

Research Ethics and Industry Relations

Radiology research often entails development of new imaging approaches to disease. Many of these new modalities necessitate that investigators and Institutions partner with industry in order to secure FDA approval and usually advance the delivery of patient care. In this session, we will discuss topics related to research, industry relations, and conflicts of interest.

CASES:

Scenario 1: Dr. B is approached by Company X which is developing a promising molecular imaging technique for breast cancer. The company provides Dr. B with the equipment and all funds to support the prospective evaluation of the new imaging technique. Dr. B. generates a lot of data, but is the only site using this piece of equipment.

1. When presenting at a national meeting, what information, if any, should Dr. B disclose to the audience? Would it matter if Dr. B is presenting specific research data or a general educational presentation on the imaging tool?
2. Dr. B. tells you that she did not allow the company to see any of her data until after it was published. Does this make any difference? Can Company X limit publication of “undesirable” results since they sponsored the research? Can Company X ever postpone publication of her data, and if so, for how long?
3. Later, you discover that Dr. B sits on the Board of Directors for Company X and as such, has stock options in the company. Dr. B. did not disclose this relationship during her presentation at RSNA. Should this have been disclosed and what impact might this have had on her research results? Should someone with this type of financial relationship be allowed to participate in this type of research? Do you have any legal obligation to report her to the leadership of RSNA?
4. What if Dr. B did not have this relationship but her spouse owns stock in the company? Would this have any relevance?

Scenario 2: Your role in Institution Z is both clinical and research oriented, and you happen to have some input into purchasing decisions for both aspects. Institution Z has decided that it wants to purchase 2 new CT scanners, one for clinical use and the other for research.

1. Prior to any purchase, the company wants to fly you to Florida to visit one of their luminary sites so that you can get a better sense of the power of their technology. Is this acceptable, and if so, what is considered appropriate and what is not?

2. While at RSNA, you stop by their booth. Can you pick up their “free” pen with their logo? Can you go out to breakfast with the sales rep?
3. What steps should Institution Z take in order to not have any conflicts of interest? Do there need to be separate agreements for the clinical and research purchases? Can you be involved in both of these agreements? If the Company decides to provide you with the research scanner, do there need to be any “deliverables” on your end? What should this agreement contain?
4. The Company wants to give you \$1000.00 for education of trainees, technologists, and students regarding their new device. Can you accept this, and if so, does the Company have an obligation to report this to the federal government? They also offer to pay salary for a research fellow? Is this acceptable?
5. A study for a clinical patient is performed on a CT scanner which was installed for research purposes because the clinical scanner went down. Is it acceptable for the radiology practice and Institution to bill insurance for the technical component of the study?

Scenario 3: You have been asked to put together a postgraduate CME course on MR imaging. You have longstanding relationships with multiple imaging vendors.

1. Can you approach each of the vendors for a grant to support your course? If so, what specifically can you ask for and what will the vendor be given in return for their financial support? For example,
 - a. Can the company have say in who speaks at the course?
 - b. Can the company have say in what topics are covered at the course?
 - c. Can the company exhibit at the course?
 - d. Should members of the planning committee have any restrictions? For example, would it be okay for one of the members to be in the speaker’s bureau for one of the vendors supporting the meeting? Can vendor’s have representatives on the committee?