

The Hazardous Consent Forms

Modified from the [American Anthropological Association](#).

As part of a long-range investigation of the social and physiological effects of heroin, Dr Researcher Knowitall, a psychiatrist affiliated with a medical school, set up a study of pregnant women and their infants. The study design involved statistical comparisons of the course of pregnancy, birth, and infant development in 30 addicts and 30 nonaddicts; data were to be gathered from hospitals and public health clinics in three inner city neighborhoods.

The medical school Institutional Review Board (IRB) approved the study, with the requirement that the women sign detailed consent forms indicating that they understood the purpose of the study and agreed to take part. It was agreed that the clinic nurses would read the consent forms to the women and ask them to sign.

Two months into the study, Dr Knowitall has instructed the nurses to obtain informal undocumented consent because, he argues, the research posed no possibility of physical harm. He insisted that the only risk to those studied came from the signed consent forms: these would document that addicted women were engaging in illegal behavior.

He instructed his clinic's nurses to read the following script for the patients, then let them sign the paper.

"This is a study that aims at studying the course of your pregnancy and how your infant develops, while you are on drugs. To protect you from any legal action against you, you are requested to sign the paper handed to you by the attending nurse"

Discuss the case among your group and submit your assignment of no less than 300 words and no more than 500 words guided by the following questions and using relevant references, as needed.

1. What are the ethical issues that are raised by studies similar to the one in the case? (Mention at least 3 issues.)
2. Do you agree with the approach used by the researcher? Justify your answer.
3. Do you think the 'consent' obtained by the nurses is ethically adequate? If not, what are your suggestions to make it an informed consent?
4. Using the details provided in the scenario and the relevant reference, write down the informed consent that you would submit along with your proposal to the IRB?