What are the human subjects challenges when conducting cognitive interviews with children?

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*Westat*
Challenges of Conducting Cognitive Interviews with Youth

- Meeting regulation requirements regarding human subjects protections, including those required for “special” or “vulnerable” populations
- Recruiting youth for cognitive interviews
- Assuring youth comprehension of assent process
Challenges of Meeting Federal Regulations with Youth

- Demonstrating research involves no greater than minimal risk.
  - Federal regulations provide for “Additional Protections for Children Involved as Subjects of Research.” Subpart D of 45 CFR 46
- Obtaining a waiver allowing permission from only one parent (rather than both parents) or guardian authorized to consent on behalf of the youth
- Demonstrating assent process and materials are appropriate for children
  - Assent is defined as “a child’s affirmative agreement to participate in research”
  - Ability to assent is determined by the ages, maturity, and psychological state of the children involved. Assent procedures and materials must be in a language that is appropriate to the child’s age, experience, maturity and condition.
Challenges of Recruiting Youth for Cognitive Interviews

- Parental/guardian consent must be obtained prior to screening or recruiting youth
- Parents must be informed of topic of cognitive interviews
Challenges of Recruiting Youth for Cognitive Interviews, continued

- 3 Cognitive Interviewing Projects
  - Recruited children ages 11-17
  - Goal of 9 respondents per study
  - Topic for each was tobacco use
- Each project used a different recruiting strategy
Challenges of Recruiting Youth for Cognitive Interviews, continued

<table>
<thead>
<tr>
<th>Recruiting Strategy</th>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruiting Strategy</td>
<td>No screening for prior tobacco use</td>
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</tr>
<tr>
<td></td>
<td>Children recruited as parent-child dyads, where parent is tobacco user</td>
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<tr>
<td>Recruitment Effort Needed</td>
<td>Minimal recruiting effort</td>
<td>Moderately difficult recruiting effort</td>
<td>Multiple outreach efforts and a lengthening of recruitment time</td>
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<td></td>
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<td>Very difficult recruiting effort</td>
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Challenges of Recruiting Youth for Cognitive Interviews, continued

Racial Diversity of Respondent Pool

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian</td>
<td>Hispanic</td>
<td>Black</td>
</tr>
<tr>
<td></td>
<td></td>
<td>White</td>
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</tbody>
</table>

Legend:
- Asian
- Hispanic
- Black
- White
<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruiting</td>
<td>Large, demographically diverse pool of potential respondents</td>
<td>Large, demographically diverse pool of potential respondents</td>
<td>Small pool, with little diversity among respondents; unable to meet full recruiting goal</td>
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<tr>
<td>Results</td>
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<tr>
<td>Impact on</td>
<td>None of the respondents had personal experience with tobacco; limited</td>
<td>3 of 9 respondents were tobacco users; useful results</td>
<td>All respondents were tobacco users; very useful results</td>
</tr>
<tr>
<td>Testing</td>
<td>usefulness</td>
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Challenges of Assenting Youth for Cognitive Interviews

- How do we know youth comprehend assent process and materials?
- What are the concepts that are difficult to understand?
Challenges of Assenting Youth for Cognitive Interviews, continued

- Limited testing of consent forms generally beyond examining readability levels
- Even less testing of assent forms with youth
- Recently tested an assent form with youth for a longitudinal tobacco and health study
Caveats

- Assent form was carefully crafted with IRB input and expert review
- Testing limited to 9 youth
- All youth were from an affluent Montgomery County suburb (one respondent explained sampling very clearly)
Challenges of Assenting Youth for Cognitive Interviews, continued

- **Results**
  - Overall, youth understood key elements of assent (e.g., volunteering, stopping, parents and other adults would not see results)
  - There were 3 exceptions:
    - Youth were unclear as to what was meant by “public records” and what information would be obtained from them
    - Youth did not understand what a Certificate of Confidentiality was
    - Youth did not fully understand the limits of confidentiality (i.e., that authorities would be informed if there was imminent danger they might harm themselves or others)
Next Steps

- Experiment with novel strategies for recruiting, particularly developing effective methods for reaching out to parents (more use of social media?)
- Test assent materials for youth further, with the goal of developing a “gold standard” assent form