

Legal Issues In Mental Health Research

Student Pugwash USA
2006 Northeast Regional Conference
May 20, 2006

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Agenda

- Legal Framework
- The Dilemma of Vulnerable Populations
- A Question of Capacity
- Current Solutions

Legal Framework for Conducting Human Subjects Research



Regulations and Policies

- Framework for the protection of human subjects
 - Federal regulations:
 - The Common Rule
 - FDA requirements
 - Both regulations embody ethical principles of Belmont Report
 - State laws

Regulations and Policies: Dept. of Health and Human Services

- “The Common Rule”
 - 45 CFR Part 46 Subpart A
 - A uniform policy for the protection of human research subjects
 - Applies to research involving human subjects that is conducted, approved, or otherwise subject to regulation by one of the 17 agencies or departments

Office for Human Research Protections (OHRP)



DEPARTMENT OF HEALTH & HUMAN SERVICES

April 11, 2006

Robert E. Burke
Managing Director
Research Foundation for Mental Hygiene, Inc.
New York Psychiatric Institute Division
44 Holland Avenue
Albany, NY 12229

RE: Human Research Subject Protections Under:

Research Project: Brain Imaging &
Encephalopathy
Principal Investigator: Brian Fallon, M.D.
Protocol Number: 3613

Research Project: An Open Label Study of the Effects of Zolofl
(Sertraline) on the Prevention of Post-Stroke Central
Nerve Lesions Following Traumatic Brain Injury

Principal Investigator:
Protocol Number:

Research Project:
Principal Investigator:
Protocol Number:

Research Project:
Principal Investigator:
Protocol Number:

Research Project:

Principal Investigator:

April 11, 2006

Robert E. Burke
Managing Director
Research Foundation for Mental Hygiene, Inc.
New York Psychiatric Institute Division
44 Holland Avenue
Albany, NY 12229

“It was alleged that investigators ... failed to obtain the legally effective informed consent of one or more subjects.... OHRP finds that there was one instance where screening was initiated prior to signing the informed consent document”

Regulations and Policies: Food and Drug Administration

- FDA Regulations and Policies
 - FDA regulates research but does not generally conduct or support
 - FDA regulations apply to “clinical investigations” involving products regulated by the FDA or in support of applications for research or marketing permits for products regulated by the FDA
 - Unlike DHHS regulations, federal funds do not have to be involved
 - Includes protection for human subjects

State Regulations

- New York Public Health Law Article 24-A
 - Sets informed consent requirements
 - Limits who may conduct research
 - Requires human research review committees
 - “In addition to the voluntary informed consent of the proposed human subject ... the consent of the committee and the commissioner shall be required with relation to the conduct of human research involving minors, incompetent persons, mentally disabled persons and prisoners.”
 - Does not apply to research subject to federal regulations

The Dilemma of Vulnerable Populations

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What is a Vulnerable Population?

- HHS Regulations contain special considerations for vulnerable subjects
- HHS Regulations include special protections for:
 - Pregnant Women and Fetuses (Subpart B)
 - Prisoners (Subpart C)
 - Children (Subpart D)

Protection of Children

- No greater than minimal risk
- Greater than minimal risk, prospect of direct benefit
- Greater than minimal risk, no prospect of direct benefit, but likely to yield generalizable knowledge about subject's disease or condition
- Otherwise unapprovable, but involves a serious problem affecting children

Models for Research with Decisionally-Impaired Adults

- Subpart D - Protection of children
- Greater than minimal risk if purpose is therapeutic and risk is commensurate with benefit
- Only appropriate subject population, research question is unique to subject population, and no more than minimal risk
- Condition causing impairment is object of study and subject has advance research directive
- Absolute prohibition

A Question of Capacity

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Consent of the Research Subject

- The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

Federal Requirements for Informed Consent

- No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject *or the subject's legally authorized representative*

45 CFR § 46.116

“Legally Authorized Representative”

- An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.

45 CFR § 46.102

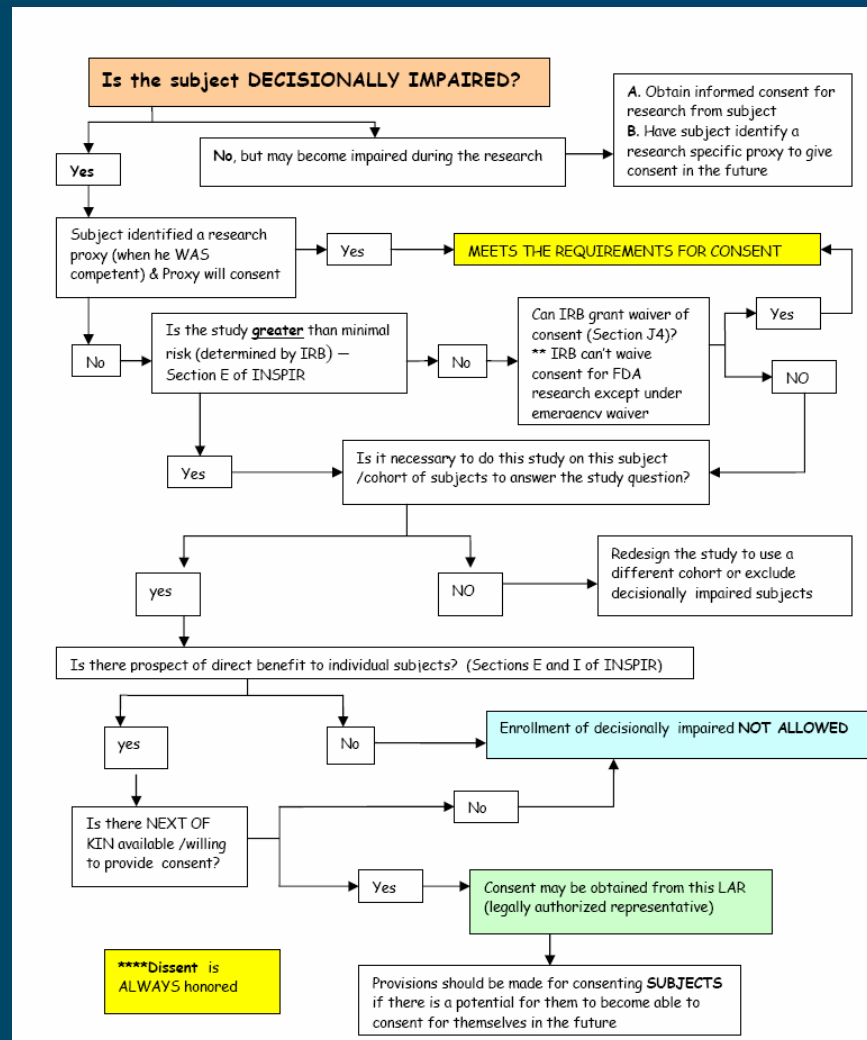
Relationship Between Consent and Capacity

- Consent to receive or refuse medical treatment is not the same as consent to participate in research
- Cognitive impairment may reduce capacity to consent

Assessing Capacity

- Condition being studied may compromise capacity to understand study or decide about participation
- Capacity may decrease or fluctuate with disease progression
- Research itself may cause subjects to lose capacity

Assessing Capacity



Current Solutions

- Clear institutional policies
- Knowledgeable and experienced IRB
- Honest assessment of risks and benefits
- Proxy Research Consent
- Advance Research Directives
- Documentation

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