

Guidance for Conflicts of Interest (COI) in Informed Consent Form (ICF)

Conflicts of interest exist when an investigator, or his/her institution, has financial or personal relationships that may compromise or present the appearance of compromising an individual's, group's or institution's judgment in conducting, reviewing, or reporting research. These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflicts of interest. A fully informed consent is one in which all related financial interests are disclosed.

To facilitate appropriate disclosure of potential conflicts of interest in the informed consent document, the following suggested language is provided. It is not mandatory to use these specific provisions as language should be modified to fit the specific facts and circumstances. The below text comes from the WCMC Institutional Review Board Consent Form last modified on 10/23/14:

COMMERCIAL INTEREST

Note to investigator: If anyone involved in the study has a financial interest related to this study, please select the appropriate language from the choices below.

- For Consulting, etc: Dr. X, [role in the study - choose PI or Co-investigator], serves as a [paid, unpaid] [use CONSULTANT for any of the following relationships - consultant, Advisory Board member, etc] for [the sponsor, the name of the company whose product is being used or tested, etc]. [State the relation of the company to the research if that would add valuable information.]
- Equity ownership: Dr. X, [role in the study], [owns stock, has an equity ownership] in [the name of the entity and its relation to the research - e.g., the sponsor of the study, the company that markets the drug being used, etc].
- Royalties: Dr. X, [role in the study], receives royalties from [the name of the entity and its relation to the research].
- Patents or patent applications: (Name of institution or individual investigator) holds a patent [or has applied for a patent or is an inventor (whatever applies)] for this [device or drug] and has a potential financial interest in the outcome of this study.

If you have any questions or would like additional information about the financial interests described in this paragraph, please contact Weill Cornell Medical College's Office of Research Integrity at (646) 962-8200.

Materials or data obtained from you in this research may be used for educational or commercial purposes. It is the policy of WCMC, NewYork-Presbyterian Hospital [and the Sponsor, if applicable] not to provide financial compensation to you should this occur.

Guidance for Conflicts of Interest (COI) Disclosure in Publications and Presentations

Financial and/or Intellectual Property (IP) interests must also be disclosed in all related publications, presentations and press releases. Questions about this can be directed to the Conflicts Management Office by telephone at (646)962-8200 or by email at conflicts@med.cornell.edu.