

---

**Joan and Sanford I. Weill Medical College  
and Graduate School of Medical Sciences  
of Cornell University**

**Conflicts of Interest and Commitment**

**Policy and Instructions**



**Fourth Edition**

(2004 – Last Update October 2005)

**Conflicts Management Office  
Research Compliance Division of the  
Office of Research and Sponsored Programs**



Conflicts Management Office  
425 East 61<sup>st</sup> Street, Suite 301  
New York, NY 10021  
[http://med.cornell.edu/research/rea\\_com/con\\_of\\_int.html](http://med.cornell.edu/research/rea_com/con_of_int.html)

# Table of Contents

<b>ABBREVIATIONS USED IN THIS BOOKLET</b>	<b>6</b>
<b>PREFACE</b>	<b>7</b>
<b>ACKNOWLEDGEMENTS</b>	<b>8</b>
<b>I. INTRODUCTION TO CONFLICTS OF INTEREST AND COMMITMENT</b>	<b>9</b>
A. Background	9
B. Definition of Conflict of Interest and Commitment	9
C. Disclosure	10
1. Introduction	10
2. WMC Annual Disclosure	10
3. Public Health Service (PHS), Including the National Institutes of Health (NIH) as well as the National Science Foundation (NSF), Disclosure Requirements	11
4. Food and Drug Administration (FDA) Required Disclosure	11
5. WMC Institutional Review Board (IRB) Required Disclosure	11
6. WMC Grants and Contracts Routing Form: Disclosure for Agreements with Industrial Sponsors of Research	11
7. Maintenance of Confidentiality of Disclosures	12
<b>II. CONFLICTS POLICY FOR THE JOAN AND SANFORD I. WEILL MEDICAL COLLEGE AND GRADUATE SCHOOL OF MEDICAL SCIENCES OF CORNELL UNIVERSITY</b>	<b>13</b>
Article I – The Primary Commitment to the University	13
Introduction	13
A. All Members	13
B. Faculty and Non-Faculty Academic Staff	14
C. Non-Academic Employees	14
D. Part-Time Appointees	14
E. Trustees, Overseers and Executive Officers	14
Article II – Categories of Conflicts	14
A. Conflict of Interest	14
B. Conflict of Commitment	14
C. Examples of Conflicts	15
Article III – Conflict Disclosure and Avoidance	15
A. Members of the Academic Staff	15
B. Non-Academic Employees	15
C. Deans	15
D. Trustees, Overseers, and Executive Officers of the Corporation	16
Article IV – Resolution of Conflicts Involving Academic Staff	16
A. Initial Disclosure	16
B. The Advisory Committee	16

Article V – Resolution of Conflicts Involving:	16
A. Deans	16
B. Trustees, Overseers and Executive Officers of the Corporation	17
C. Other Members (Non-Academic Employees)	17
Article VI – University Committee on Conflicts	17
A. Purpose	17
B. Composition	17
C. Duties	17
D. Procedures	18
Attachment A [Illustrative Examples]	19
General Considerations	19
Permissible Activities	19
Apparent Conflicts Requiring Prior Disclosure and Resolution	19
Possible Conflicts	20
Conflicts of Commitment	21
Attachment B Academic Policies/Responsibilities Consulting	22
Principles	22
Policy	22
Use of University Equipment for Private Consulting or Research	22

**III. SUMMARY OF FEDERAL REGULATIONS RELATING TO FINANCIAL CONFLICTS OF INTEREST APPLICABLE TO PHS (INCLUDING NIH) & NSF-FUNDED RESEARCH** **24**

Introduction	24
A. Purpose	24
B. Definitions	24
1. Investigator	24
2. Significant Financial Interest	24
C. Institutional Responsibilities	25
D. Management of Conflicting Interests	25
E. Remedies	26
F. Comparison of PHS and NSF Regulations	26
G. Implementation of Federal Regulations at WMC	26

**IV. IMPLEMENTATION OF CONFLICTS POLICY** **29**

A. Conflicts Management Office	29
B. Conflicts Advisory Panel	29
C. Conflict Management	29
1. Submission of disclosures	29
2. Review of disclosures	30
D. Sanctions and Disciplinary Actions	30
E. Right of Appeal	30
F. Frequently Asked Questions (FAQ) Regarding WMC Annual Disclosure	31
G. Annual Disclosure Review Process Chart	33

<b>V. DEFINITIONS AND COMMENTS</b>	<b>34</b>
A. Definition of Terms	34
1. Members	34
2. Entities	34
3. Nature of Involvement	35
4. Miscellaneous Definitions	35
B. Comments	36
1. Disclosure	36
2. Categories of Activities	36

## Abbreviations Used in This Booklet

**CAP**—Conflicts Advisory Panel

**CFR**—Code of Federal Regulations

**CMO**—Conflicts Management Office

**CRF**—Cornell Research Foundation

**FAQ**—Frequently Asked Questions

**FDA**—Food and Drug Administration

**GPM**—Grant Policy Manual

**HHS**—Department of Health and Human Services

**IACUC**—Institutional Animal Care and Use Committee

**IDE**—Investigational Device Exemption

**IND**—Investigation New Drug Application

**IRB**—Institutional Review Board

**NIH**—National Institutes of Health

**NSF**—National Science Foundation

**PHS**—United States Public Health Service

**RASP**—Office of Research and Sponsored Programs

**SBIR**—Small Business Innovation Research Program

**UCC**—University Committee on Conflicts/University Conflicts Committee

**WMC**—Joan and Sanford I. Weill Medical College of Cornell University

## **Preface**

Cornell University policy requires faculty and staff to submit an annual disclosure of financial interests and external commitments that might create a conflict or the appearance of a conflict of interest or commitment. This booklet has been prepared to assist you in understanding what is meant by “conflict of interest” and “conflict of commitment” as well as what are the requirements of University Policy and applicable Federal regulations.

By inclusion in this booklet, the Federal regulations (see Chapter III) are made part of the Cornell Conflicts Policy and are implemented as described in Chapter III, section G.

## **Acknowledgements**

This booklet was originally prepared by Dr. Gregory W. Siskind, former Associate Dean (Research Compliance).

# I. Introduction to Conflicts of Interest and Commitment

## A. Background

In recent years several widely reported events in human subjects research have brought the issue of conflict of interest to public attention. For example, the death of a teenage research subject in a gene transfer study at the University of Pennsylvania raised questions as to whether equity holdings, by the *Principal Investigator*<sup>1</sup> and by the University of Pennsylvania, in the company sponsoring the research resulted in a conflict of interest which might have led to a delay in the reporting of adverse events occurring during the course of the research. In another case, a series of articles in the Seattle Times implied that equity holdings by *investigators* might have influenced the continuation of studies, on certain potential cancer therapies, beyond when they were appropriate. Newspaper reports discussing clinical drug trials have implied that, in some cases, payments to the physician for enrolling subjects, or bonuses for rapid enrollment, might have influenced inappropriate enrollment of research subjects.

Whether in the illustrative cases cited above a conflict of interest actually influenced behavior in a negative manner has not been established and seems to the writer to be unlikely. However, the appearance of possible conflict of interest was sufficient to embarrass the *investigators* and the institutions involved, and in some cases has been among the factors resulting in time consuming and costly investigations. In this period of high public interest in science (or more precisely, in new treatments promised by science), combined with a general distrust of leaders in politics, in business as well as in science, the appearance of a conflict may be as important as the actuality in the eyes of the public and regulatory agencies. It is noteworthy that the events referred to above in the area of gene transfer research led the professional organization in the field to adopt a more rigorous policy regarding conflict of interest.

Cornell University has long had a Conflict of Interest Policy, which applies to the Medical College. Recent heightened public concern, especially in the area of human subjects research, has not altered this policy but has led to its more rigorous implementation, especially in regard to disclosure. This booklet has been prepared to describe this institution's Conflict of Interest Policy as well as the applicable Federal regulations. Your obligations under these and other related policies and regulations are described, and the operation of the disclosure review procedures at the Medical College is summarized. Questions can be brought to the Associate Dean (Research Compliance)<sup>2</sup>.

## B. Definition of Conflict of Interest and Commitment

The Joan and Sanford I. Weill Medical College and Graduate School of Medical Sciences of Cornell University (WMC) Conflicts Policy<sup>3</sup> defines Conflict of Interest as “Typically, a conflict of interest may arise when a *member* has the opportunity to influence the University's business, administrative, academic, or other decisions in ways that could lead to personal gain and advantage of any kind.” In the case of faculty engaged in research as part of their university scholarly activities, situations where expectation of personal gain or advantage might influence the design, execution or reporting of the research would represent a potential conflict of interest.

---

<sup>1</sup> Terms defined in Chapters II, III and V of this booklet are printed in *italics* for convenience.

