.

The April 3, 2009 University Senate enacting resolution required that the Policy be reviewed in two years’ time.<sup>2</sup> In March 2011, the Senate Ad Hoc Conflict of Interest Review Committee was convened with the mandate to:

- evaluate whether the current Policy is working as intended;
- assess the impact that proposed changes to NIH rules and regulations may have on the University and the Policy; and
- assess whether the Policy is sufficiently robust to manage current and potential risks to the university.

The Ad Hoc Conflict of Interest Review Committee met during the spring of 2011. The committee roster is listed in Appendix 1. Members were chosen in consultation with the

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<sup>1</sup> The commercialization of intellectual property and inventions developed with federal funding is called for by the Small Business Patent Procedures Act of 1980, also known as the Bayh-Dole Act.

<sup>2</sup> The full text of the resolution is available at:

[http://www.columbia.edu/cu/senate/archives/resolutions\\_archives/resolutions/08-09/resolution\\_COI.html](http://www.columbia.edu/cu/senate/archives/resolutions_archives/resolutions/08-09/resolution_COI.html).

Research Compliance and Training office and with the Dean's Office of each school (Business, Law, SIPA and the Arts and Sciences) undertaking reviews of its own Conflict of Interest (COI) implementation plan.

## OVERVIEW OF CONFLICT OF INTEREST POLICY

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The 2009 Policy on Financial Conflicts of Interest and Research primarily addresses Columbia research that is either funded or regulated by the University in some way.<sup>3</sup> Researchers involved with such research must report to the University all financial interests in businesses that fund their research, supply products or technology that are the subject of such research, own or license intellectual property that is the subject of such research, or otherwise qualify as "interested businesses." Researchers must also report any other financial interest held or received by themselves or their families that would reasonably appear to be affected by the research. These interests are reported to the University through an on-line disclosure process in RASCAL, the University's web-based research administration application.

Those researchers who do have a significant financial interest in an interested business may not ordinarily conduct research involving that business.<sup>4</sup> However, if the Financial Conflict of Interest Committee (FCOI) determines that countervailing circumstances exist, the researcher may proceed with the research concurrent with the outside financial interest subject to a management plan. The management plan could include such conditions as limiting the role of the individual in the research or providing independent oversight; it must also include disclosure of the interest to peers and the public, as well as to, among others, members of the laboratory or research team, students and trainees, and human subjects, as applicable. The FCOI Committee keeps all materials confidential.<sup>5</sup>

In addition, Governing Principle No. 3 of the Policy addresses transparency requirements for all research presentations and publications, regardless of whether they are funded or regulated by the University and thus subject to Committee review. Governing Principle No. 3 states:

With respect to financial conflicts of interest in research, transparency is paramount. The provisions of this Policy that require reporting of financial interests to the University apply to research sponsored by the University.... However, this Policy also requires individuals to disclose outside financial interests that relate to any of their research, including unfunded research, to peers and members of the public. These disclosures must be made in publications, reports, talks, or other presentations of research.

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<sup>3</sup> See Policy at [http://www.columbia.edu/cu/compliance/pdfs/COI\\_Policy.pdf](http://www.columbia.edu/cu/compliance/pdfs/COI_Policy.pdf).

<sup>4</sup> A significant financial interest is defined as a salary or other income, including royalties, of more than \$10,000 a year (excluding, among other things, salary paid through the University), or an equity interest valued at more than \$10,000 or representing 5 percent ownership in a publicly held business, or any equity interests in a privately held business. New NIH regulations will reduce this limit to \$5,000.

<sup>5</sup> The Policy also provides, among other things, that researchers may not receive any payment relating to research that is conditioned upon obtaining a predetermined result or successful outcome.

