

SMART Project: Recruitment, Verbal assent, & enrollment procedures by phone
(Decisional Capacity Test)

Verbal Assent/Consent

Staff member will email/text potential participant for the best time to call.

- a. If participant refuses to set up a phone call, texting and email are also options. The following will be made available through redcap, including the decisional capacity test, so participants can assent/consent electronically. * Participants will still have to perform a quick identity check through facetime, skype, Google Duo, Google Hangouts, or Facebook messenger with study staff or upload a photo ID to a secure server at Northwestern; and this will be conveyed to participants so they know at some point, they will need to video chat with staff or upload a photo ID.
 - b. If the participant is hesitant about any contact, offer to email them a PDF of the assent/consent document, and to read it carefully. If this is the case and they are interested in continuing, schedule a call, and complete the following 5 steps during the call. After that, skip to “Capacity to Consent”, and finish the script from there.
2. Upon successful contact with participant and setting up a time to talk, staff member will ask if it is still a good time to talk and give estimate of how long call will be (usually 15-20 min). If not, arrange time for callback with same staff member.
 - a. *Hi XXX, my name is XXXX and I’m with the SMART Project at Northwestern University Are you in a place where you can talk privately for about 15 minutes?*
 3. Staff member to introduce self and orient potential participant to purpose of call.
 - a. *In this call I’ll make sure you’re eligible for the study and tell you more about what’s involved in the study details. I will also give you the opportunity to ask me any questions that you might have about the project. If you are eligible, I will tell you more about the next steps.*
 4. Staff member reads assent script.
 - a. *Now I’m going to tell you more about the study and why we’re doing it. You saw some of this info when you completed the survey online, but I just want to make sure you have all the information. You’ll have some time after to ask me any questions you have, and then I’ll ask you some questions to check your understanding of the study in a minute.*
 - b. Read the following assent/consent script and capacity to assent/consent assessment in conversational tone.

Title of Research Study: A pragmatic trial of an adaptive eHealth HIV prevention program for diverse adolescent MSM (IRB STU#00201997)

Investigator: Brian Mustanski, PhD

Supported By: This research is supported by Northwestern University and the National Institute of Minority Health and Health Disparities (U01-MD011281-01).

Key Information:

Here is a short summary to help you decide whether to be a part of this study.

The SMART Project is an online sexual health education program specifically for teen guys who are gay, bisexual, queer, or attracted to other guys. The purpose of the study is to test out how well the program works to help teens prevent HIV/STIs.

You'll be asked to complete a total of 5 surveys and go through different parts of the program. You'll login to a website to watch videos and read about topics like coming out, dating, and HIV/STIs. Depending on which parts of SMART you get, you may also chat with a trained counselor.

We expect you'll be in this study for 1 year.

The main risk of being in the study is you may feel uncomfortable answering survey questions or viewing some of the content.

We cannot guarantee that being in the program will help you in any way, but the information we collect will be used to help make HIV prevention programs better for other teens like you.

Why am I being asked to take part in this research study?

You're being asked to take part because you're a 13-18 year old adolescent male who identifies as gay, bisexual, queer, or attracted to other guys, and have had sexual contact with another person.

What should I know about a research study?

- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

What happens if I say "Yes, I want to be in this research"?

First, you'll complete a survey asking questions about your sexual health and life experiences. Then, you'll receive an email with a link, which will take you to a website where you'll create an account and go through the first part of the program.

You'll be asked to complete another survey every three months and you may get randomly selected (by a flip of a coin) to do other parts of the program along the way (such as video chats with trained counselors or more videos and activities on the website). The study staff will contact you when these new parts of the program are open and every three months when it's time for you to complete another survey. Each time you complete a survey, you'll get a \$25 gift card.

Will being in this study help me in any way?

We cannot guarantee that being in the study will help you in anyway, but you may:

- Learn things about health and sexuality that you didn't know.
- Enjoy answering some of the questions or viewing some of the content.
- The information we collect will be used to make HIV prevention programs better for other teens like you. You may receive a benefit in knowing that you have helped other teens.

Is there any way being in this study could be bad for me?

- It's possible someone may find out you're in this study if they see the website and content on your phone or computer, so we ask that you please answer questions and view content in a private area.
- Video/interactive content was rated to PG-13 criteria by the Motion Picture Association of American and the Federal Communications Commission. Even with the PG-13 rating, some of these topics could make you feel uncomfortable.
- You may also feel uncomfortable answering survey questions about sex, emotional health, and alcohol/substance use.

