**Examples of Potential Reporter Scenarios Related to fCOI Reporting Procedure**

In performing research or research related duties at Cornell, there are several types of conflicts of interest that, if not identified and / or managed, may lead to a real or perceived bias in the performance and outcome of Cornell related research. The sample scenarios below are intended to serve as examples that may relate to a reporter’s own circumstances. They are intended only as guidance. Additional guidance can be found at http://www.oria.cornell.edu/

Cornell Policy “Financial Conflict of Interest Related to Research” 1.7, NIH regulations (42 CFR Part 50 subpart f, and 45 CFR Part 94) and NSF’s Grants Policy Manual (http://www.nsf.gov/pubs/2002/nsf02151/gpm5.jsp#510) state that a financial Conflict of Interest (fCOI), exists when the individual has a Significant Financial Interest (SFI) that may be reasonably viewed to significantly affect the design, conduct, or reporting of the research. The existence of an SFI does not necessarily mean there is a financial Conflict of Interest (fCOI). When a fCOI does exist, it can in most cases be managed through a documented management plan. Management plans are drafted and proposed by the fCOI Committee, and must be acknowledged and accepted by the researcher in order for the research to proceed. The goal is to support the continued funding and performance of research under the auspices of Cornell University.

Definition of Significant Financial Interest:

(1) Significant Equity Interest: For a publicly held business, an equity interest that when aggregated for you and your family, exceeds the Public Health Service (PHS) threshold, currently: (i)$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or (ii)representing 5% ownership in such business.

For a privately held business, any equity interest in such business, regardless of the amount.

And/Or

(2) Significant Financial Income: Payments of anything of monetary value (including the value of an equity interest) from a single entity that when aggregated for you and your family (as defined in the procedures for each campus) for the past 12 months or expected over the next 12 months, exceeds the Public Health Service (PHS) threshold, currently $10,000.

**Example Scenarios by Topic (click hyperlink to go to example)**

**Example 1: Significant Financial Interest not related to Cornell research (Consulting)**

**Example 2: No Significant Financial Interest**

**Example 3: Significant Financial Interest related to Cornell research**
Example 1: Significant Financial Interest not related to Cornell research (Consulting)

Dr. A consults for Small Company, which sells accounting software for engineering firms. She receives $20,000 per year for her consulting activity. Small Company does not provide any support for Dr. A’s research, which is sponsored by NSF, and Dr. A does not research any technology owned or licensed by Small Company. Neither Dr. A nor her family have any other financial interest in Small Company, nor do they have financial interests in any other external entity.

Dr. A’s receipt of payment of $20,000 per year for consulting is considered a Significant Financial Interest (SFI) because it is income that exceeds the $10,000 threshold for payment from a single entity over the past or future 12 months. However, because her consulting is unrelated to her research, it is not considered a fCOI related to research. Dr. A will need to report this commitment of time to enable an assessment of possible Conflicts of Commitment (COC) and non-research related conflict of interest (NRR-fCOI).

Dr. A would respond to the screening questions in her annual fCOI report as follows:

- A (Conduct of Cornell Research): Yes
- B1 (Financial Interest and External Commitment): Yes (Consulting)
- B2 (Family’s Financial Interest and External Commitment related to Cornell duties): No
- B3 (Significant Income for self and family related to Cornell duties): No
- C (Significant Equity Interest): No
- D (Other Significant Financial Interests): No

Based on these responses, Dr. A will be required to complete the detailed report on her responsibilities and commitments with Small Company. Upon Dr. A’s completion and submittal of her annual report, a limited subset of the reported information will be made available to Dr. A’s Unit Head for an assessment of Conflicts of Commitment (COC) and NRR COI. However, because her consulting is unrelated to her research, there is not a financial Conflict of Interest to be reviewed.

*If the facts were a little different, and the consulting was related to the same area of research as Dr. A’s Cornell research, then the financial interest could constitute a financial Conflict of Interest which would require a management plan.*

Example 2: No Significant Financial Interest

Dr. B is the Principal Investigator (PI) of a study sponsored by TechInc., the company that manufactures the technology being tested in Dr. B’s research. Dr. B also consults for TechInc., has
received $8,000 in the past year for this activity and expects to receive the same amount of money in
the coming 12 months.

The annual financial income from TechInc. is below the reportable threshold for Significant
Financial Income because it is less than $10,000. However the consulting engagement with
TechInc. must be reported to Dr. B’s unit for a determination of possible Conflict of Commitment.