## COMMITTEE'S ACTIVITIES

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### EVALUATION OF DISCLOSURE PROCESS

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The ad hoc committee first focused on evaluating how the current disclosure system is functioning, including workflow, compliance management and conflict resolution. A flow chart depicting the review process is attached in Appendix 2. In the current online research and compliance system (RASCAL), if an individual responds “yes” on the disclosure form it is sent to the Office of Research Compliance and Training for review. Often, the situation reported does not turn out to be conflicts of interest in research. Where there is a potential research conflict, however, the case goes first to an administrative committee that ensures all relevant information is gathered and then to the FCOI Committee for review. The latter also develops resolutions, which can range from making disclosures to management by third-party oversight to divestiture.

The Committee reviewed statistics provided by the Office of Research Compliance and Training, including the number of COI disclosure forms that were submitted via RASCAL, the number of forms with anomalies (i.e., disclosing a potential conflict), and the number of forms that came to the FCOI Committee for resolution. In 2010, 38,825 COI disclosure forms were submitted via RASCAL. Of those, approximately three percent reported an anomaly, meaning that a potential conflict of any kind was disclosed. Of these, a small subset of cases was reviewed in detail by the FCOI Committee.

In addition, the Committee reviewed de-identified examples of cases and resolutions and also reviewed data as to types of resolutions implemented. In some cases, resolution required disclosure in publications and presentations only. In rare cases, the FCOI Committee asked the faculty to choose between the financial interest and participation in the research. These cases involved clinical research at CUMC. In other cases, the FCOI required independent oversight of the project, revised research roles, enhanced reporting, or mandatory training as part of a management strategy.

The ad hoc committee viewed the FCOI Committee as functioning according to the 2009 Policy dictates but saw the workload as a growing concern. The Office of Research Compliance and Training received a small budget increase for staff; this should be monitored to ensure that it is sufficient. In addition, the online disclosure form is currently being revised to provide more relevant information earlier in the process and making that information available to the relevant deans for their review. The medical school plans to make information collected in RASCAL that relates to conflicts of interest in clinical care and education publicly available on a centrally maintained website. No similar university-wide website is currently envisioned.

### REVIEW OF VARIOUS SCHOOL POLICIES

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In coordination with the work of the University Senate Ad Hoc Review Committee, Law, Business, SIPA and the Arts and Sciences formed their own subgroups to develop school-specific policies as well. The school-specific policies address issues not encompassed by the

2009 Research Policy. For example, CUMC developed a policy to address conflict of interest in clinical care and medical education.

The table provided in Appendix 3 shows the differences among the various schools along lines of disclosure requirements, including what is disclosed (e.g., financial relations, amount of compensation, and/or time commitment) and where the information is to be disclosed (e.g., publications, presentation, CV and/or on a website).<sup>6</sup> The first column, labeled 2009 Policy, shows the base disclosure requirements (denoted by a check) stated in the 2009 Policy. The subsequent columns, labeled Law, Business, A&S, etc., indicate where a school-specific policy goes beyond the baseline 2009 Policy requirements. For example, in addition to the requirements of the 2009 Policy, the Law School requires the disclosure of compensated and non-compensated outside activities in all publications and presentations, as well as course lectures and media appearances.

### *Medical School*

The medical school is perhaps the most advanced in its policy development and implementation. The committee met with Professor Anne Taylor, whose office manages conflicts of interest relating to clinical care and medical education at Physicians & Surgeons (P&S). Her office plans to report the industry affiliations of faculty members on a publicly accessible web-site, including names of companies, type of relationship and range of funding.<sup>7</sup>

Highlights of the Clinical Care and Education policy include:<sup>8</sup>

- Commercial entities should not provide direct support for refreshments at educational activities at CUMC.
- Patient education materials cannot contain industry logos.
- P&S faculty, trainees and students may not accept gifts of any value from commercial entities whose businesses are in any way relevant to their professional duties.
- Consistent with University policy, up to 20 percent of a full-time faculty member's time can be spent consulting. All consulting relationships and remuneration must be disclosed.
- Nontenured faculty who do not disclose their outside relationships may face non-renewal of their appointments.
- Ghost authorship, where a commercial entity is the author of an article to which the Columbia employee lends his name without making a substantive contribution, is prohibited.
- Drug and device manufacturers may not call on faculty without an appointment.
- Drug and device samples are solely for patient use.

