Assent-- Engagement and Process

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Disclosures

• I receive royalties from UpToDate, Wolters Kluwer Health.

• I do not plan on discussing unlabeled/investigational uses of a commercial product.
Reasons for Assent

• Basic Ethics- Autonomy/Respect
• Meet regulatory requirements
• Creating partnership with research team  
  – Emphasize child's/adolescents role  
• May result in clearer/simpler discussion
HHS Guidance (Old Common Rule)

- The IRB is responsible for deciding whether child assent is required in proposed research activities. **Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent** (45 CFR 46.402(b)). Child assent is required, except in the following three circumstances described at 45 CFR 46.408(a):
  - Child’s Capability excessively limited
  - Prospect for direct benefit, only through research
  - Meets conditions for waiver of consent
Documenting Assent-Rules

• Regulations do not require documentation of assent
• IRB determines appropriate manner
  Wide latitude
New Common Rule-Consent

116(a)(5)(i)) that the informed consent begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. .... presented in a way that facilitates comprehension

- Goal of 8th grade language
- Reasonable person standard
- Sounds a bit like what’s required for Assent!.
Assent Guidance in New Common Rule

27 See https://vaers.hhs.gov/index.
Sliding Scale of Expectations

Permission 1 or 2 Parents

7-12? years

Assent

18 years

Consent
When shouldn’t you ask

• Physically/Cognitively unable
  – This may be situational
  – Document the situation

• Only way for therapy is via research
  – Need to ask “what if child says no”
Giving child some background
Educational Process and Assent

• May take time for complicated studies
• Confirm understanding as part of discussion
• Active questioning-
  – What are good and bad things that came happen to you because you are in the study?
  – What care would happen if you are not in the study?
• Uncertainty about social/cultural biases
Documenting Assent

• Waiver of written assent
• Document verbal assent
• Simple Forms
• Complicated Forms
• Main Consent
Simplified Assent

We would like to invite a member of your family to take part in a research study.

**WHY are we inviting them to take part in this study?**
- We want to learn how your family responds to your periodic fevers
- We plan to have 110 people around the world participate

**WHAT are we asking them to do?**
- Research is a way we try to find out answers to questions
- They will answer questions about how both you and they are doing
- Your doctor will tell us about how you are doing including drugs you have taken to treat your condition. You will not have to do anything.

**Does my family member HAVE to take part?**
- NO. Both you and your family members need to agree to do the study. We will still take care of you if you do not, nothing about that will change.

**Will this study HELP me?**
- We cannot promise that this study will help you, but the information we get might help treat people with your condition in the future.

**Did anyone else check that the study is OK to do?**
- Before any research is allowed to happen, it has to be checked by a group of people called an Institutional Review Board. They make sure that the research is fair. They have agreed we can carry out this study

**Will anyone else know that my family member is doing this?**
- Nobody will be told that your family member is doing this research
Separate Assent Document

Greater than Minimal Risk; Potential for Direct

Greater than Minimal Risk; No Potential for Direct Benefit

Minimal Risk; No Potential

Minimal Risk; Potential for Direct

Boston Children’s IRB Active Studies August 2017
### Possible Best Practice?

<table>
<thead>
<tr>
<th>Study Length</th>
<th>Simple</th>
<th>Complicated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Short</td>
<td>Longer</td>
</tr>
<tr>
<td>Elementary School</td>
<td>Main ICF</td>
<td>Short Assent</td>
</tr>
<tr>
<td>Early Adolescent</td>
<td>Main ICF</td>
<td>Short Assent</td>
</tr>
<tr>
<td>Late Adolescent</td>
<td>Main ICF</td>
<td>Main ICF</td>
</tr>
</tbody>
</table>

? If pregnancy/birth control/drug use issues critical
Another Variation- Parental Form is the adolescent form

<table>
<thead>
<tr>
<th>Age of Minor Participant</th>
<th>Assent Form Recommended</th>
<th>Separate Parental Permission Form Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant-6 years old</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>7-12 years old</td>
<td>Yes</td>
<td>Yes. see child assent form for model</td>
</tr>
<tr>
<td>13-17 years old (Option A)</td>
<td>Yes</td>
<td>No. Create a single document addressed to the adolescent with signature lines for assent and parental permission.</td>
</tr>
<tr>
<td>13-17 years old (Option B)</td>
<td>Yes. See adolescent assent form as model</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Moving Forward

• With substantial flexibility there is exceptionally wide variation in how assent is documented.
• The variation we see within our institution (and industry) exists between institutions.
• Everything about simplifying consent is amplified for assent.
• Psychosocial, interventional trials already with more assent documents, recognizing the process is more complicated.
Thanks

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