

Clinical trials: Comprehension unaffected by simplified consent forms or payment

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Although informed consent is an ethical cornerstone in research with humans, some studies suggests that volunteers often do not understand key aspects of the research in which they participate. Recent efforts have been made to improve informed consent by simplifying the consent forms.

A new study refutes two common assumptions about consent forms: that the length and complexity of forms affect comprehension and that people who are paid to enroll in research may be "blinded by money" and thus ignore key details of the study.

In a randomized controlled trial of a standard versus concise consent form for a low-risk phase I bioequivalence study of a marketed drug, the authors found that overall comprehension was comparable - and high - with both forms. Furthermore, the shorter form appeared to have no adverse effect on the quality of informed consent. Another intriguing finding was that comprehension was slightly higher among the paid volunteers than those who were unpaid. And, the study revealed that the overall comprehension scores of socioeconomically disadvantaged participants was good, negating the common claim that this population of research participants requires special protections.

The report of the study appeared in *IRB: Ethics & Human Research*, published by The Hastings Center. The authors include two Hastings Center Fellows and bioethics leaders in the federal government: Ezekiel Emanuel, head of the Department of Bioethics at the National Institutes

of Health Clinical Center and special advisor for health policy to the director of the White House Office of Management and Budget; and Christine Grady, acting chief of the Department of Bioethics at the NIH Clinical Center and a member of the Presidential Commission for the Study of Bioethical Issues. Other authors are Leanne Stunkel and Ninet Sinaii, of the NIH Department of Bioethics; and Meredith Benson, Louise McLellan, and Gabriella Bedarida, of Pfizer.

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Provided by The Hastings Center

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