Informed Consent Involving Children and Vulnerable Populations in Behavioral and Social Sciences Research

Celia B. Fisher, Ph.D.

Director, Center for Ethics Education

Fisher@fordham.edu

National Academies of Sciences Revisions to the Common Rule in Relation to the Behavioral and Social Sciences: A Workshop
March 21, 2013 Washington DC

Relevance of Common Rule to Informed Consent for Research Involving Children

- The Common Rule §46.116 applies to research involving all ages
- Additional protections for children in Subpart D §46.408 are linked to Common Rule provisions.

Length, Content and Documentation of Consent

IC Length & Format

- Proposal to shorten IC length is timely
- However, proposal for standardized forms may lead to confusion and misinformation.
- Need flexibility in format and language to ensure appropriate age, language, educational, and cultural understanding

Oral Consent & Documentation

IC is a process (not a document) to ensure participation decisions are informed and voluntary

- Oral consent may be more respectful for some cultural populations
- Oral assent is less coercive for young children based on their more limited reading skills, deference to authority and lack of experience signing forms
- Written consent can jeopardize participant safety (war zones, partner violence, stigmatized or illegal behaviors)
- Population sensitive guidelines for documenting oral consent are needed

Flexibility and Accuracy

- Need flexibility to waive irrelevant IC components as permitted under §46.116c
- Eliminate requiring unsubstantiated statements such as "stress" or "discomfort" when such risks are improbable or non-existent for minimal risk SBR.
- Recommended default statement for minimal risk research:

"*This research presents minimal risks no greater than those of daily life or routine medical, dental, psychological or educational examinations or tests*."

Distinguishing Research Risk from Institutional Liability

- Institutional liability statements refer to risks outside of the research procedures (e.g., falling while walking down a hall) and thus *do not* belong in the informed consent
- Liability waivers violate §46.116 "[NO IC] "may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."
- Inclusion of liability language is unfair to children and other vulnerable populations without knowledge or access to legal rights

Separate Institutional Liability from IC Document

- Institutional liability statements should be removed from informed consent documents for research participation
- Institutions that wish to notify prospective participants or their guardians about limits to the institution's legal liability do so in a separate document.

Waiver of Guardian Permission

Waiver of Guardian Permission: Emancipated & Mature Minors

- Most state emancipated/mature minor laws do not include language specific to research participation
- IRBs continue to needlessly require guardian permission for minors' involvement in research related to treatment and procedures for which they have obtained legal adult status, *e.g. adolescent sexual health behaviors, treatments and preventive interventions.*
- This deprives adolescents of their full rights and protections as "adult" participants under the Common Rule and fair access to potential benefits of research participation.

Waiver of Guardian Permission

Procedures to ensure "waiver or alteration will not adversely affect the rights and welfare of the subjects" [§46.116 (2]) should draw on the substantial body of developmental research to:

- Evaluate the age groups' understanding of their rights and research procedures
- Include educational procedures for enhancing consent
- Ensure language is age-appropriate
- Assess (when appropriate) individual minors' consent readiness
- Appoint a participant consent advocate

§46.116 (3): [Components of IC may be waived if] the research could not practicably be carried out without the waiver or alteration

GUARDIAN PERMISSION SHOULD NEVER BE WAIVED:

- For investigator convenience or solely for reasons of cost or speed or other expedient measures if doing so weakens protection of subjects' rights and welfare.

- Parents' reluctance to permit their children to participate in research is not a legitimate reason to waive this protection and is antithetical to the principles of beneficence, respect and justice.

Informed Consent for Future Use of Biospecimens and Archived Socially Sensitive Data

When is Guardian Permission Sufficient for Future Data Use When Child Reaches Adulthood?

- Appropriate security protections are in place and updated as may be required by evolving information technologies as well as federal standards and…
- The level of harm associated with informational risk has not increased with changes in societal attitudes, health coverage or other policies, and…
- The original IC informs guardians (and minors when age appropriate) that their consent represents a default permission for continuation of use of data after the child has reached the age of majority

Expanding IC Commitment to De-Identified Data for Socially Sensitive Research

- Emerging technologies may make obsolete original de-identification data security protections to which guardians/minors or vulnerable adult populations originally consented.
- The initial IC should indicate that all investigators who will have access to data in the future will be bound by the best practices in data and confidentiality protections at the time of data collection and new protections as they emerge.
- Federal regulations should ensure future investigators honor this commitment
- This recommendation is consistent with proposals to establish regulatory procedures for continuous updating of data security procedures

IC for Linking Identifiable Archival Data to the Collection of New Data

- When the original investigator or a new investigator wishes to link archival identifiable data with collection of new data, re-consent must occur.
- Re-consent should be required for the new data collection and linking to the archival data set, *not* for the new investigator's initial access to participant contact information
- The original IC should indicate that investigators interested in linking new data collection to the archival data set will have access to the participants' contact information to request addition permission for use.
- When archival data was collected during childhood, once the participants reach adulthood, consent for the linking of new data to the archival set should be obtained from the original participants not their guardian.

Conclusion

- IC is seen by many as the primary means of protecting research participants' rights and welfare
- IC procedures should be age and population sensitive, based on the substantial empirical database on consent capacities, and include when appropriate consent enhancing procedures.
- Decisions regarding waiver of IC components should provide adequate participant protections against misunderstanding and exploitation *and* ensure children and vulnerable populations have equal access to the potential benefits of research.

Acknowledgements & References

- Fisher, C.B., Brunnquell, D.J., Hughes, D.L., Maholmes, V., Plattner, P. Russell, S.T., Liben, S., & Susman, E.J. (2013). Preserving and enhancing the responsible conduct of research involving children and youth: A response to proposed changes in federal regulations. *SRCD Social Policy Report, 27* (1), pp. 1, 3 – 15.

- Secretary's Advisory Committee for Human Research Protections (SACHRP). (2005, April 18–19; November 1). *Meeting presentations and reports.* Retrieved from http://www.hhs.gov/ohrp/sachrp/mtgings/mtg04-05/505 present.htm