<sup>2</sup> Contact information can be found in Chapter VI of this booklet.

<sup>3</sup> Reprinted in Chapter II of this booklet.

The WMC Conflicts Policy defines conflict of commitment as: “A conflict of commitment arises when a *member* undertakes external commitments which burden or interfere with the *member’s* primary obligations and commitments to *Cornell*.” WMC faculty may undertake external paid consulting for the equivalent of one day per week. Consulting which involves more than an average of one day per week over the course of a year (time permitted does not accumulate from year to year), or which requires an absence from the campus for longer than seven consecutive days may only be undertaken with the approval of the Dean of the Medical College, or his/her designee. In all cases, the faculty *member* must inform and obtain approval from their department chairperson prior to undertaking any paid consulting<sup>4</sup>. Consulting by a WMC faculty *member* for more than 52 days in a year poses the possibility of a conflict of commitment and must be specifically approved by the Dean of the Medical College, or his/her designee.

Please note that use of University equipment for private consulting or research arrangements may only be done with the approval of the Dean of the Medical College, or his/her designee, and the establishment of an appropriate service charge.

These definitions are expanded upon and clarified in the Conflicts Policy by a series of illustrative examples<sup>5</sup>.

## C. Disclosure

### 1. Introduction

The approach of the WMC Conflicts Policy is that disclosure is the initial step, and in many cases the most important component, in the management of potential conflicts of interest, or the appearance thereof. The underlying concept is that if a relationship is open and disclosed it is less likely to result in improper behavior or evoke the suspicion of improper behavior. The WMC policy requires faculty to disclose to and obtain approval of their department chairperson and the Conflicts Management Office or the Dean of the Medical College, or his/her designee, for all external relationships, which could create the appearance of a conflict of interest, prior to entering into the relationship. Disclosure must be complete and in adequate detail to allow full evaluation of the potential conflict of interest. In general, as part of the process of management of potential conflicts, WMC also requires that, when relevant, disclosure of potential conflicts of interest must be made by the faculty in their publications, presentations, and other activities.

In addition to disclosure of external relationships to the faculty *member’s* department chairperson, formal disclosure of financial and other interests are required in at least five distinct situations. The specific conditions under which disclosure is necessary and the nature of what must be disclosed varies for the different situations, thus all instructions accompanying disclosure requests should be carefully followed. The commonly required disclosures do not ask for a blanket description of your financial holding, but rather are tailored to handle a specific situation. The disclosures described in I.C.2-6 are likely to be required of faculty.

### 2. WMC Annual Disclosure

University Policy requires annual disclosure of potential conflicts of interest by all *members*. Annual external Financial Disclosures are collected electronically and must be completed by faculty and staff at least once per reporting year<sup>6</sup>. The questions asked are designed to identify conflicts, or appearance of conflicts, involving business activities of the Medical College as well as situations generated by research related activities of the *member*. The disclosure process and the review of submitted information is described in Chapter IV of this booklet.

---

<sup>4</sup> See Attachment B of the WMC Conflicts Policy located in Chapter II of this booklet.

<sup>5</sup> See Attachment A of the WMC Conflicts Policy located in Chapter II of this booklet.

<sup>6</sup> Contact information and location can be found in Chapter VI of this booklet.

### **3. Public Health Service (PHS), Including the National Institutes of Health (NIH) as well as the National Science Foundation (NSF), Disclosure Requirements**

Federal regulations require that all applicants for funding by grants, contracts or cooperation agreements from the PHS (including NIH) and NSF must disclose to the institution submitting the application any “*Significant Financial Interests*” that would “reasonably appear to be affected by the research proposed” in the application. WMC is required to implement procedures to reduce, eliminate or manage any potential conflict of interest prior to using any awarded funds. The Federal regulations are summarized and procedures for disclosure are described in Chapter III of this booklet. It should be emphasized that the *Principal Investigator* and all other persons who are responsible for the design, conduct or reporting of the research must complete a disclosure. Furthermore, (1) since the relationships to be disclosed are specific for the research being proposed in the individual grant, contract or cooperative agreement, and (2) the disclosure must, by Federal regulation, be updated at least annually; a new disclosure must be submitted for every grant application including non-competing or competing continuations. Forms are available from the Grants and Contracts Division Office<sup>7</sup>, which have been designed to respond to the specific requirements of this Federal regulation.

### **4. Food and Drug Administration (FDA) Required Disclosure**

If you are involved in FDA regulated research, such as clinical trials of drugs, biologicals or devices under an Investigation New Drug Application (IND) or an Investigational Device Exemption (IDE), you will be required to submit a study-specific disclosure on FDA specified forms. The nature and value of holdings, which must be disclosed, are specified in FDA regulations and in the instructions to the disclosure forms. It is the responsibility of the “Sponsor”<sup>8</sup> to collect these disclosure forms from individual *investigators* and submit them to the FDA. One should complete these forms with care, since errors could have serious consequences. If you are the holder of the IND or IDE for a study, you should be especially diligent regarding compliance with FDA regulations since the FDA tends to hold the individual *investigator* and sponsor responsible for any violations.

### **5. WMC Institutional Review Board (IRB) Required Disclosure**

The WMC IRB requires a Protocol-specific disclosure of any relationships or financial holdings, which could give the appearance of a conflict of interest. The disclosure is required of the Responsible Investigator, each co-investigator and any other person responsible for the design, conduct or reporting of the research described in the Protocol. It is the opinion of the WMC IRB that information regarding possible conflicts of interest of *Investigators* might influence some potential research subjects as to whether to *participate* in the research and such information should therefore be provided to potential research subjects in order that they can give appropriately informed consent. Disclosure forms (the Study Specific Financial Disclosure Form) are available from the WMC IRB Office<sup>9</sup>. The disclosure is research study (Protocol) specific, so a new disclosure must be submitted with each new IRB Protocol Application.

### **6. WMC Grants and Contracts Routing Form: Disclosure for Agreements with Industrial Sponsors of Research**

The Routing Form, which must accompany all grant and contract applications submitted to the Grants and Contracts Division Office<sup>10</sup>, contains a section with a series of questions aimed at identifying potential conflicts of interest in regard to agreements with industrial sponsors of research. The information obtained is important in negotiation of and compliance with the terms of agreements with industrial sponsors of research. For example, sponsors may require the Medical College to confirm that the *Investigators* do not have any

---

<sup>7</sup> Contact information and location can be found in Chapter VI of this booklet.

<sup>8</sup> Defined in FDA terminology as the person holding the IND or IDE.

<sup>9</sup> Contact information and location can be found in Chapter VI of this booklet.

<sup>10</sup> Contact information and location can be found in Chapter VI of this booklet.

potential conflicts of interest related to their participation in the proposed research. In addition, the existence of multiple sources for funding, and commitments made in Material Transfer Agreements, can create situations where there are conflicting obligations to different sponsors as well as to providers of materials. The disclosure required is specific for the studies to be supported by the proposed industrial agreement.

## **7. Maintenance of Confidentiality of Disclosures**

In general, WMC will hold your disclosures in confidence. However, the degree of confidentiality possible varies for the different types of disclosures and the specific facts and circumstance involved. For example, with regard to the disclosure required for NIH and NSF grants, contracts and cooperative agreements, representatives from the NIH can have access to disclosure records and conflicts management records. Similarly, for FDA regulated studies, the FDA can generally have access to all relevant records including patient records, adverse events records, IRB records and conflict of interest records. Corporate sponsors of research will generally, on a contracted basis, have access to all research records. Of course, in the event of legal action, many records may be subject to subpoena. In general, it is the policy of WMC to require disclosure of potential conflicts of interest in publications and presentations and, it is the policy of the IRB, to require disclosure in the Informed Consent Document or process.

## II. Conflicts Policy for the Joan and Sanford I. Weill Medical College and Graduate School of Medical Sciences of Cornell University<sup>11</sup>

### Article I – The Primary Commitment to the University

#### Introduction

Trustees, Overseers, executive officers, deans, directors, academic and non-academic staff all serve the educational and public purposes to which the University is dedicated. Accordingly, all such *members*<sup>12</sup> of the University community (hereafter "*members*") have a clear obligation to conduct the affairs of the University in a manner consistent with those purposes and to make all decisions solely on the basis of a desire to promote the best interests of the institution.

This statement recognizes and affirms the settled tradition and expectation that *members* will conduct their relationships with each other and the University with candor and integrity.

This statement confirms the University policy that faculty and other employees who accept full-time appointments have a primary commitment to the University and that they will be sensitive to the possible adverse effects of their external activities. It is recognized, however, that the quality of teaching, research, clinical service, and the administration of University programs may be enhanced when *members* participate in extramural activities, which enhance their value to the University, so long as their primary commitments to the University are not adversely affected.

