Adolescents’ Understanding of Research Concepts
A Focus Group Study

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Objective: To identify ways to improve adolescents’ understanding of informed assent by exploring adolescent comprehension of concepts common to all clinical trials as well as those specific to a human immunodeficiency virus vaccine trial.

Design: Qualitative descriptive study.

Setting: Community-based organizations.

Participants: Healthy adolescents aged 15 to 17 years in 8 focus groups.

Intervention: Focus groups were conducted using a semistructured interview guide. Digital recordings of the groups were transcribed verbatim.

Outcome Measure: Textual data were categorized by 2 investigators using directed qualitative content analysis techniques. Major themes and subthemes were identified, and representative quotes were selected.

Results: The general research concepts that were most difficult for teens to understand were placebo and randomization. The most difficult vaccine trial concepts were how a vaccine works and that a vaccine is used for prevention rather than treatment. The most difficult human immunodeficiency virus vaccine–specific trial concept was that standard human immunodeficiency virus antibody tests might provide a false-positive result for participants receiving the test vaccine. Focus group participants wanted to be informed about adverse effects, trial procedures, and whether previous research had been performed before making a decision about trial participation.

Conclusions: Many clinical trial concepts were difficult for teens to understand. Attention needs to be directed toward developing effective ways to explain these concepts to adolescents participating in future human immunodeficiency virus vaccine and other clinical trials.


Parental permission and adolescent assent, an affirmative agreement to participate, are required for a teen who is a minor to participate in a study involving more than minimal risk.1 To make a truly informed decision about study participation, teens must be able to understand the information that is presented to them. Yet, little research has been conducted in this area. In addition, little is known about teens’ preferences for the way that the joint decision-making process with parents should be performed.

Many studies have demonstrated that adult understanding of information received during the informed consent process is only fair at best.2-5 Issues of concern are a lack of understanding about randomization in placebo-controlled trials2 and the presence of a therapeutic misconception in which the research participant fails to recognize that the primary purpose of clinical research is to produce generalizable knowledge6 rather than to focus only on patient-centered care.3-5 Siminoff6 noted that research participants often have major misunderstandings about the research in which they enroll and linked much of this misunderstanding to the difficulty of reading the consent form, especially when it contains a large amount of technical information.

Few studies have been conducted on adolescent comprehension of informed assent or on interventions to improve adolescent understanding, but those that have been performed demonstrated that adolescent understanding appears to be incomplete.6-13 Studies that have assessed interventions to improve adolescent comprehension have found that modifications to the assent form, including use of pictures, bulleted, bolding, and in-
creased font size, can significantly improve understanding; however, even with these modifications, a substantial number of participants still lack adequate understanding of some key research concepts.9,13

A second relatively unexplored area is teen preferences for how and when to share decision making about research participation with their parents.12,14 When Brody et al14 presented asthma research study vignettes to teen-parent dyads, they found that parents generally expected that adolescents would defer to the parent’s decision, whereas many of the adolescents responded that they would want to actively participate in the decision. Unguru et al12 asked adolescents who had already enrolled in therapeutic pediatric oncology research protocols how much they had participated in the decision making and what their preference would have been. Many did not perceive that they had been involved in the research decision at all but reported that they would have liked to have been involved.

Although certain concepts are common across all research situations, other concepts have implications that differ depending on the specific research protocol. Clinical trials evaluating new vaccines are just 1 category of studies in which adolescents are asked to participate. To explore research concepts that are difficult for adolescents to understand, we chose as our model issues pertinent to participation in a human immunodeficiency virus (HIV) vaccine trial. After a promising candidate HIV vaccine is identified and demonstrated to be effective in adults, vaccine trials will need to be conducted with adolescents. Adolescents will be an important target group because one quarter of new HIV infections are estimated to occur in youth younger than 21 years.15

Research has generally shown that by age 14 or 15 years, most adolescents are able to make decisions as well as adult research participants in most circumstances.16-19 Although 15- to 17-year-olds cannot legally give consent for themselves, we submit that out of respect for their evolving autonomy, the research assent process should provide them with the same information that would be included in a consent process. To identify ways in which to improve adolescent understanding of informed assent, we conducted several focus groups with teens. The goals of the focus groups were (1) to explore adolescent understanding of concepts common to all clinical trials as well as those specific to an HIV vaccine trial and (2) to explore teen preferences for when during the assent process to involve their parents.

