



Online Ethics Center
FOR ENGINEERING AND SCIENCE

The Dual Role of the Clinical Investigator

Year

2000

Description

A scenario meant to stimulate discussion about the ethical issues that arise when a clinician is also the principle investigator.

Body

You are a psychiatrist and your patient, Ms. Kay, has been enrolled in a research study that you are conducting involving a new antipsychotic drug. She enrolled in hopes of finding a medication that did not have the side-effects of her previous medication. Ms. Kay is now six days into the study following a wash-out period of her previous psychotropic. She is now becoming quite agitated and you fear that she may decompensate.

You find that despite displaying some symptoms of her psychosis, she speaks coherently about the issues of medication selection. As her clinician you hoped that you could find her a medication that would not have the side effects that she finds so burdensome with her previous medication. You try to talk to Ms. Kay about your concern that the new medication may not have had time to take full effect and may prove a better choice for her, if given that time, but she does not seem to understand that point and only insists that she now feels terrible, much worse than she used to feel on her previous antipsychotic and "wants out."

You are also concerned that the new drug may be proving ineffective or having worse side-effects for this patient and if so, and you insist, it will greatly damage her trust of you. As the lead investigator for this study, you hate to see any patient drop out before this new drug has had time to take full effect. The drug promises to be an important clinical advance in clinical treatment, especially if you can better identify the profile of patients with which it works best.

- How do you manage your dual responsibilities as clinician and as investigator in this case?
- Should the patient's treatment be based on what is best for them or what is best for the research?
- Should a long-term clinician be allowed to be the investigator with their own patient? Why or why not?
- Are there circumstances in which the clinician/investigator would not produce conflict?

The NIH has regulations that prohibit the clinician from also being the principle investigator.

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Notes

Caroline Whitbeck introduced methods and modules for discussing numerous issues in responsible conduct of research at a Sigma Xi Forum in 2000. Partial funding for the development of this material came from an NIH grant.

You can find the entire sequence on the OEC at [Scenarios for Ethics Modules in the Responsible Conduct of Research](#). Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional society's code that is referred to in an item. If you have suggestions for updates, please contact the OEC.

Contributor(s)

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Case Study / Scenario

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Topics

Conflict of Interest

Human Subjects Research

Informed Consent

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Life and Environmental Sciences

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