Online Ethics Center
FOR ENGINEERING AND SCIENCE

The Nurse Therapist's Problem

Author(s)

Barb Daley

Year

2000

Description

A scenario meant to stimulate discussion about the ethical issues that arise when a participant's spouse wishes to remove the participant from the research study.

Body

You are a co-investigator for a study of the effectiveness of a new drug-plus-intensive psychotherapy regimen for refractory depression. The physician PI manages the drug aspect and you, as a nurse therapist, oversee the group and individual therapy provided during the hospitalization phase.

After several months of the project, you have enrolled 6 subjects. So far the study is proceeding well, but one of the staff nurses approaches you with concerns about Mr. Smith, a current subject on protocol. The nurse reports that Mr. Smith seems worse now than when he was admitted and that Mrs. Smith, his wife, commented to her that she was "at her wit's end" with her husband's behavior at home and was willing to have him participate in this trial because nothing else worked and she couldn't stand his behavior any longer.

Questions:

1. In the presence of a mental disease such as severe depression, how should

capacity to give informed consent be assessed?
2. Should the stringency of the informed consent assessment vary according to the risk of the trial?
3. Who should make the informed consent assessment ` the investigator or an uninvolved clinician?
4. In most research, we want to preserve/protect subjects' rights to withdraw at any time. For protocols such as this, where capacity to make decisions may fluctuate or even grow less as the study progresses, how can we assure that this right is preserved?
5. To what extent would the staff nurse in this case retain responsibility for intervening in this situation?

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 Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional society's code that is referred to in an item.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)

Caroline Whitbeck

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Resource Type

Case Study / Scenario

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Scenarios for Ethics Modules in the Responsible Conduct of Research

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