STUDY SITES AND PARTICIPANTS

Adolescents from 4 community-based organizations providing services to vulnerable youth in a Massachusetts city were recruited to participate in 1 of 8 focus groups (4 female groups and 4 male groups). Inclusion criteria were age between 15 and 17 years and the ability to speak English. One of the investigators (C.A.L.) read the assent form to the participant, answered questions, and obtained participant signatures to document assent. The investigator then read the assent form to the parent and obtained permission by telephone. Key outreach staff at each site assisted with identification of a convenience sample of youth interested in participating.

INTERVIEW GUIDE

A focus group interview guide was developed by the investigators. The interview guide was reviewed and revised by experts in adolescent health, HIV trials, qualitative methods, and research ethics. After the interview guide was pilot tested with 4 youth from one of the community-based organizations, final revisions were made. The following categories were included in the interview guide: (1) understanding of the way a vaccine works, (2) understanding of and reactions to the concepts of placebo and randomization, (3) reactions to the possibility of the trial vaccine causing a false-positive HIV antibody test result, (4) reasons why a vaccine trial participant still needs to protect himself or herself from HIV exposure and ways to successfully communicate this information to peers, and (5) preferences for the timing of parental involvement in the decision process about trial participation.

DATA COLLECTION

Focus groups were facilitated by 2 of the investigators (D.R.B. and C.A.L.) who were trained in focus group facilitation, including the importance of limiting imposition of their own biases. Groups lasted approximately 90 minutes and were digitally recorded. Refreshments were served, and participants were compensated $25 for their time. The protocol and assent procedures were approved by the University of Massachusetts Committee for the Protection of Human Subjects in Research.

DATA ANALYSIS

Digital recordings were transcribed verbatim. Transcripts were entered into Microsoft Word (Microsoft Corporation, Redmond, Washington) to facilitate coding and then imported into SPSS software (SPSS, Inc, Chicago, Illinois) to facilitate grouping, sorting, and cross-referencing of the data. Textual data were categorized by 2 of us (D.R.B. and C.A.L.) using directed qualitative content analysis techniques as described by Hsieh and Shannon.20 An a priori list of codes corresponding to focus group questions was developed. Each code was defined, and data were sorted into relevant coding categories. The initial codes were modified and additional codes were added as needed to best reflect the content of the focus group data. Intercoder agreement was calculated, discrepancies were resolved, and the coding scheme was revised after each round until satisfactory agreement (80%) was achieved. Final intercoder agreement averaged 88.4%. Major themes and subthemes were identified, and representative quotes were selected. To ensure the relevance and comprehensiveness of the results, an audit process was used in which a qualitative analyst (M.H.K.) not involved in data collection reviewed the data collection plan, data samples, coding process, and outcomes so that the findings would appropriately reflect all major themes detected in the data.

SAMPLE

A total of 33 adolescents (16 girls and 17 boys) aged 15 to 17 years (mean [SD] age, 15.9 [0.7] years) participated. The self-reported race and ethnicity composition of participants was 39% Latino (n = 13), 52% black (n = 17), 6% multiracial (n = 2), and 3% white (n = 1).
A vague understanding of what a placebo is, but very few had never heard the term. A few participants had no idea what a placebo is or the rationale for using one in a study, and some seemed to understand the concept of randomization only in the abstract, and some participants could not be convinced that the decision is made solely by chance. They believed that in reality a systematic approach would be used to decide whether an individual receives test vaccine or placebo (Table 1).

### Themes

Themes are presented in 3 categories: general research concepts, vaccine trial concepts, and concepts specific to an HIV vaccine trial. An additional category dealing with teen preferences for shared decision making is included. Representative quotes are presented in Tables 1, 2, 3, and 4.