These policies and procedures will permit *members* of the academic and non-academic staff and administration to identify, evaluate and correct or remove real, apparent and potential conflicts of interest and commitment. The appearance that a conflict may be present may be as important as the reality. Accordingly, the first essential step in all of the procedures set forth below is disclosure and discussion.

#### A. All Members

A *member* is considered to have a conflict of interest when he or she or any of his or her *family* or *associates* (to his or her present knowledge) either (1) has an existing or potential financial or other material interest which impairs or might appear to impair the individual's independence and objectivity of judgment in the discharge of responsibilities to the University, or (2) may receive a financial or other material benefit from knowledge of information confidential to the University.

The *family* of an individual includes his or her spouse, parents, siblings, children and any other blood relative if the latter resides in the same household. An *associate* of an individual includes any person, trust, organization or enterprise (of a business nature or otherwise) with respect to which the individual or any member of his or her *family* (1) is a director, officer, employee, member, partner or trustee, or (2) has a *significant financial interest* or any other interest which enables him or her to exercise control or significantly influence policy.

---

<sup>11</sup> Adopted by the Board of Trustees May 31, 1986. Amended October 29, 1992; June 23, 1994; October 28, 2000; and January 23, 2004.

<sup>12</sup> Terms defined in Chapters II, III and V of this booklet are printed in *italics* for convenience.

## **B. Faculty and Non-Faculty Academic Staff**

Academic staff *members* who accept full-time appointments have a primary commitment which includes providing instruction, being available to students and colleagues outside the classroom, providing clinical services (where appropriate), serving departmental, college, and University committees, conducting research, publishing scholarly works, and otherwise meeting the changing needs of the University.

Although a specific workweek is not defined for academic staff *members*, it is expected that such membership constitutes a full-time obligation and that, with the exceptions explicitly permitted by University policies on consulting and other related professional activities (attached hereto and made a part hereof as Attachment B), they will not engage in other employment.

## **C. Non-Academic Employees**

In the case of non-academic employees, commitments of time and the expectations attached to such positions are more explicitly defined and, therefore, the likelihood of conflicting external activities are reduced. Nevertheless, the University expects that non-academic employees also will recognize the possibility that their external activities, commitments and interests may have adverse effects on the performance of their University obligations.

## **D. Part-Time Appointees**

Academic and non-academic employees who hold part-time appointments commonly will have major obligations and commitments, not only to the University, but to one or more outside agencies. The potential for conflict may be significant. Accordingly, part-time employees are expected to exercise special care in disclosing and fulfilling their multiple obligations.

## **E. Trustees, Overseers and Executive Officers**

Trustees, Overseers and executive officers of the University are fiduciaries and owe special duties of care and loyalty to the institution as a whole and must keep the University's interests paramount to all others.

## **Article II – Categories of Conflicts**

The University thrives when its faculty and staff pursue and support research and scholarship with vigor. Their activities must include interactions with many external agencies. Predictably, some external relationships will have the potential to create conflicts of interest or commitment, or the appearance thereof. In many situations these conflicts will be apparent only and can be resolved by disclosure. Actual conflicts fall into two categories.

### **A. Conflict of Interest**

Typically, a conflict of interest may arise when a *member* has the opportunity to influence the University's business, administrative, academic or other decisions in ways that could lead to personal gain or advantage of any kind.

### **B. Conflict of Commitment**

A conflict of commitment arises when a *member* undertakes external commitments which burden or interfere with the *member's* primary obligations and commitments to *Cornell*.

## C. Examples of Conflicts

It is difficult to specify precisely what constitutes an objectionable conflict in all situations. Illustrative examples are given in Attachment A<sup>13</sup> to assist *members* in understanding where and how such conflicts may arise.

## Article III – Conflict Disclosure and Avoidance

*Members* are expected to evaluate and arrange their external interests and commitments in order to avoid compromising their ability to carry out their primary obligations to the University. In the first instance, conflicts should be avoided or resolved through the exercise of individual judgment or discretion.

Full disclosure of the circumstances surrounding a real or potential conflict should be made prior to making the commitment or initiating the activity, which poses the possible conflict.

### A. Members of the Academic Staff

Disclosure should be made to the college or department in such form and manner as the dean (or his/her designee) or department chairman may prescribe. The department chair may act as representative of the dean for the purpose of receiving and evaluating such information. Disclosure shall be sufficiently detailed to permit an accurate and objective evaluation. Each *member* has an obligation to cooperate fully in the review of the pertinent facts and circumstances. The dean (or his/her designee) or department chairman shall make a determination, which resolves and removes the conflict or appearance of conflict.

Discussions with the department chairman and/or the dean (or his designee) should include consideration of whether an individual's role in an external agency needs to be declared or made known to other *members* of the University community to protect confidentiality or to guard against the transfer of privileged information. If such disclosure is necessary, it should be made to the academic and/or non-academic staff *member* who may be affected.

### B. Non-Academic Employees

Disclosure should be made to the department, division or other administrative unit in which the *member* is employed in such form and manner as the associate dean, department chairman, or director may prescribe. *Members* involved in the following duties must be particularly conscious of possible conflicts or the appearance of such conflicts: the procurement, exchange or sale of goods, services or other assets, the negotiation or formation of contracts or other commitments affecting the assets or interests of the institution, the handling of confidential information and the rendition of professional advice to the University. Disclosure shall be sufficiently detailed to permit an accurate and objective evaluation. Each *member* has an obligation to cooperate fully in the review of the pertinent facts and circumstances. The associate dean, department chairman or director shall make a determination, which resolves and removes the conflict or appearance of conflict.

### C. Deans

The deans of the Medical College and Graduate School of Medical Sciences shall file an annual disclosure statement with the Provost for Medical Affairs regarding their own external commitments and interests in such form as the Provost may direct. The Provost for Medical Affairs shall resolve any matter involving a conflict or appearance of a conflict in such cases.

---

<sup>13</sup> Located on page 19 of this booklet.

## **D. Trustees, Overseers, and Executive Officers of the Corporation**

The University Counsel and Secretary of the Corporation shall continue to obtain annual written disclosure statements regarding external commitments and interests from all members of the Boards of Trustees and Overseers and all executive officers of the Corporation as defined at Article VI of the University bylaws and shall advise the Audit Committee of the Board of Trustees regarding such matters as necessary.

## **Article IV – Resolution of Conflicts Involving Academic Staff**

### **A. Initial Disclosure**

In the event that disclosure reveals a real or apparent conflict, the dean, associate dean, department chairman or other authority designated by the dean shall review the facts and attempt to resolve the matter informally with the academic staff *member*.

In the event that the *member* objects to the resolution by the dean, associate dean, department chairman, or designee, the matter shall be referred to an advisory committee designated by the Provost for Medical Affairs.

### **B. The Advisory Committee**

It is anticipated that most conflicts will be resolved through disclosure and review processes at the departmental, or other subordinate level. However, if a conflict remains unresolved following earlier reviews, the dean, associate dean, department chairman or other designated authority will submit the matter, together with a recommended resolution, to the Provost for Medical Affairs who shall appoint an advisory committee which shall include, but not be limited to the Chairman of the General Faculty Council, and two senior members of the faculty. The committee shall consider the matter, determine whether a conflict exists, evaluate the severity of the conflict, and recommend to the Provost the steps necessary to resolve the conflict. The Provost may accept, reject or modify the recommendations.

If the *member* disagrees with the Provost's determination, the *member* may request a further consideration of the matter and, in that connection, may examine the recommendations of the Advisory Committee, including supporting evidence, and offer other relevant information or explanations. The University Counsel shall serve as advisor to the provost for Medical Affairs. Following such reconsiderations, the Provost shall make a final and binding determination in writing.

If the determination requires the termination of the appointment of a professor, associate professor or assistant professor, the procedure adopted by the Board of Trustees and University Faculty regarding such cases may be invoked by the affected *member*. That is, the President shall appoint a board consisting of five members of the University faculty, of whom two shall be selected by the faculty *member*, two by the President and the fifth by the other four. The Board may modify the proposed remedy but shall have no authority to alter the determination of the Provost regarding the meaning, interpretation or applicability of the Cornell University Conflicts Policy for the Medical College and Graduate School of Medical Sciences.

## **Article V – Resolution of Conflicts Involving:**

### **A. Deans**

Questions involving external commitments or interests of the deans, as defined at Article I, Section 7 of the University bylaws, shall be brought to the attention of the Provost for Medical Affairs, who shall resolve the matter.

## **B. Trustees, Overseers and Executive Officers of the Corporation**

The University Counsel shall advise on matters involving external commitments or interests of trustees, overseers and executive officers of the Corporation and, where appropriate, shall consult with the Committee on Conflicts of Interest, which shall consist of the chair of the Board, the vice chair, if any, the chair of the Executive Committee and the President of the University, which shall resolve the matter or, where appropriate or necessary, refer it to the Board of Trustees for resolution.