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<sup>6</sup> It should be noted that all plans assume the 2009 policy requirements. The chart denotes where the school implementation plan goes beyond the minimum standards of the 2009 plan.

<sup>7</sup> In 2013, in accordance with the Affordable Health Care Act, the federal government will be publishing data on pharmaceutical company payments to doctors. In addition, medical journals require extensive reporting of any outside financial interests related to the research.

<sup>8</sup> A complete statement of the conflict of interest policy for P&S faculty and a document on frequently asked questions are available at [http://www.cumc.columbia.edu/faculty/sites/faculty/files/PS\\_COIpolicy\\_2011.pdf](http://www.cumc.columbia.edu/faculty/sites/faculty/files/PS_COIpolicy_2011.pdf) and <http://www.cumc.columbia.edu/faculty/coi/FAQ>.

### *Business School*

The Business School adopted the following reporting requirements (in addition to those required by the 2009 Research Policy):

- Faculty members are to maintain a current version of their curriculum vitae on the official Columbia Business School web page, with a section entitled “Outside Activities.”
- Faculty members must include in their annual Faculty Activity Report a section entitled “Outside Activities,” listing all outside organizations for which he or she has provided paid or unpaid services during the past five years, including the names of the organizations and time commitments for each organization.
- Services provided to a not-for-profit must also be included in annual Faculty Activity Report to the extent they affected a faculty member's professional activities. Faculty must list any publications that resulted from such a relationship.

### *Law School*

The Law School has adopted the following principles (in addition to those set forth in the 2009 Research Policy):

- Faculty members disclose in published written work the payment of compensation to them, by a business enterprise, for work that discusses issues in which the business enterprise has an economic interest.
- Faculty members disclose in published written work their family's material financial interest in the issues discussed.
- Faculty members disclose in written work membership in a governing board of a corporation that a reasonable person would believe creates a significant possibility that an author could be inappropriately influenced or compromised.
- Faculty members disclose in published written work any external consulting or other activities, whether compensated or not, that a reasonable person would believe create a significant possibility that an author's views could be inappropriately influenced or compromised.
- The above principles also apply to media interviews, teaching, litigation assignments, and similar settings, as appropriate.

### *Arts and Sciences*

Three areas were highlighted regarding the implementation of the transparency principle:

- Faculty members are required to maintain current curriculum vitae on their official Columbia University department web site, including a section on “Outside Professional Activities.” This requirement applies only to activities that might reasonably be perceived to have an impact on research, public statements and publications.

- Faculty members must disclose “Outside Professional Activities” on the Faculty Information Form.
- Faculty members should disclose in their written work any funding sources or compensation received for the work. Where appropriate, a link to the researcher’s CV should be provided.

*School of International and Public Affairs*

To come.

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## NEW NIH GUIDELINES

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In late August 2011, NIH published revisions to its “Responsibility of Applicants for the Promotion of Objectivity in Research,” 42 CFR Part 50 and 45 CFR Part 94. The revised regulations take effect in August 2012. The University is still in the process of reviewing the regulations and assessing how they may be implemented. The 2009 Policy anticipated some of the revisions to the regulations, including the reduction of the threshold for “Significant Financial Interest” from \$10,000 to \$5,000. However, some definitions, such as the definition of “Business,” may need to be updated, and other technical changes may be required as well.

The revised regulations require disclosure of financial interests that relate to an individual’s institutional responsibilities, not only those related to research. They also require changes in the review process and impose new requirements for reporting conflicts of interest to the funding agency. These changes appear to relate to procedure more than policy, and may be implemented through updates to the disclosure form and publication of an appendix to the Policy regarding implementation. However, the changes will significantly increase the institution’s compliance responsibilities and the workload of the Office of Research Compliance and Training, as well as the number of cases that the FCOI Committee may need to review.

