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APPENDIX 1

Examples of Possible Applications of the Policy on Financial Conflicts of Interest and Research

The following examples are intended to provide guidance on how the Policy on Financial Conflicts of Interest and Research may be applied to specific financial relationships. These examples are not binding and are meant to be only illustrative. The Sub-Committees will decide each case based on its own particular facts and circumstances.

Example 1: No Interested Business

Professor Smith is a member of the Department of Biomedical Engineering. She consults for Small Company, which sells accounting software for engineering firms. Professor Smith receives \$12,000 per year for her consulting activity. Dr. Smith's research is supported by the National Science Foundation and the Department of Biomedical Engineering. Small Company does not provide any support for Dr. Smith's research, and Dr. Smith does not research any technology owned or licensed by Small Company. Even though Dr. Smith receives income that exceeds \$10,000, Small Company is not an Interested Business, so Dr. Smith's consulting fees need not be reviewed by the FCOI Committee.

Example 2: No Significant Financial Interest

Dr. Green is an Assistant Professor of Clinical Surgery in the Department of Surgery at Columbia. He is the PI of a study sponsored by MedDevice, the company that manufactures the technology being tested. Dr. Green also consults for MedDevice and receives \$9,000 annually for this activity. As the income he receives from MedDevice does not exceed \$10,000 per year, Dr. Green does not have a Significant Financial Interest in MedDevice, the Interested Business. Because Dr. Green does not have a Significant Financial Interest in MedDevice, his disclosure will not be reviewed by the CUMC FCOI Sub-Committee. The information will be provided to the IRB, however, which has the authority to require disclosure in the informed consent form or to impose other requirements.

Example 3: Individual with a Significant Financial Interest Who May Conduct Research

Dr. Black is an Associate Professor in the Department of Computer Science at Columbia. She is on the Scientific Advisory Board of Data Source, Inc. a company that also sponsors research in her computer laboratory at Columbia. The research that Data Source sponsors focuses on data management systems generally and in the abstract, but

might eventually lead to an advancement in the field that would interest Data Source. Dr. Black receives \$11,500 annually from Data Source for her work on the Scientific Advisory Board, and therefore has a Significant Financial Interest in the company. Dr. Black ordinarily would not be allowed to participate in research sponsored by a Business in which she has a Significant Financial Interest. In analyzing the FCOI Review Factors, however, the Morningside Sub-Committee identifies several that could justify allowing Dr. Black to conduct the research sponsored by Data Source. Among those factors are: (1) the absence of human subjects; (2) the limited potential impact of the financial interest on the integrity of the data; and (3) the limited risk that Dr. Black's financial interest would appear to have influenced the outcome of the research. As a result, the Morningside Sub-Committee may determine that there are Countervailing Circumstances and allow Dr. Black to continue participating in the research sponsored by Data Source but require that she disclose her relationship with Data Source in all publications and to any students or collaborators involved in the Data Source research.

Example 4: Individual with a Significant Financial Interest Who May Not Conduct Research

Dr. White is a Professor in the Department of Medicine at Columbia. He is a Co-Investigator of a study testing a new treatment for pediatric arthritis. Dr. White is a consultant for the marketing division of Pharma, the company that manufactures the drug being tested in the study, and receives \$20,000 per year for his work. Dr. White therefore has a Significant Financial Interest in Pharma, an Interested Business. Upon reviewing the FCOI Review Factors, the CUMC Sub-Committee finds that Dr. White's conflict of interest could pose potential risks to the integrity of the research and to human subjects and could cause the research results to appear to have been biased. The Sub-Committee further notes that Dr. White's role in the study may be easily fulfilled by another member of his department. The CUMC Sub-Committee thus determines that the risks of Dr. White's participation in this research outweigh the benefits and requires that Dr. White must either reduce his financial interest in Pharma to \$10,000 or less annually, or withdraw from participation in the study. The CUMC Sub-Committee communicates its findings and the subsequent determination to the IRB.

