

Columbia University Medical Center

Consent Form to Participate in a Research Study and HIPAA Authorisation

WHY IS THIS STUDY BEING DONE?

The purpose of this form is to give you information to help you decide if you want to take part in a study. The study coordinator will discuss the study with you. Any time you have questions about the study, please ask the study coordinator or another member of the study team. Take all the time you need to decide whether you want to take part in this study.

You are being asked to take part in this study because you are a young man, 15 to 24 years old, and you have had sex with a woman in the last 3 months. We are inviting young men to take part from the Young Men's Clinic and from clinics from schools in north Manhattan (George Washington Educational Campus and JFK Campus).

WHAT IS INVOLVED IN THIS STUDY?

You will be randomly chosen (like flipping a coin) to take part in one of the two MI projects, and you will get coaching and use an app for that project to improve your health. One project is on teen pregnancy prevention and the other is on healthy eating, physical activity, and avoiding cigarettes. You will use an app on your phone to do the project, answer survey questions, keep track of your health, and learn more about healthy behaviors.

Whether you're in the pregnancy prevention or fitness project, you will get four 30- to 40-minute sessions of one-on-one coaching with a health coach over 12 weeks (3 months). Each coaching session will be focused on you and your personal goals. You can have the coaching sessions by phone or video call.

The two projects take the same amount of time. The only difference is what coaching you will get (pregnancy prevention or fitness). Because what you get is random, you cannot choose which program you will get.

During your first or second coaching session, you will choose some health behaviors you're ready to change, and your coach will help you create a "change plan" to make those changes. In later sessions, you will review and discuss how your change plan is going, what's working, what's challenging, problems you're facing, and people who can support you.

If you agree, you would take part in this study for 64 weeks (about 15 months), using the app. If you agree, you will be asked to complete a survey with health questions before your first coaching session, right after your last session, and then 3 months, 6 months, and 12 months after your last session (5 surveys total). The survey has questions about your health and behaviors, and takes about 30-35 minutes to complete on the app. If you agree, you will also be asked to answer a few questions (about 4 minutes) every other week for the same time period (15 months). You will use the **app on your cell phone** to complete all these surveys. You earn money for each survey you complete.

Permission for future contact

The study team may want to contact you in the future. After this study ends, the same team may offer you a future study or studies on men's health that might interest you. If you agree to be contacted, this will occur at the most 4 times a year.

Please initial below to show whether or not you give permission for future contact.

___ (initial) I give permission to be contacted in the future for research purposes.

___ (initial) I give permission to be contacted in the future for information relating to this study.

Audio recording

We are asking you to allow us to audio-record your coaching sessions as part of the study.

There are two reasons we're asking to record your sessions. First, we want to make sure that the coaching sessions are of high quality and the coaches get feedback to better support you and other participants. Second, we would like to use the recordings as part of our research into young men's health goals, their plans to achieve them, and any barriers they faced in achieving their health goals. You will not be paid for either use.

The recordings will only be audio (sound), even if you do your session as a video call. The recordings may include your name, as your health coach may say your name during a coaching session. If you agree to let us use your recording for research, the recording may be transcribed (written down) for analysis, at which time we would remove your name and any other details that could identify you.

The recordings and any written version will be stored electronically on a secure server in the medical center. The recordings will be deleted either after they are transcribed or within 5 years of the end of the study.

App usage tracking

We would like your permission to track a few basic things about the way you use our app. In order to improve the way we design apps for young men like you, it would help us to know what time you get on the app, how long you spend using it, and which activities you're doing during that time. This data will not be connected to you in any way, and will only be looked at by our study team. We will never sell or give your information to advertisers or any other company.

WHAT ARE THE RISKS OF THE STUDY?

Sensitive Topics

You may find some of the questions sensitive and personal. It is possible that you might feel some stress answering some questions. If answering makes you feel uncomfortable or upset, you can skip them. If any of the questions during the coaching sessions make you feel uncomfortable or upset, the coach or the study coordinator can refer you for counseling or other additional services.