#### General Research Concepts

Before making a decision about joining a study, focus group participants were most interested in knowing the risks and adverse effects of the trial. In addition, participants from several groups wanted to know the extent of previous testing that had been performed, and participants from a few groups wanted to know what they would be asked to do.

Many teens had an altruistic view of trial participation. This came up when they were asked what possible good things could happen to them if they decided to join. Their responses reflected their perception that the good feeling that comes from helping others is a benefit in and of itself.

The majority of teens were unable to explain what a placebo is or the rationale for using one in a study, and many had never heard the term. A few participants had a vague understanding of what a placebo is, but very few had a solid understanding of the term. Many participants questioned why a placebo is used, with some having a negative reaction to the concept. A few participants also believed that placebos may be used because researchers “don’t have enough of the product yet or maybe it’s too much money.”

After the focus group facilitator provided a detailed explanation, including the use of pictograms to describe randomization, most participants stated that they believed that the decision about receiving placebo or test vaccine is determined by chance. However, many seemed to understand the concept of randomization only in the abstract, and some participants could not be convinced that the decision is made solely by chance. They believed that in reality a systematic approach would be used to decide whether an individual receives test vaccine or placebo (Table 1).

#### Vaccine Trial Concepts

Most participants in every group had little to no understanding about what a vaccine is meant to do or how it works. A few understood that a vaccine stimulates an immune response, but none linked this immune response to antibody production.

Many participants misunderstood the purpose of the vaccine, not realizing that the goal is to prevent rather
than to cure an infection. At least 1 participant in every group made a statement reflecting his or her belief that a potential HIV vaccine will cure an HIV infection.

This misconception persisted for some teens despite repeated attempts at clarification by the focus group facilitator. In addition, the belief that a potential HIV vaccine will cure an HIV infection influenced teens’ understanding of other vaccine trial concepts, including the purpose of a placebo, the need for participants in a future HIV vaccine clinical trial to continue using condoms to help prevent HIV, and randomization.

Many participants also held a therapeutic misconception: the belief that they would receive the type of shot (test vaccine vs placebo) that was in their best interest. This belief in turn shaped disbeliefs about randomization. Some participants thought the decision would be influenced by the investigator’s opinion about which shot was better for a particular individual. Others thought that the decision would be based on the individuals’ health and/or laboratory test results. Participants stated that if they injure you with a shot that has enough medicine, it gives you a little bit of the disease, but your body learns. It’s just enough where your body can fight it off, so that way if you actually do get the disease, your body knows how to fight it off already, and it will fight off the disease faster.

### Table 2. Vaccine Trial Concepts

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Representative Quote</th>
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<tbody>
<tr>
<td>How a vaccine works</td>
<td>Little to no understanding</td>
<td>“A vaccine is pretty much an aid for your white blood cells, right? It helps them out.”</td>
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<td></td>
<td>Stimulates immune system</td>
<td>“Isn’t a vaccine like, don’t they put like some of the HIV, so like just a little bit, and they put it in the shot so your immunes can like stop it and like keep the memory of that?”</td>
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<td></td>
<td></td>
<td>“It’s a weaker version of the actual virus that you have, and you get it injected into your body so that your DNA can like, like your nervous system can react to it, and then once it like destroys the actual like lower thing of the virus it keeps it in its memory how to fight it. And then when you actually get the virus, it just like fights it off.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“They inject you with a shot that has enough medicine. It gives you a little bit of the disease, but your body learns. It’s just enough where your body can fight it off, so that way if you actually do get the disease, your body knows how to fight it off already, and it will fight off the disease faster.”</td>
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<tr>
<td>Misunderstanding that vaccine would be curative</td>
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<td>“A lot of people suffer, so just to think that there is a cure for HIV, like that’s a big thing.”</td>
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<tr>
<td></td>
<td></td>
<td>“But how long will it take to actually help the cure?”</td>
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<td></td>
<td></td>
<td>“So, if they’re sick, you know, they can better their life, getting these vaccines, and then they can live their life to the fullest.”</td>
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<tr>
<td></td>
<td></td>
<td>“I think they’ll be like, he doesn’t look like he has HIV. He looks pretty healthy. I’ll give him the placebo.”</td>
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<tr>
<td>Therapeutic misconception</td>
<td></td>
<td>“Because if a person is sicker, they’re not going to give them the placebo. They’ll probably give them the vaccine. And if a person is not all right but not as bad as the other one, they’ll give them the placebo.”</td>
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<tr>
<td></td>
<td></td>
<td>“The healthier you look, they’ll probably give you the vaccine.”</td>
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<td></td>
<td></td>
<td>“To see if maybe there’s something in my body that is immune to something that’s in the placebo or the vaccine. So they would have to run tests to see which one is the right one for me.”</td>
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</table>

