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Overview of Draft Policy on Institutional Conflict of Interest in Research

Key Provisions

1) The Policy requires review of "institutional financial interests" in businesses that sponsor research or whose products or technology are the subject of Research, as defined.
   a) "Institutional financial interests" include financial interests held by the University *and* financial interests held by University officials.
   b) Institutional financial interests trigger review only if they:
      i) Meet defined thresholds; and
      ii) Relate to Research as specified above.

2) Thresholds for financial interests held by the University include:
   a) Royalties from businesses that exceeded $100,000 over the past 12 months and/or are expected to exceed $100,000 over the next 12 months;
   b) Gifts from businesses greater than $500,000;
   c) Any equity in a private company; and
   d) Equity in a public company that exceeds 5% or $100,000.

The definition *excludes* any equity held through the Columbia Investment Management Company, which was found to be sufficiently segregated from the research enterprise to mitigate potential conflicts.

3) Thresholds for financial interests held by institutional officials include:
   a) Royalty payments greater than $25,000;
   b) Any equity in a private company;
   c) Equity in a public company that exceeds 5% or $100,000;
   d) Compensation, e.g. for consulting, that exceeds $25,000.

The definition of covered "institutional officials" does not include the members of the Board of Trustees, which is subject to its own conflict of interest policies. It does include senior University officials, ranging from the President and Provost to department chairs, center directors and division chiefs.

4) Research covered by the policy has the same definition as "Research" in the University's policy on individual financial conflicts of interest in research. It *includes* all research in all disciplines, but *excludes* unfunded research that does not require any regulatory review.

5) The Policy requires establishment of an Institutional Conflict of Interest Committee. That committee is charged with reviewing institutional conflicts of interest. The Policy does not currently specify who should appoint the Committee and does not require inclusion of a member from outside the University. It provides that members should include senior representatives from CUMC, Arts & Sciences, SEAS, and other research-intensive units at the University.

6) A list of possible resolutions for potential institutional conflicts of interest is included but none is mandated in any particular case. However, the Policy provides that:

> In all cases, the ICOI Committee and the University should make every attempt to enable research to proceed at the University. However, if the ICOI Committee finds that an ICOI cannot be managed, and divestment is not feasible, then the affected research should not proceed at the University.

Based on preliminary data, the number of such instances is expected to be few.

Overview of Implementation Requirements

As currently envisioned, implementation of the new Policy will require the following steps:

Central Administration (Research Compliance; Rascal; CTV; OAD; IRB)

- Establishment of a new database and new reports in Rascal.
- Completion of a transaction-specific Institutional Financial Interest "intake form" in Rascal by CTV, OAD and possibly OGC, based on the senior officer disclosure form.
- Implementation of new review process by RCT.
- Communication to IRB of ICOI resolution for human subjects research protocols.

Principal Investigators

- Answer one new question in Rascal's Proposal Tracking form that all principal investigators must complete when submitting a new proposal for funding.

Chairs/Division Chiefs

- For some proposals, answer one new question in Rascal's Proposal Tracking form.

Senior Academic Officers of the University

- Some tweaks to the questions on the Senior Officer disclosure form may be required.

Institutional Conflict of Interest Committee

- Appointment of committee members by the President, in consultation with the Executive Vice President for Research.

Comparison to Recommendations by AAMC and AAU

The AAMC and AAU have issued white papers regarding institutional conflict of interest, most recently in 2008. These documents are considered the "gold standard" for policies in this area. The draft Policy meets the key requirements identified by AAMC and AAU, and has adopted some of the model language included in the AAMC/AAU model policy published in 2008. The draft Policy departs from the AAMC/AAU recommendations in that the thresholds for institutional financial interests that could trigger review are in some cases higher than the *de minimis* amounts suggested in the AAMC/AAU guidance. For example, the threshold for compensation for institutional officials would be $5,000 under the AAMC guidelines; it is $25,000 in the draft Policy.

The Committee took a risk-based approach to this issue, and also looked at ICOI thresholds in the policies of peer institutions; in that context, the Committee concluded that a $25,000 threshold would be appropriate for institutional officials' outside compensation.

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