Biomed Refresher 2 – Conflicts of Interest in Research Involving Human Subjects

Massachusetts Institute of Technology Affiliates - Data or Specimens Only Research

Quiz

Instructions: Please provide an answer for all questions. Each question is one point. Click on the Submit button to register your answers. After submitting your answers, the correct answer to each question and an explanation will be displayed. Navigational links to the next module will also be provided.

All quiz questions count towards your score. You should answer all questions.

Question 1

Quiz - Case Study

Dr. Jones works as a cardiologist at a Midwest University Medical Center and earns approximately $15,000 per year from Big Medicines Pharmaceuticals giving talks to other doctors about one of the company's marketed drugs that is used to treat heart infections. Dr. Jones has a SFI with Big Medicines Pharmaceuticals because he receives non-salary compensation of over $5,000 from the company. Big Medicines has approached Dr. Jones about his organization participating as a site in a clinical trial. Dr. Jones would be the local principal investigator. The research is a large multi-site, randomized, double-blind, placebo-controlled trial to examine the efficacy of an investigational drug to prevent heart attacks with 3,000 subjects total. It is expected that three to four subjects would be enrolled at Dr. Jones's site. Who determines if Dr. Jones has a FCOI with this proposed research?

- ○ Institutional Review Board (IRB)
- ● **Dr. Jones' organization**
- ○ Big Medicines Pharmaceuticals
- ○ Dr. Jones

Question 2

Quiz - Case Study

Dr. Jones works as a cardiologist at a Midwest University Medical Center and earns approximately $15,000 per year from Big Medicines Pharmaceuticals giving talks to other doctors about one of the company's marketed drugs that is used to treat heart infections. Dr. Jones has a SFI with Big Medicines Pharmaceuticals because he receives non-salary compensation of over $5,000 from the company. Big Medicines has approached Dr. Jones about his organization participating as a site in a clinical trial. Dr. Jones would be the local principal investigator. The research is a large multi-site, randomized, double-blind, placebo-controlled trial to examine the efficacy of an investigational drug to prevent heart attacks with 3,000 subjects total. It is expected that three to four subjects would be enrolled at Dr. Jones's site. In the following scenario, some existing safeguards against bias are described.

- By the time Dr. Jones is approached by Big Medicine, the drug company has already designed the research plan and the study is ongoing.
- The research design itself is randomized and double-blinded. This is one way to guard against manipulation of the study results.
- Restricting recruitment and thus the contribution of three or four sets of subject data to the study, out of the 3,000 needed to meet research aims, would also guard against significant impact solely by Dr. Jones.
- Finally, assuming there are no "subjective measurements" that Dr. Jones would be expected to obtain that would introduce bias ("How does the subject seem to be feeling at this visit?"); his role would be to collect the data and send it to the company for analysis. It is unlikely that the reporting of the results would be impacted by his FCOI.

How could the organization further add protection against bias in this scenario?

○ Remove Dr. Jones from the contract negotiation process with the company

●

Disclose Dr. Jones' remuneration from the sponsor in the consent document and the consent process

- Refuse to allow the organization's participation as a site in the research study
- Require Dr. Jones to return the $5,000 compensation to the company

Question 3

The Public Health Service (PHS), U.S. Food and Drug Administration (FDA), and National Science Foundation (NSF) regulations address:

- **Individual financial COIs**
- Individual non-financial COIs
- Institutional non-financial COIs
- Institutional financial COIs

Question 4

Quiz - Case Study

When does an investigator's significant financial interest (SFI) become a possible financial conflict of interest (FCOI)?

- When the SFI is not disclosed

- Up to 12 months (one year) after the investigator receives payment
- **When the SFI could directly and significantly affect the design, conduct or reporting of the funded research**
- Only if the SFI is over 15 percent of the investigator's salary from their organization

Question 5

The PHS regulations require:

- Each "investigator" named on a proposal to disclose "significant financial interests" to the Institutional Review Board (IRB).
- Each "investigator" named on a proposal to disclose "significant financial interests" to the FDA for drug studies.
- Each "investigator" named on a proposal to disclose "significant financial interests" to the federal funding agency.
- **Each "investigator" named on a proposal to disclose "significant financial interests" to a designated official at the applicant organization.**

Submit

9:00 a.m. – 7:00 p.m. ET

Monday – Friday

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