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## RECOMMENDATIONS

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1. *Transparency Clause*: Expand the interpretation of the transparency principle set forth in Governing Principle No. 3 of the current *Policy on Financial Conflicts of Interest and Research* to include not only research (funded or unfunded) but also white papers, policy briefs, and other similar publications available to the public where the credibility of the work relies upon the faculty member’s affiliation with Columbia University.
  - This recommendation is not intended to apply to op-eds in newspapers or other similar venues.
  - Disclosures made under Governing Principle No. 3 should include any specific financial relationship that directly relates to the publication; such disclosures should be listed in the publication itself. For other financial relationships that may relate indirectly, a link to an online faculty profile or other web site may be appropriate.
  - The transparency principle should encompass unpaid activities where they could be perceived as creating a conflict of interest.

2. *Disclosure requirement for paid consultancy:* For paid consultancy where the scope of the engagement includes authorship of a publication, such as a journal article, white paper, policy brief, or other similar work available to the public, the publication should include an acknowledgement that an individual's contribution was made "as a paid consultant and was not part of the individual's Columbia University duties or responsibilities."
3. *University v. School Disclosure:* the University has certain conflict of interest disclosure requirements, which may be updated from time to time to reflect changes in policy or regulation.
  - A single disclosure mechanism is used to fulfill these University disclosure requirements (RASCAL).
  - To the extent that individual schools wish to address school-specific issues of conflict of interest and conflict of commitment, they may develop their own policies in addition to the University's policies. School policies may be stricter but not less strict than University policies.
  - Some schools may seek to implement their own separate disclosure process. To the extent possible, schools should coordinate with the central disclosure process to reduce the burden on officers who may need to complete more than one disclosure and minimize the risk of inconsistent disclosures. School-specific disclosures made through school-specific mechanisms do not satisfy the University's disclosure requirements.
4. *Dean's Clause:* The purpose of collecting information is to protect against potential conflicts detracting from fulfillment of University responsibilities and integrity. The information is not intended for salary determination or other uses.
5. *Communication:* Communication regarding University and school conflict-of-interest policies is important. The University should continue to send annual reminders from the Provost and Executive Vice President for Research, and deans should also communicate to their schools regarding conflict of interest policy and process. In addition, the Office of Research Compliance and Training should conduct annual information sessions for faculty and staff.