Abbreviation: HIV, human immunodeficiency virus.

HIV test vaccine trial might have false-positive results on a standard, commercially available HIV antibody test.

Focus group participants were told that vaccine trial participants would be provided with a more specific HIV test at no cost, one that does not give false-positive results. Assurance of access to a more accurate test was not enough to offset concerns about the adverse impact of false-positive results from standard tests. Participants stated that the idea of falsely testing positive would produce negative feelings, would make many people feel scared, could mislead participants, could cause problems for participants, and might discourage teens from joining a trial.

Participants provided mixed responses as to whether teens participating in a vaccine trial would continue to protect themselves from HIV. Although they believed that some teens would continue practicing safer sex, many teens believed it would be difficult to persuade a subset of their peers to continue using condoms to help prevent HIV if they entered a vaccine trial. Teens discussed the importance of emphasizing that the HIV test vaccine cannot be relied upon to protect HIV vaccine trial participants from contracting HIV. Several participants stressed the importance of repeating the message to make certain the information is heard (Table 3).

### Preference for Timing of Parental Involvement in the Assent Process

Participants discussed a range of preferences for the timing of parental involvement in the assent process. Some teens wanted to decide independently whether to par-
participate in a trial before obtaining their parents’ permission. Their reasons included not wanting parents to influence their decisions or to lecture them regarding information in the assent form, not wanting information in the assent form to reveal anything to the parent about the teen’s behaviors, and wanting to be independent and treated like responsible persons. Several participants stated a preference for leading their parents through the assent form to influence their parents’ decision. Other teens preferred to make the decision together with their parents. These adolescents believed their parents know them and their medical history better than the teens themselves do, can explain concepts that the teens do not understand, are trustworthy and reliable, and have collaborative relationships with their adolescent children (Table 4).

