

# Consent forms for research: Have they improved in 25 years?

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The consent forms that people sign before participating in research are widely considered difficult to understand and sometimes inaccurate. The lack of clarity was implicated in a high-profile legal settlement in April between Arizona State University and a Native American tribe, which claimed that blood samples that its members provided for genetic research were used for purposes not stated in the consent form. Efforts have been made to improve the forms, but how effective are they?

A study in *IRB: [Ethics](#) & Human Research* examined the changes over a quarter century in the accuracy and length of research consent forms used for 215 studies by one department in a major academic center. The review, by researchers at the University of Pennsylvania Law School and Columbia University, revealed two trends with potentially opposite effects on comprehensibility.

One trend is that the information in the consent forms became more accurate over time, as measured by discrepancies in the description of risks in the consent forms compared with the descriptions in the study protocols themselves. In the early consent forms evaluated in the study, which dated back to 1978, more than 54 percent had such discrepancies, mainly with the consent forms understating the actual risk. But by 2002, there were no discrepancies.

On the other hand, the consent forms became much longer, growing from an average of a paragraph or two to more than four and a half pages. The increased length could interfere with comprehension: the

authors cite data showing that consent forms that are longer than four pages "are unlikely to be read, perhaps in part because of the time involved."

"Our findings highlight the inherent paradox in attempting to use consent forms to convey ever-more-complete information to potential research subjects," the authors write. "Greater information is associated with increased length of consent forms, and studies have shown an inverse relationship between length and individuals' comprehension of the information provided." They conclude that innovative approaches are needed - possibly including supplementary booklets or computer-based disclosures - to achieve genuinely informed consent.

Provided by The Hastings Center

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