

Informed Consent Issues

Emory University
Office of Research Compliance
Presentation to Children's Healthcare
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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 ≥ 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 Research:
 - 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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