## **C. Other Members (Non-Academic Employees)**

Questions involving external commitments or interest of employees, other than members of the academic staff, deans, trustees and executive officers, shall be disclosed to the appropriate dean, associate dean, department chairman or director, (hereafter "head") or his/her designee. In the event that disclosure reveals a real or apparent conflict, the head or designee shall review the facts and attempt to resolve the matter informally.

In the event that the *member* objects to the resolution by the head or designee, the non-academic Employee Complaint and Grievance Procedure may be invoked.

## **Article VI – University Committee on Conflicts**

### **A. Purpose**

There shall be established a University Committee on Conflicts which shall be appointed by the President and which shall serve as a University resource with respect to matters involving the general subject of conflicts of interest and commitment, the oversight and implementation of the Cornell University Conflicts Policy, and the identification and resolution of specific conflicts of interest.

### **B. Composition**

The standing University Committee on Conflicts (UCC) shall be co-chaired by the Dean of the Faculty and the Vice President for Research and Advanced Studies, shall include not less than five additional members<sup>14</sup> appointed by the President, and shall include faculty representation from the endowed colleges in Ithaca, the statutory colleges and the Medical College. Members shall serve three-year staggered terms. The University Counsel shall serve as a non-voting member.

### **C. Duties**

1. The UCC shall oversee the solicitation of a periodic uniform disclosure from all University faculty (and such other *members* of the staff of instruction and research as are deemed appropriate by the UCC) that addresses potential conflict of interest and conflict of commitment situations.

a. The circulation, collection and retention of disclosure statements, including those disclosures presently required of non-academic staff pursuant to Article III(B), will continue to be the responsibility of the college dean or director or the head of the appropriate administrative unit, who shall provide the UCC with such summaries or reports or disclosure statements as it may require.

b. The dean, or director or head of the appropriate administrative unit in the case of non-academic staff, shall provide the UCC with a copy of any disclosure statement which reveals a real or apparent conflict of interest or commitment, together with a description of the resolution of such conflict or, if the conflict remains unresolved, the recommended resolution

---

<sup>14</sup> To the extent practicable, the Committee should include individuals familiar with the circumstances that could result in possible conflicts in the physical, biological and social sciences, the humanities, engineering, medicine and veterinary medicine.

as submitted to the Provost pursuant to Article IV(B) or to grievance review pursuant to Article V(C) in the case of non-academic staff.

2. The UCC shall at the request of the Provost, a college dean or director, or an appropriate administrative officer or a faculty or staff *member*, provide advice regarding a potential conflict of interest or commitment. If a faculty or academic staff *member* objects to a dean's or director's resolution of a conflict pursuant to Article IV(A), the advisory committee appointed by the Provost pursuant to Article IV(B) shall seek the advice of the UCC, as shall any grievance review body pursuant to Article V(C) in the case of non-academic staff or any other established college or university hearing panel involved in the review of related conflict matters.
3. The UCC shall maintain an ongoing awareness of college procedures, practices, and standards with regard to conflict of interest and commitment with a view to assuring consistency with the terms of the University Conflicts Policy. It shall carry on whatever dialogue is necessary with college deans and directors or administrative officers to insure that its knowledge is sufficiently current and complete. It shall also insure that a proper balance is maintained between confidentiality and understanding of its operations and standards.
4. The UCC shall maintain an awareness of externally imposed conflict of interest requirements, and shall provide advice and recommendations to the Provost on any related policy matter.
5. The UCC may recommend to the Provost changes to the University Conflicts Policy.
6. The UCC shall perform such additional functions as may be assigned from time to time by the President.
7. The UCC will report biennially to the faculty and to the President on matters within its jurisdiction.

#### **D. Procedures**

1. The UCC shall establish its own procedures, not inconsistent with this policy, and may make use of subcommittees to carry out its various functions.
2. In the case of research or other activities subject to applicable governmental regulations on conflict of interest the requirements of such governmental regulations shall apply and supplement and/or, to the extent inconsistent herewith, supersede the provisions of this and other Articles of the University Conflicts Policy. In that event applicable reporting procedures and other substantive and procedural requirements will be adhered to.

## Attachment A [Illustrative Examples]

The following commentary and examples are intended to provide guidance in the identification of conflicts of interest or commitment. The list does not cover all possible situations, which might involve an actual or apparent conflict of interest. It is intended to be illustrative only.

### General Considerations

*Members* involved in business ventures as owner, operator, or major investor must be alert to the possibility that a conflict may arise. If the enterprise does no business with the University, only the area of conflict of commitment is likely to be involved.

If the enterprise does business with the University, or might do business with the University, the *member* is expected to disclose that fact. Generally, there will be no conflict if the *member* is not in a position to influence the University with respect to the business of the enterprise in which the *member* holds an interest.

A *member* may not review, approve, or administratively control contracts when the contract is between the University and a company in which the *member* has a substantial financial interest or when the contract is with a member of the employee's immediate family or when a member of the employee's immediate family is an employee of the contractor and directly involved with activities included under the contract or has a substantial interest in the contractor.

No gifts or accommodations of any nature may be accepted by *members* when to do so could possibly place them in a prejudicial or embarrassing position, interfere in any way with the impartial discharge of their duties to the University or reflect adversely on their integrity or that of the University. Subject to this restriction, *members* may accept modest gifts, meals, entertainment and other normal social amenities so long as such amenities are not extravagant under the circumstances.

### Permissible Activities

The following activities are clearly permissible and do not require disclosure as an actual or potential conflict under the terms of this policy.

Example 1. Acceptance of royalties under the terms of the University's Patent or Copyright Policies or publication royalties or honoraria for commissioned papers and lectures even where such works are based on materials developed pursuant to University duties such as teaching courses or conducting research.

Example 2. Services to outside educational, professional, scientific, artistic, cultural, civic, business or other organizations, which enhance the value of the *member* to the University and do not adversely affect the *member's* primary commitment to the University.

### Apparent Conflicts Requiring Prior Disclosure and Resolution

The following activities have the potential to create conflicts of interest or commitment and should be reviewed and disclosed prior to being undertaken.

Upon full disclosure, the University may approve a transaction or affiliation, provided no conflict of interest is involved and further provided that the *member* furnishes an annual statement indicating compliance with the University's Conflict of Interest Policy. The University shall disapprove the transaction or affiliation, if a conflict of interest is involved which cannot be resolved or removed.

Example 3. Situations where a *member* directly or indirectly leases, rents, trades or sells real or personal property to the University.

Example 4. Situations where a *member* possesses a substantial interest in or participates in the profits of any organization that deals or seeks to deal with the University. Participation through stockholdings, mutual funds and similar vehicles is not a conflict unless the stocks of the organization held by the individual constitute a substantial holding.

Example 5. Situations where a *member* accepts appointment as an officer or director or serves in any management capacity in an external commercial, industrial *business* or financial organization or profit-making enterprise which deals or seeks to deal with the University.

Example 6. Situations where a *member*, while serving in a position at *Cornell*, is concurrently engaged to teach a course or otherwise make a substantial contribution to the instruction or educational services offered by another *entity*. Instructional activities performed in the course of normal faculty sabbatical leave or for a subsidiary of the University, which are routinely subject to disclosure and approval processes, are not meant to be covered by this example.

Example 7. Situations where a *member* makes substantial use of University resources (e.g. studios, computer technology, research, technical or support staff) in developing and/or teaching a course to be offered by another *entity*.

Example 8. Situations where a *member*, without permission, utilizes the name of the University or one of its colleges or programs in connection with the promotion, marketing, or sale of a product or service in such a way as to imply University sponsorship, e.g. "The Cornell Book of \_\_\_\_\_."

Example 9. Situations where a *member*, as part of an arrangement with an *entity* unaffiliated with *Cornell*, agrees to any limitations on his/her performance of teaching or other instructional duties for the University (e.g. through agreements containing exclusive provider, non-competition or right of first refusal clauses).

## **Possible Conflicts**

Conflict is possible, even if unlikely, in situations such as those listed in the following examples, and *members* should give careful consideration to that potential. In many cases the potential for conflict can be removed by disclosure.

Example 10. Relationships that might enable *members* to influence *Cornell's* interactions with outside organizations in ways that may lead to personal gain, to the taking of improper advantage by anyone, or the improper diversion of University assets from the primary missions of the University, including the time and talents of its faculty and staff.

Example 11. Situations in which a *member*, while serving as a consultant to an external organization has access to unpublished, privileged information from a colleague that has potential commercial value and wishes to provide that information to the external organization.

Example 12. Situations where a *member* directs students into a research area or other activity from which the *member* intends to realize personal financial gain. A conflict may arise if students are directed to areas of lesser scientific or scholarly merit to enhance the potential for monetary gain or if the financial potential exists only for the *member*.