Table 3. HIV Vaccine Trial Specific Concepts

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Representative Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reaction to possibility of false-positive</td>
<td>General</td>
<td>“So you’re saying the vaccine, when they give it to you, it will automatically say you have HIV even if you don’t?”</td>
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<tr>
<td>of false-positive HIV antibody test result</td>
<td></td>
<td>“For how long?”</td>
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<tr>
<td>Scared</td>
<td>Scared</td>
<td>“Even if you don’t have it, somebody’s saying you’ve got HIV is scary.”</td>
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<tr>
<td>Could mislead people</td>
<td>Scared</td>
<td>“You could think in your head yeah, well, I got the vaccine, and it says I’m positive but I’m not. I know I’m not, that doesn’t mean you’re not.”</td>
</tr>
<tr>
<td>Cause problems for trial participant</td>
<td>Cause problems for trial participant</td>
<td>“Like let’s say your partner, for some reason, wants you to take an HIV test, but you can’t travel there, so he or she wants you to get a regular test, and you keep on telling them oh, the doctor, researcher told me that if I get a regular one, it’s going to be positive even though I don’t have it. That might put worry into their partner.”</td>
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<tr>
<td>People won’t participate</td>
<td>People won’t participate</td>
<td>“If you don’t lose everybody, you’re going to lose a good handful because something like that, it is life changing.”</td>
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<td></td>
<td></td>
<td>“But for the average person trying to decide whether to be in the study or not, that could be a deal breaker.”</td>
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<tr>
<td>Disinhibition</td>
<td>Would continue to use</td>
<td>“If it’s not broke, don’t fix it. Like old habits die hard, so if you’re using condoms already, why stop now just because some little vaccine that you don’t even know if it’s going to work, comes into play.”</td>
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<tr>
<td></td>
<td>condoms</td>
<td>“But then there are some other people that would be like, they’ll take that to heart. They’re okay, all right, but I’ll take that extra step on protecting myself even though I have the shot.”</td>
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<tr>
<td></td>
<td>Would not continue to use</td>
<td>“If you did tell them that, oh, well, this is not 100% sure, I think that people our age still might not be taking it very serious. Oh, well, I got the shot and they could be wrong. I don’t care.”</td>
</tr>
<tr>
<td></td>
<td>condoms</td>
<td>“Let’s say they end up, oh, well, I got the vaccine, so I’m protected from HIV, so now I can go have unprotected sex. So they’re thinking they’re protected the whole time and they end up messing up.”</td>
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<tr>
<td>Depends on the Individual</td>
<td>Depends on the Individual</td>
<td>“I think that like 50-50. Say if you take a big group of people and just divided them, I think each of them would think their own way.”</td>
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<td></td>
<td></td>
<td>“Yes, like if you care, you’d be more protective or what not. But then if you don’t care, you’re going to depend on it.”</td>
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<tr>
<td>Important to repeat the message</td>
<td>Important to repeat the message</td>
<td>“I don’t know. It depends who the person is.”</td>
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</table>

Abbreviation: See Table 2.

Table 4. Preference for Timing of Parental Involvement in the Assent Process

<table>
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<tr>
<th>Theme</th>
<th>Representative Quote</th>
</tr>
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<tbody>
<tr>
<td>Teen decides before involving parent</td>
<td>“I would feel uncomfortable like going through that with my mom, and then I’m going to have to hear her giving you, like, the whole speech...”</td>
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<td></td>
<td>“Because I don’t really like talking to my mom about personal stuff like that, so I probably would go by myself and then talk to her about it.”</td>
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<td></td>
<td>“I think less would want to do it with their parents, because most teens like, like to do things by themselves, more independent, than depend on their parents.”</td>
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<td>Teen decides together with parent</td>
<td>“Maybe to you it’s important for them to be there for you and get their thoughts on everything.”</td>
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<td></td>
<td>“Because they probably know better than you do.”</td>
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<td></td>
<td>“And maybe they know something about a certain reaction you’ll have to a certain medicine that you don’t know about, but your doctor and your mother know about it, and then you find out after the fact.”</td>
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</table>
Many of the teens in our sample knew very little about research concepts that are complex yet necessary to understand to provide informed assent. Even after receiving detailed explanations about several of these concepts, many teens continued to have difficulty grasping important points. Given what is known about adult understanding of information provided during the informed consent process, these findings are not surprising. Nevertheless, they are concerning. Obtaining informed consent and assent is essential to the conduct of ethical research and is a fundamental component of respect for persons and their autonomy. However, in practice, the goal is frequently not attained. A troubling number of studies have revealed that most adults understand very little about what is presented to them during the informed consent process, and the few studies conducted with adolescents have found similar results.

Very few interventions to improve adolescent understanding of information presented during the assent process have been conducted. Tait et al modified a standard assent form for a study on postoperative nausea and vomiting by reducing the reading level to seventh grade, using bullets and bolding, increasing font size, and adding pictures. The modified form did improve understanding; however, participants thought they understood the information better than the measured levels of understanding indicated.

Murphy et al simplified a 35-page booklet explaining an HIV vaccine trial by reducing the reading level, using pictures to illustrate key concepts, eliminating redundant text, and reorganizing information to improve flow. A randomized trial among adolescents comparing the simplified, picture-based version with the booklet demonstrated much better comprehension among participants assigned to the simplified version, but more than 25% did not understand that people who join the study could still be susceptible to catching HIV and that standard HIV tests may show false-positive results.

