The Thalidomide Study

It was found that those taking the drug were not informed that they were being given an experimental substance, nor had they been asked to give their consent.

These events lead to the passage of the Drug Amendments of 1962 to the Food, Drug and Cosmetic Act (Kefauver Harris Amendment).

This was the first US statutes that required subjects be informed of a drug's experimental nature and to consent before starting the research study.