Example 13. Situations where the *member* is asked to assume executive or managerial positions with outside organizations that might seriously divert the *member's* attention from University duties, or create other conflicts of loyalty.

Example 14. Disclosure or use for personal profit of unpublished information coming from University research or other confidential University sources, or assisting outside organizations by giving them access to such information except as may be authorized by official University policies.

Example 15. Consultation that imposes obligations that conflict with *Cornell's* Patent Policy or with *Cornell's* obligations to research sponsors.

Example 16. Situations where a substantial body of research that could and ordinarily would be conducted by the *investigator* within the University is directed elsewhere.

Example 17. Situations where the *member* is invited to advise or serve an organization doing business in the general area of the *member's* University responsibility or which is related to that field.

Example 18. Situations where a *member* is offered a position on a scientific or administrative board of an organization that has research contracts with the *member's* unit.

Example 19. Situations where a *member* is offered research support from an organization in which the *member* serves as a director, a member of an advisory board or as a consultant, or in which the *member* holds a significant equity position.

Example 20. Situations where the *member* occupies a position in an enterprise doing business in the area of the *member's* University responsibility of which is related to that field.

Example 21. Situations where the *member* is involved in independent *business* ventures as owner, operator or major investor, particularly if the corporation is doing business with the University.

Example 22. Situations in which an individual can require others to purchase a product in which the individual has a proprietary interest and from which the individual will receive income.

Example 23. Situations where a *member*, while serving in a position at *Cornell*, makes a substantial contribution to the non-educational services offered by another *entity*.

Example 24. Situations where a *member*, as part of an arrangement with an *entity* unaffiliated with *Cornell*, agrees to any limitations on his/her performance of non-teaching duties for the University (e.g. through agreements containing exclusive provider, non-competition or right of first refusal clauses).

## **Conflicts of Commitment**

Assessment of a conflict of commitment is more difficult than assessment of a conflict of interest. Generally, such conflicts will be apparent in the failure of individuals to discharge fully the role and duties expected of them.

1. Commitments that involve frequent or prolonged absence from the University on non-University business.
2. Commitments that engage a substantial portion of the time a *member* is expected to spend in University related activities and which thereby dilutes the amount or quality of participation in the instructional, scholarly or administrative work of the University.

## Attachment B Academic Policies/Responsibilities Consulting\*

### Principles

Consulting privileges are limited to the professorial staff and there are many reasons why faculty *members* should engage in outside consulting work. It is desirable that they remain in close communication with the world outside the institution and especially with that part of the world concerned with their area of specialization. Consulting is a means of maintaining this liaison as well as of offering solutions to practical problems and thereby testing the soundness of theories taught in the classroom and laboratories. While consulting activities often enhance a faculty *member's* value to *Cornell*, it can result in conflicts of interest and conflicts of commitment, which compromise the faculty *member* and the institution.

In private consulting it must be kept clear that the faculty *member* does not represent the University. Private consulting activities of faculty *members* must be viewed in relation to their overall responsibilities to *Cornell*, and should not become so extensive that they interfere with those responsibilities.

### Policy

Full-time faculty *members* must inform their department chairpersons of all plans to do private consulting for which they are compensated. Unless the regular duties include consulting services to the public, each full-time professor may engage in private consulting work, provided such work, in the judgment of the department chairperson and in accordance with the principles stated above, enhances the value of the individual to the University and does not interfere with regular University duties. Consulting work of an unusual nature may be undertaken only when approved by the dean of the faculty *member's* college.

The law establishing the statutory colleges requires faculty *members* in those colleges to perform teaching, research, and extension duties. Faculty *members* in statutory units should therefore check with their department chairpersons before consulting for a fee with New York State corporations or organizations that may be entitled to extension help without cost.

In general, faculty *members* in the endowed colleges may undertake paid consulting for the equivalent of one day a week during the period for which they are paid for service. Faculty *members* in the New York State College of Agriculture and Life Sciences, the New York State College of Human Ecology, and the New York State College of Veterinary Medicine may consult for the equivalent of two days a month; those in the New York State School of Industrial and Labor Relations may consult for the equivalent of one day a week. The time that a faculty *member* is allowed to consult does not accumulate from year to year. Consulting involving time beyond that allowed, or necessitating an absence from the campus longer than seven consecutive days, may be undertaken only when approved by the dean of the faculty *member's* school or college.

Note: Individual schools, colleges or divisions may have promulgated additional consulting rules consistent with the *Cornell* University Conflicts Policy. Such supplemental rules may be obtained from the individual schools, colleges or divisions.

### Use of University Equipment for Private Consulting or Research

The following University guidelines were adopted by the Deans' Council on April 7, 1981:

Faculty *members* who have external private consulting or research arrangements, which involve personal financial gain, may use University equipment for such purposes only after the approval of the department chairperson, director, or dean. Approval will be contingent on the establishment of a

---

\* From the Cornell University Faculty Handbook (1990), pages 63-64. Note: The Faculty Handbook text on consulting has been amended since that section was incorporated into this Conflicts Policy at the time of its original adoption in May 1986. This attachment reflects the most current language.

service charge by the unit providing the service where such a charge is appropriate. If such charges are on a continuing basis, they should be discussed with the Controller's Office.

# III. Summary of Federal Regulations Relating to Financial Conflicts of Interest Applicable to PHS (Including NIH) & NSF-Funded Research

## Introduction

Federal regulations<sup>15</sup> were promulgated in 1995 to ensure that Public Health Service (PHS) [including the National Institutes of Health (NIH)] and National Science Foundation (NSF)-funded research (grants, collaborative agreements and contracts) would not be biased by conflicting financial interests of *investigators*<sup>16</sup>. Briefly, these regulations place specific requirements upon *investigators* to disclose financial interests and upon the institution to identify conflicts; to arrange for conflicts to be managed, reduced or eliminated; to maintain records of financial disclosures; and to inform faculty of these Federal regulations and of the institution's Conflicts Policy. A summary of the applicable Federal regulations follows:

### A. Purpose

The purpose of these regulations is to promote “objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS [or NSF] grants and cooperative agreements [and contracts] will be biased by any conflicting financial interest of an *investigator*.”<sup>17</sup>

### B. Definitions<sup>18</sup>

For the purposes of these regulations, the following definitions apply:

#### 1. Investigator

“*Investigator*’ means the *principal investigator* and any other person who is responsible for the design, conduct, or reporting of research funded by PHS [or NSF], or proposed for such funding...[In considerations of financial interests,] ‘*Investigator*’ includes the *investigator*’s spouse and dependent children...”

#### 2. Significant Financial Interest

“*Significant Financial Interest*’ means anything of monetary value, including but not limited to salary or other payments for service (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term [*significant financial interest*] does not include:

- (1) salary, royalties, or other remuneration from [*Cornell*];
- (2) any ownership in the institution if the institution is an applicant under the SBIR [Small Business Innovation Research] Program;
- (3) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit *entities*;

---

<sup>15</sup> 42 CFR part 50, subpart F; 45 CFR 94; NSF’s GPM 510; see Federal Register Vol. 60, No. 132, pp. 35810 and 35820 for PHS rules and NSF rules respectively.

<sup>16</sup> Terms defined in Chapters II, III and V are printed in *italics* for convenience.

<sup>17</sup> Quoted from 42 CFR 50.601.

<sup>18</sup> 42 CFR 50.603

- (4) income from service on advising committees or review panels for public or nonprofit *entities*;
- (5) an equity interest that when aggregated for the *investigator* and the *investigator's* spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than five percent ownership interest in a single entity; or
- (6) salary, royalties or other payments that, when aggregated for the *investigator* and the *investigator's* spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.”<sup>19</sup>

## C. Institutional Responsibilities

The regulations<sup>20</sup> require that each institution which applies for funding from the PHS (including the NIH) or from the NSF must “maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each *Investigator* of that policy, the *Investigator's* reporting responsibilities, and of these regulations” and must ensure that *investigators* working for subgrantees also comply with these regulations. The institution must also “designate an institutional official(s) to solicit and review financial disclosure statements from each *Investigator* who is planning to *participate* in PHS [or NSF] –funded research.” In addition, the institution must “Require that by the time an application is submitted to PHS each *Investigator* who is planning to *participate* in the PHS-funded research has submitted to the designated official(s) a listing of his/her known *Significant Financial Interests* (and those of his/her spouse and dependent children):

- (i) That would reasonably appear to be affected by the research for which PHS funding is sought: and
- (ii) In entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable *Significant Financial Interests* are obtained.”

The institution is further required:

- (1) to “provide guidelines...for the designated official(s) to identify conflicting interests;”
- (2) to “maintain records of all financial disclosures and all actions taken by the institution;”
- (3) to “establish adequate enforcement mechanisms and provide for sanctions where appropriate;”
- (4) to “certify, in each application for funding...that there is...a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests...[and that] prior to the Institution’s expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced, or eliminated...”

