



Case 2: Incentives and Coercion for Researchers

A biotechnology company approaches a researcher with a proposal for a Phase II drug study. The drug in question has been found to reverse obesity in animals (mice and rats) and has proved safe in humans at comparable serum levels in two small Phase I studies. The company now seeks larger populations for efficacy studies and has approached the researcher because of his previous work on risk factors for obesity among a primary care population. The biotechnology company offers 20% salary support and the assistance of a research manager. To maintain this support, the researcher will need to recruit 20 subjects per month for the first year of the study, randomize them to treatment/non-treatment and then follow them monthly for 24 months.

- Is this an appropriate arrangement for this researcher?
- Is there a conflict of interest? Why or why not?

Two months into the recruitment phase, the company notifies the researcher that it would like to speed up the study because of information about a competitor drug. It requests recruitment of 40 subjects per month, and will increase the researchers' support to 50% FTE for the duration of the recruitment process. The researcher has been recruiting subjects through a general notice to patients in a primary care plan; he thinks he can increase recruitment to the new target level if he personally recruits patients from his own primary care practice.

- Is this an appropriate arrangement for this researcher?
- Is there a conflict of interest? Why or why not?



Case 2: Variations Incentives and Coercion for Researchers

The following variations in this case can be used to explore issues further.

- Researcher receives cash for each participant recruited.
- Researcher is a key investor in the device/pharmaceutical/genetic company for which the product/drug is being researched.
- Researcher needs preliminary data in order to have a competitive grant renewal.