Example No. 5: Royalties Under an Institutional License Agreement

Pursuant to a federal grant, Dr. Brown invented a new knee implant (the "Brown Implant"). Columbia obtained a patent on the Brown Implant and licensed the patent to Big Ortho Company. Big Ortho is now marketing the product. Over the past year, Columbia earned \$100,000 in royalties on the Brown Implant. Pursuant to Columbia's policies, Dr. Brown receives a 50% "Inventor's Share" of those royalties directly, or \$50,000. Dr. Brown has now improved the Brown Implant. Dr. Brown would like to begin testing the new version in human subjects. Big Ortho has agreed to fund this human subjects research.

When Dr. Brown submits his research protocol to Columbia's IRB, he will need to disclose the \$50,000 Inventor's Share of royalties. These royalties meet the definition

of Significant Financial Interest under the Policy and will need to be reviewed by the FCOI Committee. However, because they are paid pursuant to an institutional license agreement, the FCOI Committee might determine that the public policy objective of the Bayh-Dole Act and the potential benefit to the public justify permitting Dr. Brown to participate in the research on the improved implant. In that case, however, the Committee would require a management plan. Because human subjects are involved, the management plan might require, for example, an independent investigator to make enrollment decisions, and outside oversight of the data collection and analysis. In any case, management would include Dr. Brown's disclosure of his financial interest to his collaborators and in relevant publications and presentations.

Example No. 6: Book Royalties

McGraw-Hill Inc. contacts Professor Jones, a renowned historian and legal scholar, and asks her whether she would be interested in writing a new treatise on constitutional law. Professor Jones agrees. Through her book contract, Professor Jones receives an advance of \$50,000. Under the contract, she is also entitled to 7%-12% of proceeds for sales, depending on the number of copies sold. The book is successful, and Professor Jones' royalties exceed \$50,000 in the first year.

Because the advance and royalty payments issue from an independent publishing company for authoring a book, they are not included in the definition of Financial Interest. Therefore, they need not be reviewed by the Financial Conflict of Interest Committee.

Example No. 7: Consulting for a Not-for-Profit Organization

Professor Jackson is an economist. The Ford Foundation asks Professor Jackson to produce a white paper on economic indicators in developing countries, using data the Ford Foundation has collected. Professor Jackson is paid \$15,000 for this work. At the same time, Professor Jackson applies for and receives a Ford Foundation grant to fund a graduate student to work on a book Professor Jackson is writing on the economics of developing countries.

Because the Ford Foundation is an independent not-for-profit, it is not an Interested Business and no FCOI Committee review is required. Professor Jackson may consult for the Ford Foundation and conduct research sponsored by the Ford Foundation simultaneously.

Note, however, that the Ford Foundation and other not-for-profits could have their own policies governing such arrangements.

Example 8: Expert Witness Fees

Professor Terrence, an economist, is retained by Equipment Co. to provide expert testimony on potential damages in a personal injury litigation against Equipment Co.

Professor Terrence is paid \$20,000 for his services. Equipment Co. is not a sponsor of Professor Terrence's research and has no relationship to Professor Terrence's research at Columbia. Accordingly, Equipment Co. is not an Interested Business and no FCOI Committee review is required.

Example 9: Consulting for a Company and Receiving Data for Unfunded Research

Professor Jones consults for Fast Airline regarding air traffic control and receives \$50,000 per year. Fast Airline provides Professor Jones company data on actual air traffic flow patterns over the past 2 years. Professor Jones analyzes this data for his own research purposes, separate from his consulting. He then publishes this research in an article on the impact of new regulations on air traffic patterns.

Because Professor Jones' research on the Fast Airline's data is not funded through Columbia and does not require Columbia regulatory review, it is not Research sponsored by the University subject to University reporting requirements. Accordingly, Professor Jones is not required to report his consulting fees to the University for research conflict of interest purposes. However, if any other school or University policy requires reporting of the consulting fees (e.g., the P&S Conflict of Interest Policy on Education and Clinical Care), then Professor Jones must report them in compliance with such other policy. Finally, Professor Jones must also disclose the financial interest to the public, in any publications and presentations of this research.