APPENDIX 1: COMMITTEE ROSTER

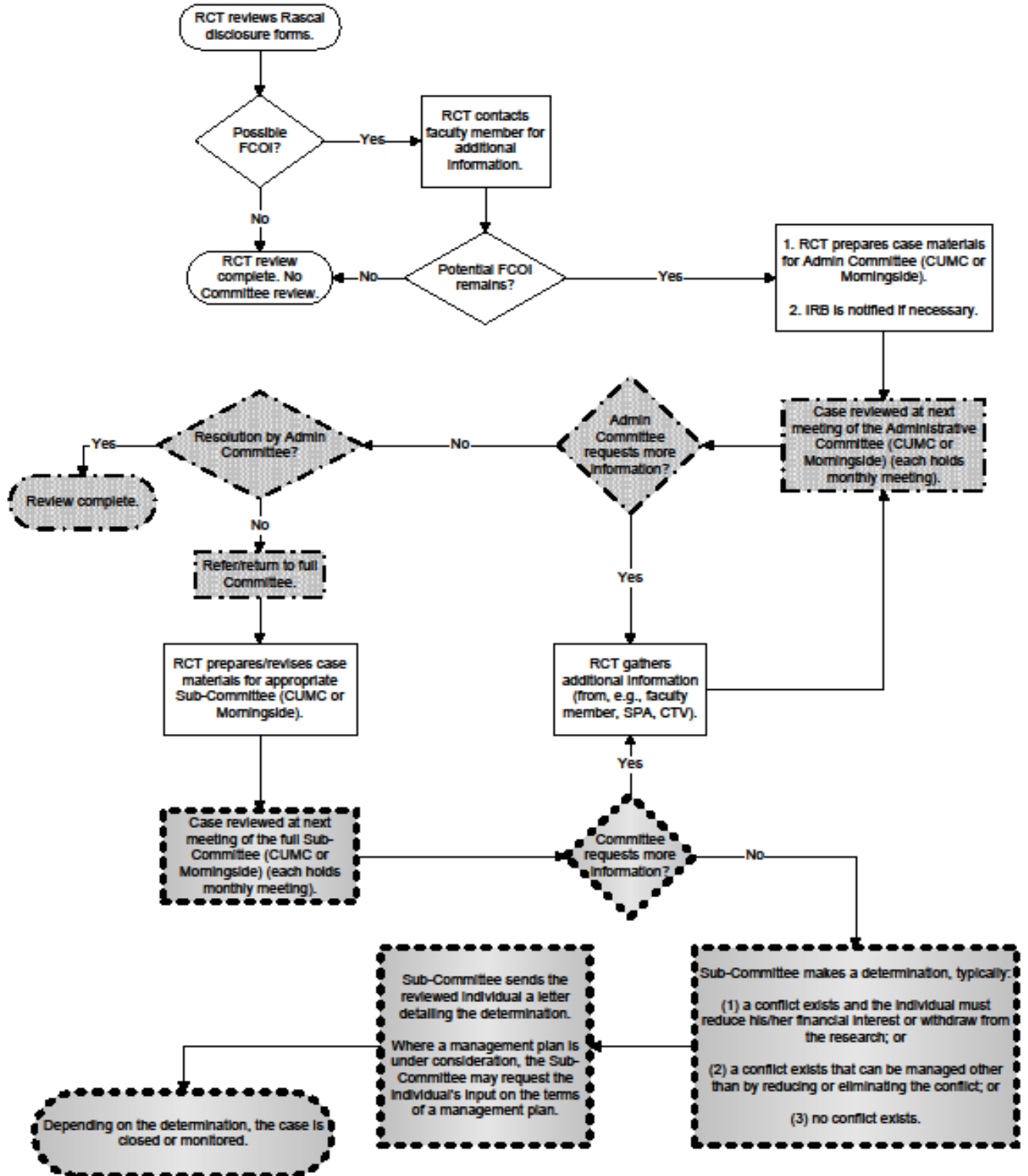
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APPENDIX 2: FLOW CHART

3/18/11 Confidential

Attachment 1



Source: The Office of Research Compliance and Training

APPENDIX 3: COMPARISON CHART OF COI POLICIES

*School-Specific Plans*

<i>Disclosure Criteria</i>	<b>2009 Policy</b>	<b>Law</b>	<b>Business</b>	<b>A&amp;S</b>	<b>SIPA</b>	<b>CUMC</b>	<b>Senate Recommendation</b>
<i>Where Disclosed</i>							
Publications and Presentations	√	X		X		X	<b>Broaden</b>
Media Appearance		X				X	
Course Lectures		X				X	
CV (Outside Activities)			X	X			
Website			X	X			
Annual Faculty Information Form			X	X			
Rascal (online form)	√					X	X
<i>What Disclosed</i>							
Compensated Outside Activities	√						X
Non-Compensated Outside Activities	√*	X					X
Boards of Public and Nonprofits Corporations	√**	X					X
Time Commitment			X	X			
Amount of Compensation		X				X	

Note: All plans adopt the 2009 Policy standards. An X denotes that the school implementation plan goes beyond the minimum requirements of the 2009 plan.

\*Requires disclosure of financial interests that relate to any funded or unfunded research.

\*\*Requires disclosure of all fiduciary or special relationships with businesses and certain non-profits, where the relationships have the potential for personal financial gain.