

Ethics Grand Rounds '08-'09

All Wednesdays at noon in Lipsett

- October 1st, 2008
- December 3rd, 2008
- February 4th, 2009
- April 1, 2009

Financial Conflicts of Interest in
Clinical Research:
When are they problematic?
How should they be managed?

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The Consortium

- The Blood and Marrow Transplant Clinical Trials Network sponsors clinical trials that are developed and conducted by non-NIH institutions (clinical sites).
- The Data Coordinating Center manages the operations of Network studies.

The Study

- Investigators of the Network designed a randomized Phase III study, the Wonder Study, to be conducted at 35 clinical sites around the country.
- Primary objective: determine whether Wonder Drug improves overall survival for patients receiving a stem cell transplant for the treatment of their hematological malignancy.

The Conflict

- The Data Coordinating Center for the Network trains staff and collects and reviews study documents at each of the clinical sites.
- Review of the materials from one of the sites revealed that this institution and one of the co-investigators, Dr. No, were partial owners of patents related to Wonder Drug.

The Consent Form

- The informed consent document at the site included a section titled “Who could benefit financially from the study?”
- This section explained that the institution and Dr. No were partial owners of patents related to the drug being studied.

The NIH Policy

- NIH policy states that extramural institutions participating in NIH funded studies must have policies for disclosing and managing conflicts of interest.
- The NIH policy does not specify how conflicts of interest should be managed or disclosed.

The Concern

- Dr. No was not involved in designing the study, would not be performing transplants for patients, and would not be involved in data analysis.
- However, Dr. No did plan to refer patients to the BMT clinic for enrollment on the study and might obtain prospective subjects' informed consent.

The Consultation

- The NHBLI project officer called a bioethics consultation to discuss the case.

Questions I

- Is it appropriate for a patent holder of the Wonder Drug to be a co-investigator on this study?
- If so, is disclosure in the consent form sufficient for managing this conflict?

Questions II

- Is it appropriate for a co-investigator who partially owns patents to refer her patients for enrollment on the trial?
- Is it appropriate for a co-investigator who partially owns patents to obtain informed consent for the trial?