

Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences

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Body

Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences examines how to update human subjects protections regulations so that they effectively respond to current research contexts and methods. With a specific focus on social and behavioral sciences, this consensus report aims to address the dramatic alterations in the research landscapes that institutional review boards (IRBs) have come to inhabit during the past 40 years. The report aims to balance respect for the individual persons whose consent to participate makes research possible and respect for the social benefits that productive research communities make possible.

The ethics of human subjects research has captured scientific and regulatory attention for half a century. To keep abreast of the universe of changes that factor into the ethical conduct of research today, the Department of Health and Human Services published an Advance Notice of Proposed Rulemaking (ANPRM) in July

2011. Recognizing that widespread technological and societal transformations have occurred in the contexts for and conduct of human research since the passage of the National Research Act of 1974, the ANPRM revisits the regulations mandated by the Act in a correspondingly comprehensive manner. Its proposals aim to modernize the Common Rule and to improve the efficiency of the work conducted under its auspices.

Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences identifies issues raised in the ANPRM that are critical and feasible for the federal government to address for the protection of participants and for the advancement of the social and behavioral sciences. For each identified issue, this report provides guidance for IRBs on techniques to address it, with specific examples and best practice models to illustrate how the techniques would be applied to different behavioral and social sciences research procedures.

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