

ETHICAL CONSIDERATIONS FOR RESEARCH WITH CHILDREN

Danielle DeNigris, Phil Kreniske, & Kasey Powers

Ethical Considerations for Research with Children

- 5 Moral Principles Applied to Research Ethics:

(Sales & Folkman, 2000)

- Respect for Persons & Their Autonomy
- Beneficence and Nonmaleficence
- Justice
- Trust
- Fidelity and Scientific Integrity

Why assent?

- Accepted that assent can be waived in children under the age of 7.
- However, when possible assent should be attained.
 - Risks and benefits of the research
 - Differences in medical vs. behavioral research
 - In medical procedures if a child does not want to consent, the child has the right to explain why and these concerns should be taken seriously. It is up to the parent and doctors to work together to know if a child has the ability and competence to give assent. (Levy, Larcher, & Kurz, 2002)

For the parents



- It should be stated in the consent form that child assent will be obtained.
- It should be clear that there is no penalty if the child does not want to do the study. Compensation will be given for their time either way.
- There should be a procedure in place if a child does not give assent. For example:
 - ▣ We will take a break and try again in a few minutes.
 - ▣ We will take a break for today and we can reschedule.
 - ▣ If you cannot reschedule we will compensate you for your time thus far.

Research with Young Children

What if they can't read?

Infants & Toddlers



- Pre-verbal children (0-2) give assent through cooperation rather than being specifically asked.
 - ▣ The parent or caregiver should be present throughout the research.
 - ▣ The researcher should make sure the parent is fully informed about each step of the research.
 - ▣ The researcher and parent should both be aware of the babies cues for willing participation.
 - ▣ The researcher or parent can suggest a break at any time.

Pre-schoolers

- Verbal but pre-literate children (3-7) are asked for verbal assent.
 - ▣ Explain in age appropriate terms what you would like their help with.
 - ▣ Tell them they can say no if there is anything they don't want to do and that it's ok to say no.
 - ▣ Ask them to repeat instructions. To make sure they understand.
 - ▣ Since the child cannot sign an assent form a statement can be added for the researcher to sign to be kept on file with the parental consent form:
 - I have discussed this research study with ____ using language which is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assent to participate in this study.

Early Childhood



- Children who are early literate (5-7) can be given a simple assent form where they can check yes or no, or color in a smiley or frown face and write their name (Harcourt & Conroy, 2005).
 - The assent form should be in simple language.
 - Children should be asked to repeat back the information to ensure they understand.
 - Clarify any mis-understanding
 - Allow time for any questions

Research with Early Adolescents

The Nuts and Bolts



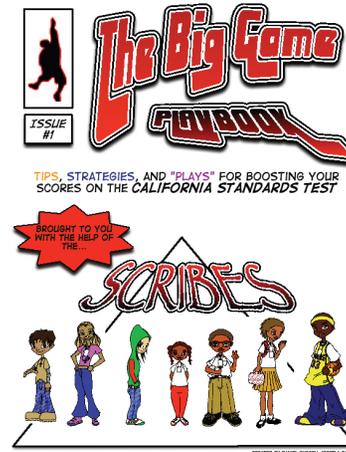
Key Developments in Middle Childhood (7-12)

How do the following relate to ethics and research?

- Piaget concrete operations
(Piaget, 1977, 1983)



- Executive functioning increases
(Anderson, 2002)



- Transitional period interacting in many new contexts
(Barber & Olsen, 2004; Chung, Elias & Schneider, 1998; George, 2007; Isakson, 1999)



Participant Assent Form



- Word Choice
- Clarity
- Breadth

Middle Childhood

Reviewing Guidelines for Permission Forms

□ Review 16 Guidelines



Middle Childhood (7-12)

Parental Permission Form

SAMPLE

*(To be printed on **Department Letterhead**)*

CONSENT FORM

(Forms requesting parental permission for their children to participate in research must be headed: "Parental Permission Form.")

My name is _____ and I am (a professor/student) in the _____ Ph.D. Program at The Graduate Center of the City University of New York (CUNY), and Principal Investigator of this project, entitled "_____." This is a research study of _____ . The study is expected to _____ . I would like permission to interview you about your experiences, and would like you to fill out the 5-page questionnaire (describe in some detail whatever it is you are asking the participant to do).

This interview will take from one to two hours, and the questionnaire should take approximately one hour. I will pay you \$\$ to fill out the questionnaire (if compensation is being offered). With your permission, I would like to audio-tape this interview so I can record the details accurately. The tapes will only be heard by me and my advisors. All information gathered will be kept strictly confidential, and will be stored in a locked file cabinet, to which only I, and my advisor, will have access. At any time you can refuse to answer any questions or end this interview.

Middle Childhood (7-12)

Parental Permission Form Continued

The risk involved in this study, is that (*describe any risk or the following may be used if applicable: "The risks from participating in this study are no more than encountered in everyday life.*).

The benefits of your participation is that (**describe the benefits of the study that you hope will add to the generalized knowledge of your research topic,[there usually are not any direct benefits to the participant]**). **There will be approximately (total number) of participants taking part in this study.**

I may publish results of the study, but names of people, or any identifying characteristics, will not be used in any of the publications. If you would like a copy of the study, please provide me with your address and I will send you a copy in the future.

If you have any questions about this research, you can contact me at (000) 000-0000 or email address, or my advisor name at (212) 000-0000 or email address. If you have questions about your rights as a participant in this study, you can contact Kay Powell, IRB Administrator, The Graduate Center/City University of New York, (212) 817-7525, kpowell@gc.cuny.edu.

Thank you for your participation in the study. I will give you a copy of this form to take with you.

