

Attitudes toward Risk and Informed Consent for Research on Medical Practices

A Cross-sectional Survey

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Background: The U.S. Office for Human Research Protections has proposed that end points of randomized trials comparing the effectiveness of standard medical practices are risks of research that would require disclosure and written informed consent, but data are lacking on the views of potential participants.

Objective: To assess attitudes of U.S. adults about risks and preferences for notification and consent for research on medical practices.

Design: Cross-sectional survey conducted in August 2014.

Setting: Web-based questionnaire.

Patients: 1095 U.S. adults sampled from an online panel ($n = 805$) and an online convenience river sample ($n = 290$).

Measurements: Attitudes toward risk, informed consent, and willingness to participate in 3 research scenarios involving medical record review and randomization of usual medical practices.

Results: 97% of respondents agreed that health systems should evaluate standard treatments. Most wanted to be asked for permission to participate in each of 3 scenarios (range, 75.2% to 80.4%), even if it involved only medical record review, but most would accept no written (oral) permission or general notification if obtaining written permission would make the research too difficult to conduct (range, 70.2% to 82.7%). Most perceived additional risk from each scenario (range, 64.0% to 81.6%).

Limitation: Use of hypothetical scenarios and a nonprobability sample that was not fully representative of the U.S. population.

Conclusion: Most respondents preferred to be asked for permission to participate in observational and randomized research evaluating usual medical practices, but they are willing to accept less elaborate approaches than written consent if research would otherwise be impracticable. These attitudes are not aligned with proposed regulatory guidance.

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