RCR topic: Protection of Human Subjects

Title: Free Health Care

Case: Professor Smith and his research group are interested in investigating the natural progression of untreated peptic ulcer disease. However, investigators have already discovered that clinically significant peptic ulcers are the result of a bacterial infection. A standard treatment of antibiotics is given, leading to eradication of the bacteria. Symptoms improve as the ulcer begins to heal.

Professor Smith's research group designs a case-control study that will enroll a large number (n=200) of rural participants with peptic ulcer disease and appropriate unaffected controls (n=200). These individuals will be offered the promise of free health care for themselves and their immediate families throughout the duration of the study. However, these individuals will not be told of the therapeutic (curative) options (antibiotics) that are readily available.

- Professor Smith encourages his research team to actively recruit volunteers with the promise that this study will result in a better understanding of their disease and related symptoms. The recruitment methods emphasize that expensive health care services will be available to participants and their immediate family members.
- Professor Smith's study was halted by the participating health care agency after several of his patients developed gastrointestinal bleeding. In addition, six patients suffered perforated peptic ulcers that lead to acute pancreatitis in one patient and death in another.

Discussion Questions:

1. Were any ethical principles from the Belmont Report were violated in the design and conduct of this trial? Explain.
2. What protections are in place at Michigan State University (and elsewhere) to protect human subjects of research, such as the persons with peptic ulcers who participated in this study?
    a. Is it likely that the Institutional Review Board (IRB) at MSU would have approved this study? Why or why not?
    b. Do investigators have any responsibilities for monitoring the health and safety of participants during the conduct of the research and after the research project has been completed?

3. Should Professor Smith or his/her research team take responsibility for manipulating patient participants?