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Preserving and Enhancing Responsible Conduct of Research Involving Children

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This brief summarizes a longer Social Policy Report

Preserving and Enhancing the Responsible Conduct of Research Involving Children and Youth: A Response to Proposed Changes in Federal Regulations

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Why Does This Matter?

For the first time in 20 years, the U.S. Department of Health and Human Services is considering changes to federal regulations governing protections for people who participate in research. The proposed changes to the policy for the Protection of Human Subjects, known as the Common Rule, represent a watershed moment. By providing scientists and institutional review boards (IRBs)—independent ethics committees that review, approve, and monitor studies involving human subjects— updated guidance, a revised Common Rule will provide a framework for protecting human subjects for decades to come.

Common Rule changes will affect institutional review board evaluations of research involving children because the rule applies to research with all ages and additional protections for children are linked to its provisions.

Policy Implications

To preserve and enhance the responsible conduct of research involving children, policymakers should support changes to the Common Rule that:

- Remove inconsistencies and overestimation of probable harms preventing children from participating in the benefits of research while also instituting age-appropriate protections of children's rights as research participants:
    - Help children benefit from the results of research by making clear to institutional review boards (IRBs) that they do not need to add extra protections as long as they meet the special protections in the Common Rule for research involving vulnerable participants, including children.
- Clarify how children fit into research involving "minimal risk" and research that qualifies for the proposed category of "excused/registered" research:
    - Take into account the age of research participants in defining minimal risk, and include examinations and tests in educational settings as part of routine tests.
    - Update and expand the list of research that qualifies for expedited review (not requiring review by a full IRB) by providing examples of research procedures that involve minimal risk for research participants of different ages, including children.

    - Provide an age-indexed listing of examples of research that qualify under the new category of "excused/registered" research, including examples involving children.
- Address special issues required to ensure appropriate security procedures for different age groups in the newly proposed requirements for protecting confidentiality of data ("information risk"):
    - Address issues related to confidentiality of child data, especially in research involving adolescents, that would result from using the data security guidelines in the Health Information Portability and Accountability Act (HIPAA).
    - For the newly proposed requirements for protecting the confidentiality of data ("informational risk"), use examples of security procedures for different age groups.
    - Appoint a panel to provide periodic updates of the guidelines on informational risk in light of changing technologies that includes individuals with expertise in child- related research.
    - Clarify the circumstances under which researchers should disclose the possibility of serious risk to a child or adolescent revealed during data collection, balancing the need for confidentiality and the need for protection.
- Acknowledge the need for flexible informed-consent procedures that take into account children's and adolescents' developing consent capacities and provide age-appropriate guidance for waiver of guardian permission:
    - Encourage IRBs to take into account the research on children's developing capacity to provide consent. Include educational procedures to help children understand their research rights as part of the consent process. When this is not possible, appoint an independent participant advocate to ensure children's informed and voluntary participation.
    - Oral assent may be more respectful and less coercive for young children who do not yet read well and may defer to authority. When oral assent is determined to be appropriate, it is important to provide a written summary of the details to them and/or their guardians.
    - When adolescents are considered "mature" or "emancipated" according to state law, they should be accorded adult status when asked to consent to participate in research. Under these circumstances, guardian permission or waiver of guardian permission should not be required.
    - Provide for waivers of guardian permission for minimal risk pediatric and developmental research, not for investigator convenience or when parents are reluctant for legitimate reasons, but when sufficient protections are in place for participants and there is a clear reason that the scientific validity and value of the study would be compromised if guardian permission is required.
- Take into account the continuously evolving changes in biomedical technologies and software when considering whether de-identified data in longitudinal datasets starting in childhood can remain anonymous:

    - In most instances, secondary analysis of de-identified longitudinal data will not involve a change in risk about the confidentiality of the information provided.
    - However because of the possibility of change in biomedical technologies and software, consent forms for biospecimen and socially sensitive data should indicate that investigators who will have access to the data in the future will be bound by current best practices for confidentiality.
- Develop appropriate procedures for protecting privacy of information when new data are collected and linked with archived data from children and adolescents:
    - Sometimes it will be valuable to add new data to archived data collected from children and adolescents. In these instances, re- consent must occur to protect the privacy rights of children and adolescents.
    - This re-consent should focus on the linking of the datasets. There should be a signed letter of agreement between institutions involved in the archived and new data collection that security and confidentiality rules will be followed.

What the Research Says

- IRBs can draw on a growing body of research establishing age differences in children's understanding of the informed-consent process. IRBs can also draw on research to inform steps that can be taken to enhance children's and adolescents' understanding of research procedures and of their rights to refuse or withdraw from participation.
- IRBs and investigators should draw on developmental science to appropriately minimize research risks and maximize research benefits for child participants. While it is critical to protect children from research harms, overemphasizing risk has sometimes resulted in children becoming "therapeutic orphans" who are unable to benefit from scientific advances.
- Some IRBs have assumed that asking adolescents about sexuality or drug use in surveys or interviews may cause harm or encourage them to engage in such behaviors, when this conclusion is not supported by research.

Facts at a Glance

- The Common Rule refers to the U.S. regulations governing research with human subjects. It was last revised in 1991.
- It is called the Common Rule because it has been signed on to by many federal agencies and departments, including the Department of Health and Human Services, the Federal Drug Administration, the Department of Education, and the National Science Foundation.

- A separate section of regulations (called Subpart D) provides additional guidance on research with children. Although this subpart is not being considered for revision, investigators conducting, and IRBs reviewing, child-relevant research must comply with all requirements in the sections being revised, not only Subpart D. So revisions to the Common Rule have important implications for children.
- Concern has been expressed that children do not always benefit to the extent possible from research that could contribute to their health and well being. Variation in IRBs' definitions and practices has sometimes contributed to this problem by involving overzealous protection of children.

This brief summarizes a longer *Social Policy Report*, "Preserving and Enhancing the Responsible Conduct of Research Involving Children and Youth: A Response to Proposed Changes in Federal Regulations," the report of the SRCD Task Force on Proposed Changes to the Common Rule, by **Celia B. Fisher**, Director, Center for Ethics Education, Marie Ward Doty Endowed University Chair and Professor of Psychology, Fordham University; **Donald J. Brunnquell**, Director, Office of Ethics, Children's Health Care; **Diane L. Hughes**, Professor, Steinhardt School of Culture, Development, and Education Co-Director, Center for Research on Culture, Development, and Education, New York University; **Lynn S. Liben**, Distinguished Professor, Department of Psychology, Health and Human Development, and College of Education, The Pennsylvania State University; **Valerie Maholmes**, Acting Chief, Pediatric Trauma and Critical Illness Branch, Director, Child and Family Processes/Child Maltreatment & Violence Program, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health; **Stuart Plattner**, Program Officer (retired), National Science Foundation; **Stephen T. Russell**, Professor, Fitch Nesbitt Endowed Chair and Director, Frances McClelland Institute, University of Arizona; and **Elizabeth J. Susman**, Jean Phillips Shibley Professor of Biobehavioral Health, The Pennsylvania State University.

The role of federal staff on this report is advisory. The opinions and assertions presented in this report do not purport to represent those of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the National Institutes of Health, the U.S. Department of Health and Human Services.