## D. Management of Conflicting Interests<sup>21</sup>

“A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

---

<sup>19</sup> 42 CFR 50.603  
<sup>20</sup> 42 CFR 50.604  
<sup>21</sup> 42 CFR 50.605

- (1) Public disclosure of *significant financial interests*;
- (2) Monitoring of research by independent reviewers;
- (3) Modification of the research plan;
- (4) Disqualification from participation in all or a portion of the research funded by the PHS [or NSF];
- (5) Divestiture of *significant financial interests*; or
- (6) Severance of relationships that create actual or potential conflicts.”

## E. Remedies<sup>22</sup>

“If the failure of an *Investigator* to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken...[In addition] the [Department of Health and Human Services] HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart...[If] the PHS Awarding Component decide(s) that a particular conflict of interest will bias the objectivity of the PHS-funded research [it] may determine that suspension of funding under 45 CFR § 74.62 is necessary until the matter is resolved. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an *Investigator* with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the *Investigator(s)* involved to disclose the conflicting interest in each public presentation of the results of the research.”

## F. Comparison of PHS and NSF Regulations

In most regards, the PHS regulations<sup>23</sup> and the NSF regulations<sup>24</sup> relating to financial conflict of interest are comparable. Several differences do exist which should be noted. (1) Unlike PHS, the NSF regulations state that “If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a *significant financial interest* are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.”<sup>25</sup> (2) The NSF requires that “Conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF”<sup>26</sup> by the Institutional Official.

## G. Implementation of Federal Regulations at WMC

WMC has adopted the following procedures for implementing the requirements of the Federal regulations discussed in this chapter. Please note that the inclusion of these Federal regulations in this booklet makes them a part of the WMC Conflicts Policy, implemented as described in this section (G).

---

<sup>22</sup> 42 CFR 50.606

<sup>23</sup> 42 CFR part 50, 45 CFR part 94

<sup>24</sup> GPM 510

<sup>25</sup> Federal Register Vol. 60, No. 132, p. 35822

<sup>26</sup> Federal Register Vol.60, No. 132, p. 35820

1. WMC has designated two institutional officials responsible for implementing this Federal policy as described in this section, the Associate Dean (Research Compliance) and the Senior Director, Grants and Contracts Division of RASP. Their individual responsibilities in implementing these regulations are described as follows in this section (G).

2. The *Principal Investigator* and every other person responsible for the design, conduct or reporting of research must complete a Study Specific Financial Disclosure Form which is available from the Grants and Contracts Division of the Office of Research and Sponsored Programs (RASP), or from the Research Compliance Division of RASP<sup>27</sup>. Please note that every question asked on the disclosure form is seeking specific information, which must be documented under the Federal regulations, described in this chapter (III). The disclosure required is project specific and must, by Federal regulations, be updated at least annually so that a new disclosure form must be completed by every *investigator* for every application (new or continuing).

3. The Senior Director of the Grants and Contracts Division of RASP, or his/her designee, will review the submitted disclosure forms and determine whether all required disclosure forms have been submitted and if any *investigators* have disclosed any *significant financial interests*. If all required disclosures have not been submitted, the Senior Director of the Grants and Contracts Division will withhold submission of the application as required by Federal regulations. Any disclosure forms indicating *significant financial interests* by *investigators* will be forwarded to the Associate Dean (Research Compliance) for evaluation.

4. If the Associate Dean (Research Compliance), or his/her designee, upon consideration of the facts and circumstances of the case, determines “ that a *significant financial interest* could directly and significantly affect the design, conduct, or reporting of the PHS-funded research” then a conflict of interest exists, and the Associate Dean (Research Compliance) will forward the relevant material to the Conflicts Management Office.

5. The Conflicts Management Office shall determine if the financial relationship(s) under consideration has been previously reported and if so what action was taken. The Conflicts Management Office shall inform the Associate Dean (Research Compliance) as to the findings.

6. If the financial relationship(s) has been previously reported to the WMC Conflicts Management Office and actions recommended to manage, reduce or eliminate the conflict have been accepted by the *investigator*, then the Associate Dean (Research Compliance) shall so inform the Senior Director of the Grants and Contracts Division, who will notify the Granting Agency, prior to the use of any awarded funds, of the existence of a conflict of interest and that actions have been taken to manage, reduce or eliminate the conflict.

7. If the matter has not been previously reported to the WMC Conflicts Management Office or if no resolution of the reported conflict of interest has been achieved, the Associate Dean (Research Compliance) will contact the *investigator* to discuss the facts and circumstances involved and obtain any required additional information. The Associate Dean (Research Compliance) will attempt to achieve a resolution, to which the *investigator* would agree, which would manage, reduce or eliminate the conflict. If necessary, in his/her opinion, the Associate Dean (Research Compliance) may refer the matter to the Conflicts Advisory Panel (CAP) for its advice. When an agreeable resolution is achieved the matter will be reported to the dean of the Medical College, or his/her designee, for his/her review and approval. Copies of the approved resolution of the potential conflict will be forwarded to the *investigator's* department chairperson and to the Office of Faculty Affairs. The Senior Director of the Grants and Contracts Division shall be informed that the potential conflict has been managed, reduced or eliminated and shall notify the Granting Agency, prior to the use of any awarded funds, of the existence of a conflict of and that actions have been taken to manage, reduce or eliminate the conflict.

---

<sup>27</sup> Contact information and location can be found at  
<[<http://med.cornell.edu/research/rea\\_com/con\\_of\\_int.html?name1=Conflicts+Management+Office&type1=2Active>>](http://med.cornell.edu/research/rea_com/con_of_int.html?name1=Conflicts+Management+Office&type1=2Active)>

8. If the Associate Dean (Research Compliance) is unable to achieve a reasonable resolution of the potential conflict of interest in a manner that would reasonably manage, reduce or eliminate the conflict, he/she shall so notify the Senior Director of the Grants and Contracts Division who will ensure that no awarded funds are used and will appropriately notify the awarding unit.

9. No awarded funds may be used if a conflict of interest exists to which a reasonable arrangement to manage, reduce or eliminate the conflict has not been achieved, to which the *investigator* has agreed. The Senior Director of the Grants and Contracts Division will ensure that use of awarded funds does not occur in the absence of a reasonable resolution of the conflict of interest documented by the Associate Dean (Research Compliance), or his/her designee.

## IV. Implementation of Conflicts Policy

### A. Conflicts Management Office

The Dean or his/her designee shall establish a Conflicts Management Office, which shall be responsible for the overall management of issues related to conflicts of interest and commitment. The office shall be responsible for: (1) implementation of the WMC conflicts policy; (2) serving as a resource to the faculty and staff regarding questions relevant to issues of conflict of interest or commitment and regulations related to conflicts of interest; (3) collection of an annual disclosure of conflict related information from the faculty and staff; (4) evaluation of information submitted in the annual disclosure as well as other individual disclosures; (5) development and implementation of conflicts management plans; (6) providing staff support for the Conflicts Advisory Panel (see below) and for any conflicts oversight committees; (7) development of educational programs for faculty and staff regarding conflicts related issues.

The office shall be under the direction of the Associate Dean, Research Compliance or his/her designee. The Conflicts Management office shall establish its own procedures to accomplish its mission as indicated above. Its procedures and actions are not to be inconsistent with the WMC Conflicts Policy.

### B. Conflicts Advisory Panel

The Dean shall appoint a Conflicts Advisory Panel (CAP) consisting of the Chairman of the General Faculty Council and between four and six members of the faculty of the medical college (at least two of whom shall be senior members of the faculty).

CAP shall, upon request: (1) provide advice to the Dean or his/her designee, the Associate Dean and the Conflicts Management Office, in consultation with other staff to the Panel such as the Associate University Counsels, with regard to conflicts of interest and commitment related matters; (2) advise and make recommendations to the Dean on the acceptability of conflicts management plans submitted to the Panel by the Conflicts Management Office on behalf of Members of Cornell regarding potential conflicts of interest or commitment. In addition to review of conflicts management plans submitted by the Conflicts Management Office, CAP will also review possible conflicts of interest or commitment issues as referred to it by the Grants and Contracts Division, Office of the University Counsel, the Cornell Research Foundation, the Office of Technology Development and the Institutional Review Board.

### C. Conflicts Management

#### 1. Submission of disclosures

Each full-time, part-time, and voluntary faculty and staff *member*<sup>28</sup> is required to complete and submit a financial disclosure survey on an annual basis.

Amendments to disclosure surveys must be submitted whenever there is a change of circumstance that could give rise to a conflict situation as defined in the Conflicts Policy<sup>29</sup>. This amendment must be submitted prior to engagement in such an activity.