Dr. B would respond to the screening questions in the annual fCOI and COC report as follows:

A (Conduct of Cornell Research) : Yes
B1 (Financial Interest and External Commitment) : Yes (Consulting)
B2 (Family’s Financial Interest and External Commitment related to Cornell duties) : No
B3 (Significant Income for self and family related to Cornell duties): No
C (Significant Equity Interest): No
D (Other Significant Financial Interests): No

Based on these responses, Dr. B will be required to complete the entity report section related to the
consulting arrangement with TechInc. The relevant sections of Dr. B’s report will be made available
to Dr. B’s Unit Head for an assessment of Conflicts of Commitment.

Example 3: Significant Financial Interest related to Cornell research

Dr. C is on the Scientific Advisory Board of Data, Inc., a company that also sponsors research in her
computer laboratory at Cornell. The research that Data Inc. sponsors focuses on data management
systems and might eventually lead to an advancement in the field that would benefit Data Inc. Dr. C
receives $15,000 annually from Data Inc. for her work on the Scientific Advisory Board.

There are two fCOI considerations in this fact pattern. First, the annual financial income that Dr. C
receives from Data Inc. of $15,000 exceeds the threshold for SFI that must be reported. Second,
Data Inc. sponsors Dr. C’s research in her computer laboratory, and the outcome of the research
could benefit the company. Dr. C will also have to report her role on the Advisory Board as a time
commitment.

Dr. C would respond to the screening questions in her annual fCOI and COC report as follows:

A (Conduct of Cornell Research) : Yes
B1 (Financial Interest and External Commitment) : Yes (Consulting)
B2 (Family’s Financial Interest and External Commitment related to Cornell duties) : No
B3 (Significant Income for self and family related to Cornell duties): Yes
C (Significant Equity Interest): No
D (Other Significant Financial Interests): No

Based on the relatedness of Dr. C’s SFI to her research, it can be concluded that Dr. C has a fCOI
that will require a management plan. Depending on the perceived risk related to the integrity of
research data and reporting, the unique expertise of Dr. C in the particular area, and other factors, the
management plan may or may not allow Dr. C to serve as the Principal Investigator for the research.
It will likely require full disclosure of the relationship to the editors of all journals to which
manuscripts discussing the research are submitted and to all conference organizers where the work is
presented, oversight and possible limitations on the use of Cornell resources in the research and independent data monitoring or oversight.

A separate review will be undertaken at the unit level to review Dr. C’s time commitments regarding her Cornell role and her role on the Scientific Advisory Board.

**Example 4: Royalties Under a Cornell License Agreement**

Pursuant to a grant from the National Institutes of Health (NIH), Dr. D, a professor in the engineering college, invented a new technology. Cornell obtained a patent on the technology and licensed the patent to Company Z. Company Z is now aggressively marketing the product. Over the past year, Cornell earned $100,000 in royalties on this technology. Per Cornell’s policies, Dr. D receives a 33.3% “Inventor’s Share” of those royalties directly, which amounted to $33,333 last year. Dr. D has now improved the technology and would like to begin testing the new version in human subjects. Company Z has agreed to fund this human subject research.

In addition to the specifics of the financial interest, the involvement of human participants in the research adds another consideration. Cornell University has instituted a rebuttable presumption that researchers who are involved in the design, participant selection, informed consent process or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research, with a requirement that a management plan and management strategies for the involvement of conflicted researchers would be carefully written to adjust management of the conflicts to the level of anticipated risk. In addition to review by the Financial Conflicts of Interest Committee, Cornell’s Institutional Review Board for Human Participants will also review Dr. D’s report to determine if the conflict presents real or potential risks to human participants.

Since payments or anything of monetary value including royalties are included in the definition of SFI, Dr. D’s royalty payments of $33,000 over the past year must be reported.

Further, because the research is related to Dr. D’s research area at Cornell, and both Cornell and the company could benefit from the outcome of the research, this SFI is considered to be directly related to Dr. D’s research. In both his annual report and in his application to the IRB, Dr. D will need to fully disclose his relationships and interests, as well as his role in the research in his request for approval from the IRB.

