



Westat[®]

| **idea** *services*

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

Kerry Levin, Martha Stapleton, and Jocelyn Newsome
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

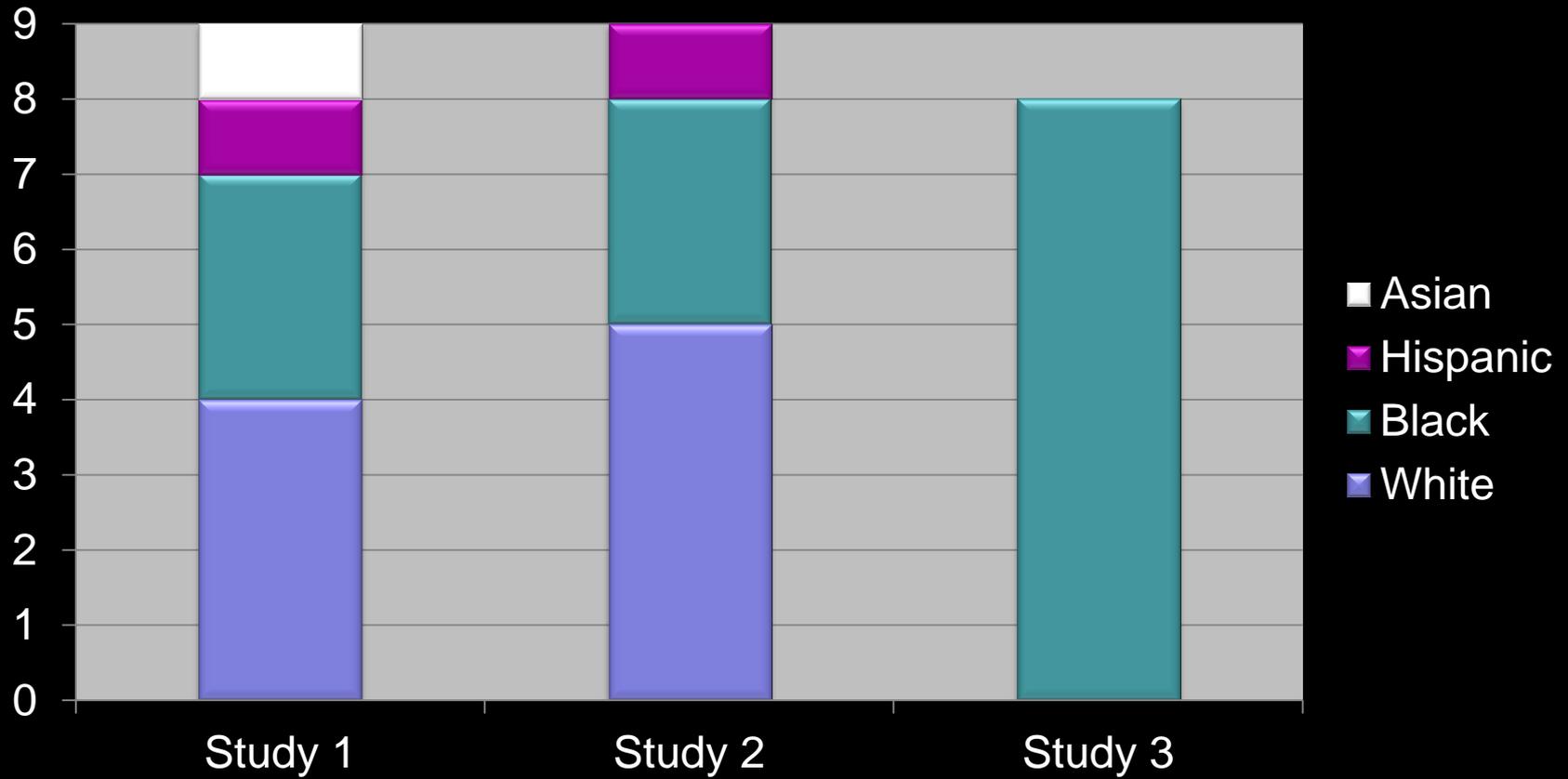
- 3 Cognitive Interviewing Projects
 - Recruited children ages 11-17
 - Goal of 9 respondents per study
 - Topic for each was tobacco use
- Each project used a different recruiting strategy

Challenges of Recruiting Youth for Cognitive Interviews, continued

| | Study 1 | Study 2 | Study 3 |
|---------------------------|------------------------------------|--|---|
| Recruiting Strategy | No screening for prior tobacco use | No screening for prior tobacco use Children recruited as parent-child dyads, where parent is tobacco user | Screening for prior tobacco use |
| Recruitment Effort Needed | Minimal recruiting effort | Moderately difficult recruiting effort | Multiple outreach efforts and a lengthening of recruitment time Very difficult recruiting effort |

Challenges of Recruiting Youth for Cognitive Interviews, continued

Racial Diversity of Respondent Pool



Challenges of Recruiting Youth for Cognitive Interviews, continued

| | Study 1 | Study 2 | Study 3 |
|--------------------|--|--|--|
| Recruiting Results | Large, demographically diverse pool of potential respondents | Large, demographically diverse pool of potential respondents | Small pool, with little diversity among respondents; unable to meet full recruiting goal |
| Impact on Testing | None of the respondents had personal experience with tobacco; limited usefulness | 3 of 9 respondents were tobacco users; useful results | All respondents were tobacco users; very useful results |

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

Challenges of Assenting Youth for Cognitive Interviews, continued

- 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