I agree to have this interview audio recorded please [circle one]:

Yes No

Participant's signature

Date

Investigator's signature

Date



Middle Childhood (7-12)

Parental Permission Form II

- There are uniform practices but like research there is also variation.

- Examine Parental Permission Form II

- Compare and Contrast
 - Different research- different components



Be Sensitive of Context and Variation



Children with Cognitive Disabilities

The “Doubly” Vulnerable

Double “Otherness”

Children as a vulnerable population

People with cognitive disabilities as a vulnerable population

Children with cognitive disabilities as a double vulnerable population

Assent

- Cognitive challenges limit ability to understand complex concepts, to read and understand the implications of the research (Lott, 2005)
- 3 aspects of consent that should be applied to Assent:
 - Capacity
 - Information
 - Voluntariness
- Ethical Considerations

Using a Modified Informed Consent Process

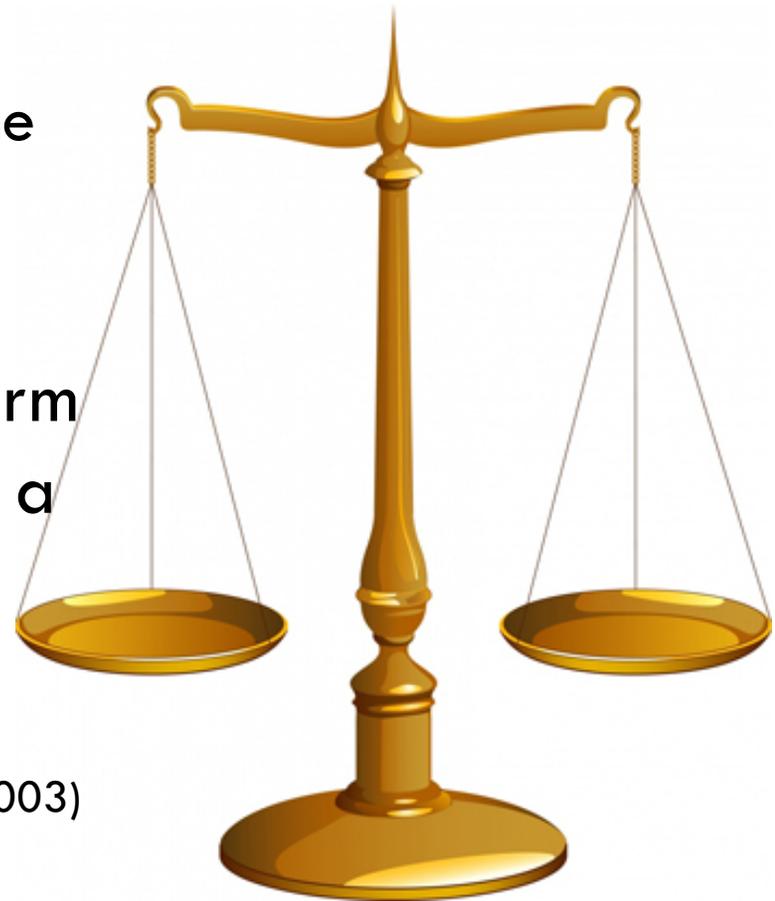
- 40-80% of participants with capacity to consent do not understand 1 or more aspects of consent information (Wendler, 2004)
- Using techniques that may enhance understanding:
 - Teach-to-Goal (Sudore et al., 2006)
 - Supported Decision Making (Iacono, 2006)

Reactive Dynamics

- Central part of ethical considerations about research with vulnerable populations is protection from harm
- Some argue we have gone too far—overly restrictive ethical requirements
- Pettit (1992) describes Reactive Dynamics as arising as a result of a four-step process:
 - “(1) an evil occurs that needs to be dealt with; (2) the evil is exposed in a sensational manner; (3) there is popular outrage; and (4) governments react by putting in place legislation or administrative strategies to ensure a similar evil will not recur” (as cited in Iacono, 2006, p. 173).

The Balancing Act

- Risk-Benefit Analysis
 - Do the benefits outweigh the risks?
- Protecting children with cognitive disabilities from harm VS. promoting their rights as a person
 - Back to the UNCRC
- Goodness-of-Fit Ethics (Fisher, 2003)





“Given dependent status and compromised capacity to give consent [vulnerable populations] should be protected against the danger of being involved in research solely for convenience or ease of manipulation” (Sales & Folkman, 2000, p. 205).

The Willowbrook Hepatitis Study

An example from the past

Study Overview



- Willowbrook State School: institution in Staten Island for children with cognitive disabilities
- 1950's hepatitis epidemic due to overcrowded facilities
- Dr. Saul Krugman, Dr. Robert Ward, Dr. Joan P. Giles, and colleagues developed a study of the progression of hepatitis and possible prevention
- Children given hepatitis
- Consent process varied by the time of recruitment

Willowbrook Study Activity

Directions

- With your group/partner read through the handouts given to you to gain background on the Willowbrook Hepatitis Study
- Determine what your role during the study was
- What are the benefits/risks of the study (as viewed by your character)?
- Come up with questions to ask the other group about any ethical considerations
- Debate

Roles

- Dr. Saul Krugman, Dr. Robert Ward & Dr. Joan Giles
 - John, Michael, Ozy
- Children's Rights Activists
 - Damon, Max, Dr. Vietze
- Sales, Folkman, & VandeCreek (facilitators)
 - Danielle, Phil, Kasey

References & Materials

For an annotated reference list and consent/assent materials, please refer to our blog:

<http://ethicalchildresearch12.commons.gc.cuny.edu/>