

Responsibility Reminder

2010

REQUIRED REPORTING: CONFLICTS OF INTEREST

Compass IRB's reporting requirements for Conflicts of Interest are more strict than the FDA Regulations. This notice should help you in identifying whether or not the PI and/or their research staff have a conflict of interest according to Compass IRB's reporting requirements.

Our goal is to identify and manage financial conflict of interest related to research and ensure it does not impact the integrity of the clinical research reviewed by Compass IRB. Financial conflict of interest related to research most often presents itself in three ways:

- ownership interest or stock options in the product, sponsor, or service being tested or any competitor product, sponsor or service
- compensation related to the research
- proprietary interest such as a patent, trademark, copyright or licensing agreement.

When evaluating if any of these conflicts of interest are present, please remember to include immediate family members (spouse and children) in the evaluation. If you suspect a conflict of interest due to an ownership interest or stock option, ask yourself the following questions:

1. Does the total dollar amount for my immediate family as a whole exceed \$10,000?
2. Is it publicly traded on a stock exchange?
3. Have I made an arrangement where my value of ownership will be affected by the outcome of the research?
4. Does my family as a whole hold more than a 5% interest in any sponsor, product, service or competitor related to the research?

If you suspect a conflict of interest arising from compensation related to the research, ask yourself the following questions:

1. Did the compensation that I and my family as a whole receive exceed \$10,000 in the past 12 months?
2. Have I made an arrangement where the amount of compensation is affected by the outcome of the research?

If at any point during your conduct of a study you have a yes answer to any of these questions, it indicates a potential for a conflict of interest. Please provide a written explanation to the Board of how you plan to prevent the conflict of interest from interfering in study design, conduct and reporting of results. Please specifically address how you plan to ensure that your conflict of interest will not interfere with your protection of the participants.

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For your reference

Additional information on Financial Disclosure by Clinical Investigators can be located on the FDA website at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=54>

If you have additional questions, please visit our FAQ section at www.compassirb.com or feel free to contact us directly.