

# Conducting Human Use Research with Children: Challenges and Rewards

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12/1/09

“The Institutional Official is the individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance.” (OHRP Training Module)

# Administratively, the Institutional Official is responsible for:

- Designating one or more IRBs that will review research covered by the institution's FWA.
- Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties.
- Providing training and educational opportunities for the IRB and investigators.
- Depending on the organizational structure at a given institution, other administrative arrangements may be appropriate.

(OHRP Training Module)

# **Institutional Official Responsibilities (continued)**

- Setting the "tone" for an institutional culture of respect for human subjects;
- Ensuring effective institution-wide communication and guidance on human subjects research;
- Ensuring that investigators fulfill their responsibilities;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;
- Serving as a knowledgeable point of contact for OHRP, or delegating this responsibility to another appropriate individual.

(OHRP training module)

# Institutional Responsibilities

## (continued)

- Developing policies and procedures for effective and efficient administration of the Human Research Protections Program (HRPP).
- Ensuring that Assurances are in place and certifications of IRB review are submitted to the appropriate authorities for all HHS-sponsored research, not only for themselves, but also for collaborating performance sites for which the institution has agreed to accept oversight responsibility.
- Implementing appropriate oversight mechanisms to ensure compliance with HHS regulations and effective administration of the HRPP.

(OHRP training module)

# Responsibilities IOs should *not* delegate

- Signatory authority
- Completing IO training
- Ensuring independent IRB functioning and direct access to the IO
- Ensuring adequate resources for the IRB

(Recommendation of the Secretary's Advisory Committee for Human Research Protections)

# The Five Dimensional Institutional Official

- Legal/regulatory
- Administrative
- Economic
- Educational
- Ethical/cultural

# Hot Topics for Institutional Officials (PRIMR, November 2009):

## Or, Why I don't want to grow up to be an Institutional Official

- The IO must depend on others
- The person who is the IO has other responsibilities
- The IO must operate in the inter-institutional matrix of the current research infrastructure

# Major regulatory provisions specific to research involving children

- What is nonexempt human use research?
- Categories of allowable research
- Child assent and parental permission

# What is nonexempt human use research? (The .101(b)(2) exemption modified)

- All research involving survey procedures
- All research involving interview procedures
- All research involving observation of nonpublic behavior, and participatory observation of public behavior

# Categories of allowable research

- .404, .405, 406, .407.
- “minimal risk”, “a minor increase over minimal risk”, and other conditions.
- One parent’s permission, or both.

# Child Assent and Parental Permission

- “*Assent* means a child’s affirmative agreement to participate in research....”  
(.402(b))
- *Parental Permission* in conformity with the informed consent provisions of .116.  
Waiver is allowable in conformity with .116 or .408(c).

# Other legal and regulatory concerns

- Who is a *child*?
- Who is a *guardian*?
- What other pertinent federal laws or regulations provide additional protections for human subjects?
- What state, local or foreign laws or regulations provide additional protections for human subjects?
- What are the relevant institutional commitments and regulations, applicable law, and standards of professional conduct and practice?

# Why bother?

- Protection from harm
- Protection from wrong
- Support for the practice of research
- Avoiding waste of resources