



When Should We Accept Consent?

Author(s)

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Description

A scenario meant to stimulate discussion about the ethical issues that arise when a researcher is unsure if a study participant is too incapacitated to actually give informed consent.

Body

You are the principal investigator of a phase II study of refractory depression funded by a large pharmaceutical company. Mr. Smith has been unsuccessfully treated by a psychiatrist in the community. This psychiatrist has referred Mr. Smith to you at the academic medical center where you work and are conducting the study.

The study involves hospitalization, a washout period of four weeks, and assignment to a placebo or treatment arm. Mr. Smith agrees to the study saying, "I don't care anymore. I don't care if I get the medicine or the placebo. What difference does it make?"

- Do you think Mr. Smith should be allowed to participate in the study? Why or why not?
- What other information would you want to help you make this decision?

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 Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional society's code that is referred to in an item.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

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