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Ethical Issues in Human Subjects Research

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BY NC ND

Some Basics

- What is research?
- What is beneficence?
  - What are some potential benefits?
  - What types of risks may exist?
  - How are risks assessed?
- How is consent handled with minors?

Think about

- Is it research?
  - Applicable federal, state and local regulations
- Foreseeable risks and potential benefits
  - Are risks reasonable given the potential benefits?
  - Are there some risks that are so objectionable that they should never be authorized regardless of the benefits?
  - Physical, Psychological, Social, Economic and Legal risks

Think about

- Consent and Assent processes
  - What is the relationship between risk assessment and informed consent?
    - If the participants are informed does that make the risks acceptable?
  - Most appropriate consent/assent for the study
    - Should potential participants be engaged in a discussion?
- Maintaining participant privacy and data confidentiality
- Protections for vulnerable populations

Case Example 1

- A researcher wants to conduct a chart review of patients from 1999 to 2006. This researcher is interested in collecting height, weight, amount of blood drawn and reason for blood draw. The researcher hopes to establish standard practices and based on results may want to continue the study to affect change in standard practices.
  - Is this research?

Case Example 2

- A child has been treated unsuccessfully over the years and has finally decided that he does not want any more treatment.
  - What should happen if the parents want to enroll the child in a protocol examining a promising new treatment that might benefit the child, but the child is unwilling to assent?
  - Is there a therapeutic misconception in play?

Case Example 3

- A study wants to conduct allergy skin testing on children. There is no direct benefit to the children enrolled in this study. The children being enrolled are considered “healthy, with no known allergies.”
  - When do you transition from minimal risk to greater than minimal risk?
  - Would one or two parent signatures be required?

Risk Ratings for Minors

- 46.404; 50.51: Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - One parent signature

46.405

- 46.405; 50.52: The research risk is greater than minimal and it presents the prospect of direct benefit to the participant.
  - One parent signature

46.406

- 46.406; 50.53: The research is greater than minimal risk with no direct benefit to the minors but it is likely to yield generalizable knowledge about the subject's disorder or condition. And/or, the minors being recruited have a disorder or condition that would place them in a group other than average healthy child therefore, the research is a minor increment over minimal risk. (This risk is slightly more than what the average healthy minor would experience but is an experience or an expectation given their condition.)
  - Two parent signatures

407

- 46.407; 50.54: The research uses minors that do not have the disease being studied and is greater than minimal risk. It presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of minors but presents no direct benefits to the participants. (Please note, research in this category must be reviewed by the HRPO and then submitted to the DHHS Secretary for review by a panel of experts.)
  - Two parent signatures

Reference Material

Found at http://hrpohome.wustl.edu.

- 45 CFR 46, subpart D children
- 45 CFR 46.404, 46.405, 46.406, 46.407
- 21 CFR 50.51, 50.52, 50.53, 50.54
- WU Assent Guideline,
- WU Consent Guideline
- WU Wards of State Guideline

Reference Material

- The Ethics and Regulation of Research with Human Subjects by Carl H. Coleman, Jerry A. Menikoff, Jesse A. Goldner, and Nancy Neveloff Dubler published by Lexis Nexis

Bonus Case Example

- A researcher is interested in studying contraceptive choices amongst adolescents. As adolescents present to Planned Parenthood, they will be given a questionnaire about current contraceptive choices and information about contraceptives available. The idea is to not only gather information about current beliefs and choices but also educate adolescents about choices.
  - Can the minors consent for themselves?
  - What about privacy and confidentiality?
  - What are the risks?
  - What happens if a minor turns out to be a Ward of the State? Does this change matters? How?

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