Ethics of Pediatric Research

Ethics: Bioethics (Fall 2014)

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Case to Consider: Kennedy-Krieger Lead Paint Study

- What are the competing ethical standards for evaluating this study?
  - Contrast the standards used by the Maryland Court of Appeals and the KKI.
- What are holes you would poke in the arguments offered by the Court and the KKI?
- Do you think the study as done by the KKI was ethically permissible? Do you think it *could be* ethically permissible if certain modifications were made?

Link

TABLE 3 Categories of Research

Category 1: Research not involving greater-than-minimal risk to children

To approve this category of research, the IRB must make the following determinations:

the research presents no greater-than-minimal risk to the children; and

adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians

Category 2: Research involving greater-than-minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research

To approve research in this category, the IRB must make the following determinations:

the risk is justified by the anticipated benefits to the subjects;

the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; and

adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians

Category 3: Research involving greater-than-minimal risk and no prospect of direct benefit to the individual child subjects involved in the research but likely to yield generalizable knowledge about the subject's disorder or condition

To approve research in this category, the IRB must make the following determinations:

the risk of the research represents a minor increase over minimal risk;

the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected, medical, dental, psychological, social, or educational situations;

the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the disorder or condition; and

adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians

Category 4: Research that requires a special level of DHHS or FDA review beyond that provided by the IRB

Research that the IRB believes does not meet the conditions of the above-listed categories but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem that affects the health or welfare of children

If the IRB believes that the research does not meet the requirements of the categories listed above but finds that it presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem that affects the health or welfare of children, it may refer the protocol to DHHS or FDA for review; the research may proceed only if, after consulting with a panel of experts in pertinent disciplines (eg, science, medicine, education, ethics, law) and after an opportunity for public review and comment, it is determined that either (1) the research, in fact, satisfies the conditions of category 1, 2, or 3 or (2) the following:

the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem that affects the health or welfare of children;

the research will be conducted in accordance with sound ethical principles; and

adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians

Basics of Pediatric Research

- "Minimal risk" – harms, risks anticipated in research are not higher than what is expected in everyday life or routine exams
  - *Baseline for "everyday life"??*

- Standards for pediatric research:
  - Informed consent of parents: nec, ~ suff.
    - Child's **assent**: ALSO nec, ~suff.
  - Informed consent of parents: nec & suff.
    - Child's **assent**: ~nec, ~suff

Assent

- "Positive agreement"
  - *What indicates assent, especially in young children?*
  - *Which children are capable of assent?*
  - *When should assent be solicited? Which factors are relevant?*
  - *What is the ethical justification for soliciting assent from certain subjects?*

Respect for Autonomy & Nonmaleficence

- **Autonomous decision-making from children**
  - Understand elements of informed consent…
  - Appreciation of how research affects them
    - Must understand *altruistic reasons* (why one might put him-/herself at risk for the sake of others)
- **Protection from harm**
  - Includes not subjecting them to decision they are not capable of understanding

Dissent Requirement

- Recommendation: dissent of all children should be respected in nonbeneficial research
- Err in favor of protecting children when signal/communication unclear
- Relies on the ongoing experiences, preferences that children could have in course of research

Another Requirement

- Need "mature and enduring notion of what human flourishing entails" (14)
  - In order to understand how research decision could affect his/her well-being
- Cannot be captured with age thresholds
  - *Experiential knowledge* makes all the difference

Discussion Questions

- If the bar for *assent* is requiring that the child is capable of understanding and appreciating the elements of informed consent…what might be problematic about this?
- Should respecting pediatric subjects' dissent *always* be respected in nonbeneficial research? What about for beneficial research?
- Do Sharp & Quigley make a convincing argument for an additional requirement for autonomous decision-making for children?
- Is it morally permissible for parents to choose to enroll their children in research in which the subjects' assent will not be solicited for the sake of teaching their children the importance of altruism?


Questions? Comments?