---

<sup>28</sup> Terms defined in Chapters II, III and V are printed in *italics* for convenience.

The disclosure survey will be considered confidential. The information disclosed on the form is available only to individuals charged with responsibility for review and for ensuring compliance with University, Federal and State conflict of interest policies and regulations. Please note the discussion of limitations on maintenance of confidentiality in section I. C. 7, the Introduction to Conflicts of Interest and Commitment. In addition, you should be aware that University Policy requires that any compensated consulting must be reported to, and approved by, the faculty *member's* department chairperson prior to being undertaken<sup>30</sup>.

## 2. Review of disclosures

All conflicts disclosures, including the required annual disclosure, will be reviewed by the Conflicts Management Office. All disclosures indicating a less than significant conflict will be managed by sending the *member* a letter indicating his/her responsibilities regarding departmental and public disclosure of the conflict. Copies of these letters will be forwarded to the Office of Faculty Affairs.

For those disclosures indicating a significant conflict of interest or commitment, the Conflicts Management Office will work with the *member* to develop an appropriate conflict management plan. Once a management plan has been developed, it will be submitted to the CAP for review. CAP may request additional information from the Conflicts Management Office and may recommend changes in the plan. Based on its review, CAP will make a recommendation to the Dean as to whether the plan should be approved. The final authority regarding the acceptability of a conflict management plan rests with the Dean. All conflicts management plans will be signed by the *member's* department chairperson and a copy will be included in the *member's* file in the Office of Faculty Affairs.

## D. Sanctions and Disciplinary Actions

Sanctions and disciplinary actions may include, but are not limited to, the following:

1. The inclusion in the faculty or staff *member's* file of a letter from the Provost for Medical Affairs indicating that the individual's good standing as a *member* of the faculty or staff has been called into question; i.e., censure.
2. Ineligibility of the faculty or staff *member* to submit sponsored project applications, to teach or organize Continuing Medical Education programs, to obtain Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval, or to supervise graduate students.
3. Non-renewal of appointment.
4. Dismissal from the University.

## E. Right of Appeal

Faculty and staff *members* have the right to appeal all sanctions proposed by the Provost for Medical Affairs.

If the *member* disagrees with the Provost'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 Provost for Medical Affairs. Following such consideration, the Provost shall make a final and binding determination in writing.

---

<sup>29</sup> See Chapter II of this booklet.

<sup>30</sup> See Chapter II, Attachment B.

## F. Frequently Asked Questions (FAQ) Regarding WMC Annual Disclosure

The following questions are in regard to all disclosures:

**Q1: Do I have to fill out the disclosure survey? I am certain I have no conflicts.**

A1: Cornell University Policy requires that all employees, including faculty, must complete a disclosure annually.

**Q2: Do I have to indicate that I receive a salary/stipend from WMC?**

A2: No! Financial arrangements outside of WMC are what you must disclose.

**Q3: If my position at WMC does not involve any research activity, must I still complete the disclosure survey?**

A3: The disclosure requirement applies to all persons who hold appointments at WMC or are employees of WMC. There are types of conflicts that do not involve research.

**Q4: I have no change in my external activities since I reported last year. Must I still complete this disclosure survey?**

A4: University Policy requires reporting every year. For the first round of electronic disclosure reporting, you will have to complete the survey. In subsequent years, your disclosure record may be updated electronically.

**Q5: Will I receive a response from the Conflicts Management Office (CMO) regarding my disclosure?**

A5: If you have disclosed a possible conflict of interest or commitment and a determination is made that further information is required or that there are special procedures you must follow in view of the possible conflict, you will receive a letter from the CMO. If you fully complete the disclosure survey and indicate no possible conflicts, to conserve staff effort, you will receive no communication from the CMO.

**Q6: What should I do if I do not understand how to fill out the survey to communicate my specific situation?**

A6: If your situation is such that completing the survey is difficult or does not provide a clear and accurate picture of your situation, you should feel free to forward a written description. There is no limitation in length. The survey is provided to facilitate the process of reporting and evaluating the reports. Do not allow adherence to the survey to cause you to provide an incomplete or misleading disclosure. If you have any questions, you may always call or write to the Conflicts Management Office at 212-821-0710, Box 6 or [conflicts@med.cornell.edu](mailto:conflicts@med.cornell.edu).

**Q7: What happens if I disclose a potential conflict of interest or commitment?**

A7: That depends on the specific details of the disclosed potential conflict. The procedures for handling disclosures as well as WMC's Conflict Policy are provided in this booklet.

**Q8: When the disclosure survey asks about the financial interests of my family, what is meant?**

A8: The term "*family*" is meant to include spouse (or significant other), siblings, parents, children, and any other blood relative if the latter resides in the same household. In some circumstances, you may feel that it is appropriate for you to include other persons as "*family*". Feel free to do so and forward an explanation (see Q7) as you feel appropriate for the situation.

**Q9: Is it necessary for me to disclose all of my external financial activities, even those unrelated to my work for the WMC?**

A9: The policy requires disclosure of all activities/relationships, which could be or give the appearance of a conflict of interest or commitment. Investments in mutual funds or similar situations in which you do not have control over the specific investments generally need not be reported. If a problem should arise in the future, your having reported the activity/relationship offers some protection to you and to the institution in terms of how people may interpret the problem. A failure to report an activity/relationship may be interpreted as a desire to hide the activity because you feel there is something undesirable about it. No one is criticized for “over-reporting.”

**The following questions are in regard to the hard copy disclosure format:**

**Q10: What if I cannot utilize the electronic format?**

A10: A hard copy disclosure will be provided to you.

**Q11: What is the purpose of the I.D. number?**

A11: The I.D. number is used for identification purposes on the confidential Conflicts Database and provides security against inappropriate access to the information in your file or unauthorized insertion of information into your file.

**Q12: Do I have to fill in the information requested on page one of the disclosure form, even though I can be identified by my ID number?**

A12: Please fill out the information section on page one. Although we can trace your name using the ID number, your detailed completion of the form will facilitate handling and may provide contact information not otherwise available. Thank you.

**Q13: Do I have to sign the form?**

A13: Yes, to indicate that you have personally provided the information and that the information provided is accurate to the best of your knowledge.

**Q14: After I complete it, what do I do with the form?**

A14: Make a copy of the form for your records and send the original to Box 6 in the mailroom in the return envelope provided.

**Q15: What do I do with the cover letter, which bears my confidential ID number?**

A15: Retain it for your records with your copy of your disclosure. There is no need to return the cover letter.

**Q16: Can I use the white return envelope even though the form is being returned via interoffice mail?**

A16: Yes, you may use the white envelope. The mailroom will process white envelopes for interoffice delivery. Since forms are sent to persons both on and off campus in the same mailing, using only one type of envelope simplifies the distribution process. The mailroom staff know that those envelopes go to Box 6.

**Q17: Can I make a copy of my form for another employee who needs one?**

A17: You should not share the form with anyone, because of the individual I.D. number placed on it.

**Q18: If I lose the form, can the Conflicts Management Office fax another copy to me?**

A18: Due to the unique identifiers on the form, the Conflicts Management Office generally avoids faxing it. Upon request from you, the Conflicts Management Office will be happy to issue a new form and will send or hand deliver it to you.

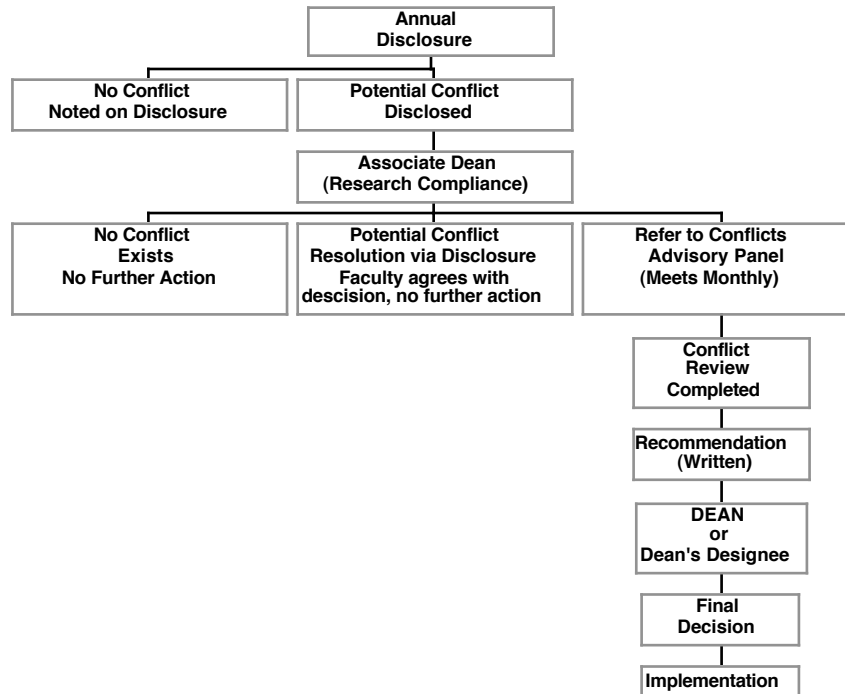
**Q19: If I forgot to keep a copy, can I get my old form faxed to me?**

A19: Due to the importance of maintaining confidentiality, the Conflicts Management Office generally avoids faxing a completed form but you can request a copy of your old form in writing, and the Conflicts Management Office will be happy to mail it or deliver it to you.