Our findings demonstrate that teens recognize the need to understand the potential adverse effects of an intervention, want to know the extent of previous research that has been performed, and want to know what is expected of them before making a decision about participation. Nevertheless, key research concepts such as randomization and the difference between research and clinical care are hard for most to grasp. Concepts specific to the science of an HIV vaccine study were also very hard for these teens to understand. One might look at our findings and conclude that adolescents should not be allowed to share in the study participation decision-making process because they have difficulty understanding key concepts. However, this problem is not unique to adolescents.

With respect to vaccine trials, many concepts were difficult for teens to comprehend. Attention must be directed toward developing effective ways to explain these concepts when soliciting assent from adolescents in any future vaccine trials, including those targeted at HIV. Special effort must be undertaken to effectively communicate the many reasons why a study injection may not protect someone from contracting an HIV infection. Participants’ statements supported our concern that participation in an HIV vaccine trial could lead to disinhibition by trial participants, which could then put them at greater risk for HIV infection.

In addition, the possibility of trial participation leading to the development of a false-positive HIV antibody test result was difficult for our participants to grasp. It is crucial that teens understand this concept before joining a trial, because when our participants acquired a better understanding of the concept, many indicated reluctance to participate in a future trial. If this essential information is not effectively conveyed, adolescents’ ability to provide truly informed assent for HIV vaccine trials will be jeopardized.

It is important to consider teens’ preferences regarding when to involve their parents in the decision-making process. Preferences may differ depending on the nature of the trial. For instance, an adolescent may have a different preference if considering participation in a cancer chemotherapy trial compared with participation in a vaccine trial. In either situation, parental permission will be necessary for participation. However, if an adolescent has no interest in participating, then perhaps there is no need to involve a parent. Conversely, a parent may be able to help his or her adolescent understand the study better such that the teen decides that he or she does want to participate. Although it may be neither feasible nor desirable to present a cancer chemotherapy trial to a teen before discussing it with a parent, it may be appropriate with a vaccine trial. Either way, our results highlight the importance of involving teens in the decision-making process and optimizing their ability to understand the information presented to them.

There are limitations to this study. Our participants were recruited from the same city, and their responses may not be generalizable to adolescents from other parts of the country. Nonetheless, we were able to recruit an urban, mostly minority sample of teens from community-based venues. The teens who participated in our study were recruited from a convenience sample of easily engaged youth. As a result, they do not represent youth for whom the greatest barrier to study participation may be engagement in the assent process. It is also possible that our findings may not be generalizable to obtaining assent for other types of studies. However, many of the issues discussed are common to most trials, and our findings have the potential to inform the development of better assent models for a wide range of studies.

Information from this formative process will be used to develop and to evaluate an interactive computerized assent model for use with a future HIV vaccine trial. Other applications of our findings include assent for cancer chemotherapy trials, asthma trials, and diabetes mellitus trials as well as consent for adult trials.

Lack of understanding about key research issues is a problem for research participants of all ages. We suggest that further study is needed to develop interventions that will improve understanding of the information presented during the research assent process. We are evaluating the use of a computerized assent process...
as one possible approach to improving adolescent understanding of key trial concepts. Approaches that are found to work for adolescents can be adapted to adult populations.

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Author Contributions: Dr Blake had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Blake and Mazor. Acquisition of data: Blake and Lemay. Analysis and interpretation of data: Blake, Lemay, Kearney, and Mazor. Drafting of the manuscript: Blake and Lemay. Critical revision of the manuscript for important intellectual content: Blake, Kearney, and Mazor. Obtained funding: Blake. Administrative, technical, and material support: Lemay. Study supervision: Blake.

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REFERENCES


That's the whole problem with science. You've got a bunch of empiricists trying to describe things of unimaginable wonder. —Calvin
—Calvin and Hobbes comic strip, by Bill Watterson

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