Dr. D would respond to the screening questions in the annual fCOI and COC report as follows:

- A (Conduct of Cornell Research) : Yes
- B1 (Financial Interest and External Commitment): Yes (e and f)
- B2 (Family’s Financial Interest and External Commitment related to Cornell duties) : No
- B3 (Significant Income for self and family related to Cornell duties): Yes
- C (Significant Equity Interest): No
- D (Other Significant Financial Interests): No

Although this situation falls clearly into the path of the rebuttable presumption regarding human participant research, there are several factors that may be considered compelling in this case. The
SFI is paid to Dr. D through an institutional license agreement, not directly from the entity. If the performance of the research is to the benefit of the public and may be managed so as to mitigate or eliminate Dr. D’s conflict, the fCOI Committee (fCOIC) may determine that the research can proceed; a comprehensive management plan will likely consider removing Dr. D from certain roles within the research, or may impose third party oversight to ensure objectivity, and will certainly require disclosure of the interest in any publication of the research results.

The IRB will also review the proposed research, independent of the fCOIC, and under its mandate will determine whether there is any potential harm to any of the human participants, and at a minimum will require disclosure to the participants. The IRB will review the fCOIC proposed management plan, and may supplement the management plan. In any event, the IRB will not approve the research until it has fully reviewed all aspects of the issue, including the fCOI management plan.

**Example 5: Book Royalties**

Professor E has written a text book to use in her Introduction to Agribusiness course at Cornell. Professor E is an expert in the field of Agribusiness and does extensive research in this area. Publishing House Ltd. has decided that it would like to print and market Professor E’s text book. Professor E signs a contract with Publishing House. Through her book contract, Professor E receives an advance of $50,000, and may receive royalties depending on the sales success of the book.

Since the payment of $50,000 is towards the publication of a scholarly work, this income is excluded from the definition of Significant Financial Income. Payments or royalties for activities other than those related to the publication of scholarly or academic work are not excluded.

Professor E would respond to the screening questions in his annual fCOI and COC report as follows:

A (Conduct of Cornell Research): Yes  
B1 (Financial Interest and External Commitment): No  
B2 (Family’s Financial Interest and External Commitment related to Cornell duties): No  
B3 (Significant Income for self and family related to Cornell duties): No  
C (Significant Equity Interest): No  
D (Other Significant Financial Interests): No

Since there are no situations that may result in a conflict of interest or commitment, no further review of this report is required.

**Example 6: Consulting for a Non-Profit Organization**

Professor F is an economist and professor at Cornell, currently on sabbatical leave (or unpaid leave) in Sweden. The Ford Foundation, a private non-profit organization, has asked Professor F due to his research expertise to produce a white paper on economic indicators in developing countries, using data the Ford Foundation has collected. Professor F is paid $15,000 for this work.

Since the payment is from a private non-profit organization which is not a professional society, this income does have to be reported, as it is above the $10,000 threshold. Since Professor F is on leave, there are no issues of Conflict of Commitment.

Prof. F would respond to the screening questions in her annual fCOI and COC report as follows:
A (Conduct of Cornell Research): Yes
B1 (Financial Interest and External Commitment): No
B2 (Family’s Financial Interest and External Commitment related to Cornell duties): No
B3 (Significant Income for self and family related to Cornell duties): Yes
C (Significant Equity Interest): No
D (Other Significant Financial Interests): No

A review of the facts will likely determine that the outcome of Prof. F’s Cornell research is unlikely to be improperly affected by this consulting engagement with the Ford Foundation and hence that there is no conflict and no management required.

**Example 7: Expert Witness Fees**

Professor G, a professor of labor disability laws at Cornell, is retained by Big Law Firm to provide expert testimony on potential damages to an employee in a workplace injury litigation. Professor G is paid $20,000 for his one day of services. Neither Big Law Firm, nor the employee’s workplace is a sponsor of Professor G’s research and Professor G has no other commitment with either entity.

The payment of $20,000 constitutes a SFI. Although Professor G’s area of expertise is labor disability law, the Big Law Firm has no interest in the outcome of any of Professor G’s research, nor is it a sponsor in his work. However, Professor G’s commitment to serve as an expert witness may lead to a commitment related issue, which will need to be reviewed at the unit level.

Prof. G would respond to the screening questions in the annual fCOI and COC report as follows:

A (Conduct of Cornell Research): Yes
B1 (Financial Interest and External Commitment): Yes
B2 (Family’s Financial Interest and External Commitment related to Cornell duties): No
B3 (Significant Income for self and family related to Cornell duties): Yes
C (Significant Equity Interest): No
D (Other Significant Financial Interests): No

Based on the responses, Prof. G’s external commitment will not require a review by the fCOI Committee, but will be referred to the unit for COC review.

