Informed Consent Issues

Emory University
Office of Research Compliance
Presentation to Children’s Healthcare
May 18, 2012
Overview

- Parents and Legal Guardians
- Consent/Permission/Assent in Pediatric Studies – the Basics
- Assent
- Wards of the State
- Emancipated Minors
- Non-English Speaking Subjects and their Parents/Legal Guardians
Parents & Legal Guardians

• Parent – Biological or adoptive parent
  • Minor parent get the rights of parents for non-emancipated minor children
• Legal Guardian – appointed by court to serve as guardian for the child.
  • Request copy of court appointment.
Terms

• Consent – what adult subject or legally authorized representative of adult subject gives.
• Permission – what parents/legal guardian of minor subject gives.
• Assent – what minor subject gives.
Permission – One Parent or Two

• Minimal Risk
  • Reviewed under 45 CFR 46.404 or 21 CFR 50.51
  • IRB can OK permission of one parent
  • Some form of Assent required if child ≥6
• More than minimal Risk with Direct Benefit to Participants
  • Reviewed under 45 CFR 46.405 or 21 CFR 50.52
  • IRB can OK permission of one parent
  • Some form of Assent required if child ≥6
Permission – One Parent or Two

- More than Minimal Risk + No Prospect of Direct Benefit + Generalizable Knowledge about Subject’s Condition
  - Reviewed under 45 CFR 46.406 or 21 CFR 50.53
  - Permission of 2 parents required unless reasonably unavailable or only 1 parent has legal custody
  - Some form of Assent required if child $\geq 6$
- 45 CFR 46.407/21 CFR 50.54 Research – Not otherwise approvable but presents opportunity to understand, prevent or alleviate serious problem affecting health or welfare of children.
Research Involving Medical/Surgical Treatment

- Optimal Situations v. Permissible Situations
- Optimal – parent or legal guardian
- Permissible – Person temporarily standing in the place of a parent, whether formally serving or not, for a non-Emancipated Minor under his/her care.
  - EXCEPTION – Wards of State
Pure Research

- No medical or surgical treatment recommended by duly licensed physician:
  - Must have permission of parent or legal guardian.
  - Ward of State provisions may apply.
Waiver of Permission

- Waiver requirements of 45 CFR 46.116/21 CFR 50.55 are met:
  - Minimal risk
  - No adverse affect on rights or welfare of subjects
  - Provide subjects with additional information after participation, if appropriate; AND
- Based on protocol design or subject population, permission from parent/legal guardian is not reasonable requirement to protect child; appropriate protection mechanism is substituted; and no violation of state/local law.
Assent

• Purpose – child should actively show willing to participate in Research.
• Assent requirements depend on age, maturity and psychological status of child.
• IRB may not require assent if child can’t reasonably be consulted OR Research has prospect of direct benefit that is important to child’s health/well-being and can’t be obtained outside of Research.
Waiver of Assent

- Child subject capable of assent, but IRB determines waiver requirements of 45 CFR 46.116/21 CFR 50.55 are met:
  - Minimal risk
  - No adverse affect on rights or welfare of subjects
  - Provide subjects with additional information after participation, if appropriate
What Happens if Parent Gives Permission, but Child Does not Assent?

• Generally, failure to assent will override parental permission.
• BUT IRB can consider request to waive assent on individual basis.
Child Becomes an Adult

- If child subject is still participating in research when he/she becomes an adult, then he/she must give informed consent to continue participating in the research.
Wards of the State

• Wards of State = Children under care of governmental agency either directly or through placement in individual or group foster care setting.
Wards of State

- For Ward to participate in Research:
  - Governmental agency must give permission for child to participate and authorize named agency representative to sign appropriate documents.
- If Research is > Minimal Risk with no prospect of direct benefit or is 45 CFR 46.407/21 CFR 50.54

  - IRB must appoint an advocate for the ward
Emancipated Minors – Georgia

• Under 18 but Married; in armed services; or self-supporting and declared emancipated by court.

• Emancipated Minor may give informed consent for research.
Special Situations in Non-Emancipated Minor Can Give Consent

- Non-Emancipated Minor can give consent for research involving medical treatment recommended by licensed physician for:
  - Pregnancy
  - Childbirth
  - Pregnancy Prevention
  - Drug Abuse
  - Treatment of syphilis, gonorrhea or chancroid
Non-English Speaking Subjects/Parents

• Must provide description of research in a language subject can understand.

• May use certified translated copy of consent document.
  • Best practice – use certified translator to assist in consent process and document in research record.
  • If non-certified translator is used – must submit letter verifying credentials/expertise to IRB
    • Back translation of informed consent documents into English required.
Non-English Speaking Subjects/Parents

• Use of Short Form – May be used if IRB allows verbal informed consent.
• May be used to unexpected enrollment of non-English speaking subject.
Short Form Process

• English long-form consent document.
• Short form must be in subject’s language.
  • States that there has been oral presentation to subject of elements of informed consent in subject’s language.
• Witness to consent who is fluent in English and subject’s language; may be translator.
• IRB must approve written summary of what is to be said to subject – may be long-form consent.
Short Form Process

• Subject must sign and date short form and written summary.
• Person obtaining consent must sign and date copy of summary.
• Copy of summary and copy of short form must be given to subject.
• If optional items on long form, then translator must include on last page of short form a comment that subject made specific choices on long form.
Scenarios

• Mother is unavailable and father consents, but you later find out the father is not the biological or adoptive father.
• Restraining order against father.
• Mom signs consent, but is not legal guardian.
Other Issues/Questions

• What do you do if you discover informed consent was obtained improperly?
• What if you enroll a subject and later find they are not a good candidate?
• Remember HIPAA
  • When is partial HIPAA waiver necessary?
Questions

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