Ethics and Responsible Conduct

A summary of the scientific literature on ethics and responsible conduct in research with children.



How This Impacts Children's Development

In 2013, for the first time in twenty years, the United States (U.S.) Department of Health and Human Services (HHS) considered changes to the policy for the “Protection of Human Subjects”, known as the “Common

Rule". Common Rule changes 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.

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Talking Points from the SRCD Brief

- The Common Rule establishes the core procedures for human research subject protections, which include informed consent and review by an Institutional Review Board (IRB).
    - HHS regulations include Subparts B, C, and D, which provide additional protections for certain vulnerable populations including pregnant women, incarcerated persons, and children.
- A separate section of regulations (Subpart D) provides additional guidance on research with children, and 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.
- It is called "the Common Rule" because it has been signed on to by many federal agencies and departments, including the HHS, the Federal Drug Administration (FDA), the Department of Education (ED), and the National Science Foundation (NSF).
- 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 due to variation in IRB's definitions and practices.

Policy Considerations in the Brief

1. 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.
2. Clarify how children fit into research involving "minimal risk" and research that qualifies for the proposed category of "excused/registered" research.
3. Address special security needs for different age groups in new data confidentiality requirements, considering evolving biomedical technologies and software. Ensure procedures protect privacy when new data are collected and linked with existing data sets from children and adolescents, especially regarding de-identified data in longitudinal studies.

4. Acknowledge the need for flexible informed-consent procedures that consider children's and adolescents' developing consent capacities and provide age-appropriate guidance for waiver of guardian permission.
5. Institutional Review Boards (IRBs) and investigators should draw on developmental science to inform students of steps that can be taken to enhance children's and adolescents' understanding of research procedures, their rights to refuse or withdraw from participation, and to appropriately minimize research risks and maximize research benefits for child participants.

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