Loss of confidentiality

A risk of taking part in this study is a possible loss of confidentiality. The study team has strong plans to protect your confidentiality, which you can read about in the "What About Confidentiality?" section of this form. However, it's possible that someone who is not on the study team could see your personal information despite our best efforts.

Criminal or Civil Liability - Child Abuse

If you give us information which suggests that you, your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

Criminal or Civil Liability - Illegal Activities

Telling us about your involvement in illegal activities may result in criminal penalties and/or prosecution if your identity is revealed. In some cases, we may be required to report such information. However, we have been given a Certificate of Confidentiality for this study. Therefore, information that you may share with us about your involvement in illegal activities is protected. But if you give us information that you may hurt yourself or someone else, we must report this information to the authorities.

The Department of Health and Human Services (DHHS) has given us a Certificate of Confidentiality for this study. This certificate will protect the study team from being forced to release any information you give us in which you are identified, even under a court order or subpoena. This protects you from being identified in any civil, criminal, administrative, legislative or other proceedings whether federal, state, or local.

This protection, however, is not absolute. Because this research is sponsored by the Centers for Disease Control (CDC) and the Office of Adolescent Health (OAH), staff from these or other DHHS agencies may review records that identify you. However, it is the policy of these agencies and of the investigators that every attempt will be made to resist demands to release information that identifies you. The Certificate of Confidentiality does not represent an endorsement of this research project by the Secretary of Health and Human Services. In addition, representatives from the Columbia University Medical Center Institutional Review Board (CUMC IRB) may examine your study record and may contact you regarding your participation in this study. It is also possible that representatives from the Office of Human Research Protection (OHRP) may inspect your study records.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

It is possible that you may benefit from this study. You may learn ways to improve your health, or feel supported to make a healthy change for yourself. You may also benefit from knowing that you are helping us learn how this kind of coaching can help young men make changes in their lives, and that the information collected from this research may help others in the future.

WHAT ABOUT CONFIDENTIALITY?

Confidentiality Protection

We will keep all your data confidential. Your name will not be connected to your data. Instead, you will receive an ID code that's different from everyone else who takes part. Only project staff will be able to see your name and ID code.

Your name will never be written in any of our reports. We will store all your data on a secure server that only certain members of the project team can access, and we will destroy the data and documents with your name when we are done. We will not tell anyone what you wrote.

You may be chosen for medical record verification, which would mean we look at your medical record and check a few things. These are the things we would check: whether you had an appointment at one of our clinic sites and whether you had an STI test.

Certificate of Confidentiality

Your records in this study are strictly private. No one other than study staff can ever look at them unless you agree to it. This is because the study has been granted a Certificate of Confidentiality under a federal law [Section 301(d) of the Public Health Service Act]. This means that the records of this study may not even be called into federal, state, or local court without your OK. That applies forever.

The Certificate of Confidentiality does not stop you or a member of your family from telling others about yourself or your involvement in this research.

You should also know that this Certificate does not protect you from our responsibility to report certain communicable diseases, suspected child abuse, or danger of physical or mental harm, to appropriate agencies or authorities.

WILL I GET PAID?

Over the course of the study, you will be paid up to \$240 for your time completing surveys. The amount you get paid depends on how many surveys you complete.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study.

DO I HAVE TO BE IN THE STUDY?

It is your choice to take part in this study. You can decide not to take part or to stop being in the study at any time.

Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and New York-Presbyterian Hospital, The Young Men's Clinic or the George Washington Educational Campus or JFK Educational Campus School Based Health Centers.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions or concerns about the study, you may contact Dr. David L. Bell, MD at (212) 304-7737) or Dr. Melanie Gold at (646) 740-6525.

If you have any questions about your rights as a participant, you may contact:

Institutional Review Board

Columbia University Medical Center

722 West 168th Street, 4th Floor

New York, NY 10032

Telephone: (212) 305-5883

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

STATEMENT OF CONSENT

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this assent form. I will be given a copy of this form to keep for my records.

**Participant
Name**

Signature

Date

**Investigator
Name**

Signature

Date