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PI Responsibilities and Conflict of Interest

Faculty Presenter
Stacey Berg, MD, Texas Children's Cancer Center, Texas Children's Hospital, Baylor College of Medicine, Houston TX, USA

Scholar Summary

*Authored by **Katelyn M. Atkins, MD, PhD**, Harvard Radiation Oncology Program, Boston, MA, USA*

There are multiple types of conflict of interest; the most notable are those regarding role and finances. To better understand these conflicts, we must first understand the roles and methods of those involved in clinical and translational research. The role of the principal investigator is to write a protocol, obtain approvals, monitor studies (including compliance, adverse events, and amendments), analyze results, and report results. General methods in clinical trials include the eligible subject population, treatment assignment, and detailed rules for conduct, fixed definitions of toxicity and response, and correlative studies. The principal investigator has the responsibility to find out the answer to the given question while maintaining safety of the subjects and with respect for the subjects' welfare. Conversely, it is the responsibility of the physician to take the best care of the patient using logical decision-making and with respect for the information to be gained. Thus, the paradigm of the physician-researcher is that the principle investigator advocates for the study and the physician advocates for the patient. Ideally, all primary interests would align and there would be no conflict or parting of these responsibilities; however, the physician-researcher may face scenarios in which decisions will differentially affect the study versus the patient. The importance of this issue of professional integrity in clinical/translational research was described and defined by Miller et al. (JAMA 1998): "the roles of clinician and scientist must be integrated to manage conscientiously the ethical complexity, ambiguity, and tensions between the potentially competing loyalties of science and care of volunteer patients." Furthermore, the NIH Guidance on Informed Consent for Gene Transfer Research reports the following disclosure: "Your physician is a researcher in this study. As a researcher in this study, he/she is interested not only in your health and well-being, but also in the results of this study. It is possible that sometimes these two goals may conflict with one another". The second category of conflicts of interest are those financially-related. Importantly, these can be both perceived conflicts and real conflicts. According to clinicaltrials.gov, there are nearly 15,000 clinical trials recruiting patients in the U.S., of which approximately 2,600 are NIH-funded while ~5,000 are industry-sponsored. Investigator-mediated financial conflict concerns include conscious or unconscious bias, coercion of human subjects, potential to affect results, and loss of public trust. The NIH defines significant financial conflict as equity interest less than or equal to $5,000 or other payments less than or equal to $5,000 per year. The FDA conflict of interest rules state that an interest must be disclosed if the value of compensation could be affected by the study outcome, if there is proprietary interest (e.g., patent), equity greater than $50,000, or significant other payments greater than $25,000. Management strategies include public disclosure, monitoring by independent reviewers, modification of the research plan, disqualification from participation, and/or divestiture/severance of relationships. In summary, it is important to identify temptation and potential conflicts of interest and to know regulations and local policies. When in doubt—ask (the earlier the better).