What happens if I do not want to be in this research or if I say "Yes", but I change my mind later?

You can drop out of the study at any time and it will not be held against you. If you decide to drop out of the study, please contact study staff at smart.project@northwestern.edu). Should you end your participation mid-study, we'll keep your data unless you tell us you don't want us to.

What happens to the information collected for the research?

The study team will work very hard to make sure your information is kept private. Some people might review our records that may identify you to make sure we are following the required rules. For example, the Northwestern University Institutional Review Board or the National Institute of Minority Health Disparities (who funds the project). If they look at our records, they'll also keep your information private.

We'll give you a study ID number so your name is not connected with your surveys. When we analyze your survey data, we'll remove any identifying information. Personal information such as your name, phone number or e-mail, will not be released to anyone without your written approval. Only study staff that need this information to contact you will have access to it. Staff members may contact you to remind you about completing surveys and when different parts of the program open. We'll only contact you using contact information that you approved and we'll use discretion if you request it (this means we will not tell anyone who is calling or why we are calling).

The link between your study ID name and your contact information will be destroyed after the completion of the study. The data that only has your ID number on it will not be destroyed. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept private.

We have a Certificate of Confidentiality from the National Institutes of Health. This is a legal document that helps us protect your privacy. It protects us from sharing information that may identify you in any legal or government actions, like if a court asks us for your information. It protects us from sharing information with anyone who isn't involved in the research except, if there's a law that requires us to

share it (like to report child abuse, see below) or if you tell us to share your information. If you want your information shared with anyone who isn't involved with this research, you must tell us to share it.

If you tell us you are hurting or planning to hurt a child, or you're planning to hurt yourself or another person, or someone has hurt or abused you, we're required to report it to the appropriate agencies for your safety and the safety of others.

What else do I need to know?

Because this is all done online, it's important to make sure you are who you say you are. You can do this one of several different ways:

1. Upload a photo ID that should have your name and your photo to our secure server at Northwestern. This can be a state/government-issued ID or a school ID. This will be deleted after it is reviewed by study staff (after 72 hours). If study staff have any concerns about whether the photo ID you sent is real or belongs to someone else, we may request to do a video chat to verify your identity.

Or, if you don't have a photo-ID or don't feel comfortable sending us a picture.

2. You can (live) video-chat with our staff so we can see you and ask you additional questions.

This check is necessary and needs to be done before we can send you your first survey. If you send us the picture to our secure server, it will be deleted after being reviewed by study staff, usually within 72 hours or 3 days after being received by us. We will not be keeping it on file.

To be in the program, you must also be able to read written English, have reliable and private access to the internet and a smart device (a smart phone, laptop, desktop or tablet), and be willing to take part in a video-chat and/or phone call with trained counselors if asked.

We'll send you a \$25 online gift card for each survey you complete. You will not get paid if you decide to stop being in the study or if you don't complete the surveys. If you don't use the gift card within 6 months, it will lose \$3 for each following month that you don't use it.

In addition to the \$25 gift cards you get paid for completing each of the surveys, you may be eligible for raffles to win \$25 Amazon e-gift cards. Staff will announce raffles throughout the year you're in SMART. You'll be able to stay in the study even if you don't take part in the raffles.

Can I be removed from the research without giving my OK?

The person in charge of the study can remove you from the study without your approval. Possible reasons for removal include: The team believes it is in your best interest; You did not agree with any changes that may (or may not) be made; The research team believes that you do not understand the purpose or instructions of the program; The research team believes your identity to be fraudulent or misrepresentative; You do not conduct a quick facetime/video chat with research staff or upload a photo ID to verify your identity; Or for any other reason.

Who can I talk to?

If you have any questions about the study you may contact the person in charge of the study, Dr. David Moskowitz, by phone at [REDACTED] or email at [REDACTED].

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Do you have any questions about the information I just read to you about the study?