**Example 8: Equity Interest and Receipt of Funds from Entity and Government Agency**

Professor H is an expert in the development of protections for satellites from high radiation exposure. He owns a 10% equity interest in Company X, a privately held satellite manufacturer that he started with a friend, and the equity is valued at $50,000. Professor H also holds a position on the Scientific Advisory Board of Company X. In addition, Company X funds some of Professor H’s research at Cornell. Professor H’s research is also funded by an agency of the Department of Defense.

There are several issues in this series of relationships. The equity interest of Professor H meets the reporting requirement because it is an equity interest that exceeds $10,000 in value. Company X could benefit from the results of Professor H’s research in areas that are related to his primary research at Cornell, and because of Professor H’s interest in the company, he could personally benefit as well. In addition, because he receives DoD funding for research from which he could personally
benefit, the institution will need to ascertain that the DoD funded research is not actually or perceived to be skewed or biased for personal interest. Dr. H’s time commitment as a member of the Scientific Advisory Board for Company X will need to be reviewed for conflict of commitment, by his unit.

Professor H would respond to the screening questions in her annual fCOI and COC report as follows:

A (Conduct of Cornell Research): Yes
B1 (Financial Interest and External Commitment): Yes
B2 (Family’s Financial Interest and External Commitment related to Cornell duties): No
B3 (Significant Income for self and family related to Cornell duties): No
C (Significant Equity Interest): Yes
D (Other Significant Financial Interests): No

A management plan will need to cover all aspects of the financial interrelationships. This may include data monitoring, oversight by an objective third party, disclosures to students and collaborators, disclosure to the editors of all publications and to conference organizers, as well as other steps to mitigate the conflicts.

Example 9: Company Ownership and Work Outside Regular Hours

Professor I’s department funded research deals with ways to reduce traffic congestion in university towns. Professor I owns a company that provides traffic calming consulting in small towns. She manages the affairs of the company on the weekend and after hours. Annual income from the company exceeds $10,000.

Professor I’s 100% equity interest in her own company, and receipt of income in excess of $10,000 each constitute an SFI which must be reported. Professor I’s time commitment to her own company will also need to be reviewed for potential COC.

Prof. I would respond to the screening questions in her annual fCOI and COC report as follows:

A (Conduct of Cornell Research): Yes
B1 (Financial Interest and External Commitment): Yes
B2 (Family’s Financial Interest and External Commitment related to Cornell duties): No
B3 (Significant Income for self and family related to Cornell duties): Yes
C (Significant Equity Interest): Yes (100% equity in own company)
D (Other Significant Financial Interests): No

The SFI likely constitutes a COI, for which a management plan needs to be in place. The COC will be reviewed within the unit, which may include review of use of Cornell resources and time.

Example 10: Licensing Technology for which Researcher Holds a Patent

Cornell has patented an invention developed by Professor J, an instructional tool that he developed as a direct outcome of his department funded research. A company owned by Professor J’s wife wants to get an exclusive license for this technology from CCTEC. Income from licensing is expected to be less than $10,000 in the coming year.

Under Cornell’s licensing policy, Professor J will receive 33% of any licensing income for his new invention. The portion of Professor J’s income from the anticipated sales will be approximately $3,000, which does not meet the threshold of SFI and does not need to be disclosed. However, any
sales of the product will also benefit Professor J’s family because his wife owns the company that is seeking the exclusive license for the product. Therefore, Professor J’s wife’s equity interest in her company which is imputed to be known to Professor J, is considered related to Professor J’s research.

Prof. J would respond to the screening questions in his annual fCOI and COC report as follows:
A (Conduct of Cornell Research): Yes
B1 (Financial Interest and External Commitment): No
B2 (Family’s Financial Interest and External Commitment related to Cornell duties): Yes
B3 (Significant Income for self and family related to Cornell duties): No
C (Significant Equity Interest): Yes
D (Other Significant Financial Interests): No

A fCOI review will be required based on the equity interest of Prof. J’s wife. A fCOI review may determine that there is no fCOI if the transactions are distanced sufficiently, however there would be an apparent conflict just based on the relationships. At a minimum, a management plan may require transparency in the event of publication.

Additional examples will be added as common scenarios arise. If you have a specific circumstance for which you would like guidance, please contact one of the administrators for Financial Conflicts of Interest:

For questions about the fCOI policy, procedures or the review process, please contact Martha Westbrook at x58994 or mrw59@cornell.edu.

For assistance with using the fCOI Report Management System, please contact Bridget MacRae, x48878 or coi@cornell.edu.

Please visit the Cornell fCOI website http://www.oria.cornell.edu/COI/ for additional information about the fCOI policy and procedures, case studies and FAQs.