**Q20: If I have not received a form but believe that I should have received one, what should I do?**

A20: Contact the Conflicts Management Office at 212-821-0710, and provide an interoffice, outside or hand delivery mailing address. The Conflicts Management Office will check the database and provide a form if appropriate.

## G. Annual Disclosure Review Process



## V. Definitions and Comments

### A. Definition of Terms

#### 1. Members

A *member*<sup>31</sup> includes any person who:

- a. Possesses a full-time, part-time, or voluntary appointment (including a fellowship position) on the faculty of the Joan and Sanford I. Weill Medical College and Graduate School of Medical Sciences of Cornell University (collectively “*Cornell*”);
- b. Is on the staff of an affiliate institution and holds a *Cornell* appointment;
- c. Is a full-time or part-time employee on the academic or non-academic staff of *Cornell*;
- d. Is engaged in research or other activity utilizing resources or facilities<sup>32</sup> of *Cornell*, or any of their respective joint programs.

The *family* of a *member* includes his or her spouse, dependent children, and any other immediate family member (e.g., sibling, parent, adult child, or any other blood relative if the latter resides in the same household) whose financial holdings are known to the *member*. This includes *de facto* spouses.

*Cornell* includes all units operated by Cornell University.

#### 2. Entities

An *entity* includes, but is not limited to, the following: a for-profit *business*, a not-for-profit organization, a governmental agency.

An *affiliated clinical care entity* means any *entity* organized to provide medical and health care, including patient consultations that has a formal affiliation agreement with *Cornell*.

An *associated entity* of a *member* means any trust, organization, or enterprise other than *Cornell*, or any *affiliated clinical care entity*, over which the *member*, alone or together with the *member's family*, exercises a *significant financial interest*.

*Activities of an entity* include both direct activities and *financial interest* in the activities of other *businesses*.

*Business* means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal *entity*, including, but not limited to, for-profit organizations. It does not include mutual funds over which the *member* has no control, or any governmental committee, community, political, academic, charitable, religious, social, professional nonprofit organization, or the private practice of voluntary clinical faculty *members*.

---

<sup>31</sup> Terms defined in Chapters II, III and V are printed in *italics* for convenience.

<sup>32</sup> Resources or facilities do not include the *member's* office, office equipment and incidental supplies (e.g., personal computers and local telephone service), libraries, and commonly available services (e.g., copying, facsimile, long-distance telephone service for which the *member* reimburses *Cornell*, or infrequent secretarial support).

### 3. Nature of Involvement

*Financial interest* is an interest in a *business* consisting of:

- a. An *equity interest*, including any stock, stock option, other investment, or similar ownership interest in such *business*, but not including any interest arising solely by reason of investment in such *business* by a mutual, pension, or other institutional investment fund over which the *member* does not exercise control.
- b. Receipt of or the right or expectation to receive any income from such *business*. The income can be in any form, including but not limited to consulting fees, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of *technology*, rent, capital gain, real or personal property.

*Significant financial interest* is used as defined by Federal regulations<sup>33</sup>.

*Executive position* refers to any salaried position, which includes responsibilities for a material segment of the operation or management of a *business*.

*Received funds* include loans, gifts, royalties, consulting fees, and other earned income. It does not include royalties from publications, unearned income, travel reimbursements, and grants, contracts, or any other sum that the *member* or the *member's family* receives through *Cornell*, no matter what the original source.

*Contract* does not include the *member's* or any *family member's* employment contract with *Cornell*.

### 4. Miscellaneous Definitions

*Clinical research* means any research needing approval by the Institutional Review Board (IRB). Thus, *clinical research* includes all procedures involving human subjects or the use of samples from human subjects for the development of diagnostic tests or therapeutic agents, or to expand biological knowledge. It includes clinical drug or device trials. It does not include a *member's* participation in the design of a clinical study for which he/she is subsequently neither a participant nor an author.

*Sponsored research* means research, training, and instructional projects supported in whole or in part by funds, materials, equipment, or compensation, including gifts, from sources outside *Cornell*.

*Technology* means any methodology, information, compound, drug, device, diagnostic, medical or surgical procedure.

*Intellectual property* includes organized information, ideas, fabrication methods, devices, or substances that are patented, copyrighted, or have that potential, and that are partially or fully owned by *Cornell*. It does not include any intellectual property for which the *member* holds a license from Cornell Research Foundation (CRF) or which is in the public domain.

To *participate in research* means to be part of the described activity in any capacity, including, but not limited to, serving as the *Principal Investigator*, co-investigator, research collaborator, teacher, or student. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (i.e., exercising no control over its collection or analysis). In addition, in the case of *clinical research*, the term is not intended to apply to the research subjects, unless they are in a position to influence the study's results or have privileged information regarding the outcome.

---

<sup>33</sup> See Chapter III of this booklet.

## B. Comments

### 1. Disclosure

Many potential conflicts can be resolved by disclosure. Full disclosure of the circumstances surrounding a real or potential conflict situation must therefore be submitted prior to making the commitment or initiating the activity, which poses the possible conflict. In addition, regular disclosure of all activities is a central element of the *Cornell* Conflicts Policy.

All faculty *participating* in sponsored programs are expected to disclose in publications and presentations any real or apparent conflict of interest related to the content of the publication or presentation.

### 2. Categories of Activities

Activities that cannot be undertaken without the approval of the *member's* department chairperson or program chairperson and the Dean of the Medical College<sup>34</sup>:

#### a. Research, teaching, and patient care:

A *member* may not *participate in research*, including *clinical research* on a *technology* owned by, or contractually obligated<sup>35</sup> to, a *business* in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest* other than royalties and/or licensing fees under institutional agreements.

A *member* may not receive support from any source to conduct research for a *business* in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

A *member* may not assign students, post-doctoral fellows, or other trainees to projects sponsored by a *business* in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

A *member* may not *participate* in teaching or patient care activities involving a *technology* developed or owned by a *business* in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

#### b. External activities:

Committee participation: A *member* serving on a committee of the Food and Drug Administration (FDA), other governmental or non-governmental agency, or private insurer may not *participate*, without prior disclosure to and with the expressed consent of the "agency," in deliberations or recommendations by such a committee on a *technology* that is owned by or contractually obligated to a *business* in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

A full-time *member* may not assume an *executive position* in a for-profit *business* engaged in commercial or research activities of a biomedical nature.

A *member* may not make clinical referrals to a *business* in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

A *member* may not possess a *significant financial interest* in a *business*, which competes with the services provided by Cornell, or any *affiliated clinical care entity*.

#### c. Administrative responsibilities:

---

<sup>34</sup> In certain circumstances, approval of an outside agency or public disclosure may be required.

<sup>35</sup> By license or exercise of an option to license.

A *member* may not take administrative action within *Cornell* or any *affiliated clinical care entity*, which is beneficial to a *business* in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

A *member* may not *participate* in or otherwise influence the selection by *Cornell* of a contractor, vendor, or supplier of goods or services in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

A *member* may not *participate* in, or otherwise influence, any *Cornell* transaction to buy, sell, lease, or license real or intellectual property in which the *member*, a member of the *member's family*, or an *associated entity* has a *significant financial interest*.

Allowable activities, which must be disclosed to the *member's* department chairperson:

a. Board memberships:

A *member* may, after disclosure, serve on the board of directors or scientific advisory board of a *business*, provided that the *member*, a member of the *member's family*, or an *associated entity* does not receive *sponsored research* support from that *business*.

b. Activities conducted pursuant to consulting agreements or while on sabbatical or other leave:

A *member* may, with prior disclosure, engage in consulting for commercial organizations as long as such consulting is consistent with any applicable *Cornell* guidelines or policies governing consulting.

This Policy is not intended to limit the rights of *members* to conduct research at other institutions while on sabbatical or other leave from *Cornell*. Such activities should, however, be disclosed in advance to the *member's* department chairperson and are subject to any guidelines governing such research that *Cornell* and *affiliated clinical care entities* may have in place.

For the latest Office of Research and Sponsored Programs (RASP)  
contact information, go to our website at:

<http://med.cornell.edu/research>

The Conflicts Management Office can be found under the  
Research Compliance tab