[Answer any questions youth has and proceed to Capacity to Consent]

Now I have a few questions for you before we can ask you to verbally assent/consent to participation into the study:

- What will you be asked to do in this study?
 - A. Have my blood drawn
 - B. Test how medication works
 - C. Be asked about my knowledge and attitudes about HIV/STIS, my previous sexual behaviors, and to use a smart device to watch sexual education programming (correct response)
 - D. Talk about my hometown
- Please name a potential risk of participating in the study.
 - A. Upset stomach
 - B. The researchers might tell my parents I'm in the study
 - C. Feeling uncomfortable answering questions about myself to researchers (correct response)
 - D. Computer viruses
- If I have problems within the study or want to stop participating, I should immediately talk to:
 - A. Project staff
 - B. The principal investigator (the head of the study)
 - C. The Institution Review Board at Northwestern University
 - D. Any of the above can help (correct response)
- When viewing the program videos and playing with the activities on my device, I should make sure:
 - A. My homework is done first
 - B. No one is around (especially people who you don't want to know you're in the study) (correct response)
 - C. To use a public smart device
 - D. My friends are around

Respondents will be eligible to proceed to identity verification process only if they are able to provide all of the correct answers each of these items. If they don't know the answer immediately you can offer to re-read the assent form for more information before they answer.

If respondents are ineligible based on their decisional capacity:

- "Based on all of your answers to our study questions it turns out that you are not eligible for this particular study. We really appreciate your interest in participating and willingness to answer all of the screening questions. Thank you so much for your time."
- If respondents ask why they aren't eligible: "We make decisions about eligibility based on all of the information that you have provided to us so far in the screeners and in the questions I just asked you. Unfortunately for scientific reasons I can't tell you which questions led you to not be eligible for this particular study." If they press you for an answer after you have said "no" several times I would blame it on your "boss" (i.e., "I really wish I could tell you, but I would get in trouble with my boss if I broke that rule.").

For respondents who are eligible: We need to get your verbal assent/consent. Do you agree to take part in this study?

- Participant must clearly say, "yes, I assent/consent to participating in this study."
- For those who assent: Great! I can email you a copy of this form that I just read to you that has all this contact information on it, if you would like. You will also receive some instructions by email that will help you begin the research study. Those instructions will have project contact information along with the contact information for the Institutional Review Board at Northwestern.
- For those who don't assent: Thank you for your time. We respect your decision not to take part in the program. To help us design future studies, can you please tell me why you decided not to take part?

5. If youth does not agree to participate, note reason why in REDCap > Interactions section.
 - a. *Thanks for your time and have a nice day!*

6. If youth agrees to participate, proceed to next section while youth is still on phone.

Enrollment following/during the phone call

1. Here is how it will work...

- *We will need to do an identification check by having a quick (less than one minute) facetime/videochat with you or you can upload a photo ID that has your name and your photo to our secure server at Northwestern. Which would you prefer?*
- If participant says photo ID: Okay, sounds good, we will send you the link to the secure server to upload your photo ID after we get off the phone. After we verify your ID, we will send you the link

to your first survey. [Next steps are explained to participant and all questions regarding the study are answered.]

- *If participant says video chat: Is now a good time to complete your video chat?*
- *If participant says this is not a good time then attempt to schedule a time to complete the video chat.*
- *If participant says it is a good time then call participant via their preferred contact method.*
- For participants who are available to complete video chat a staff member will review the following eligibility criteria, comparing these answers to those given on screener.
 - a. *What is your full name?*
 - b. *What is your email address?*
 - c. *Can we text that phone number?*
 - d. *Can we call that number?*
 - e. *Can we leave a voicemail at that number?*
 - f. *What is your date of birth?*
 - g. *How old are you?*
 - h. *What username would you like to use for your SMART account? (This username cannot contain any identifiable information.)*
- If respondents are ineligible based on their responses:
 - a. *"Based on all of your answers to our study questions it turns out that you are not eligible for this particular study. We really appreciate your interest in participating and willingness to answer all of the screening questions. Thank you so much for your time."*
- *If all the answers match with the answers given on the screener then participant has successfully completed the video chat and can be enrolled in the study.*
 - a. *Next steps are explained to participant and all questions regarding the study are answered.*

Post-enrollment

1. Update information in REDcap > Overview (e.g., Staff member that completed ID check, and baseline status)) and REDCap > Interactions (staff's initials, mode and content of contact, and result of attempt)
2. Participant will automatically receive an invitation to their baseline after successful completion of video chat or verification of photo ID.
3. Email the instructions/contact information for the study to the participant and in the email indicate if they would like the pdf of the consent form.