# Dr. Eric

# Informed Consent

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## NCT04969289

**Department of Emergency Medicine**

**Approved: 4.22.2022**

# Columbia University Information Sheet Form

## Protocol Information

**Attached to Protocol:** IRB-AAAT6680
**Principal Investigator:** Lauren Chernick (lc2243)
**IRB Protocol Title:** Improving Male Health in the Emergency Department

## General Information

**Consent Number:** CF-AACN7100
**Participation Duration:** 16 weeks
**Anticipated Number of Subjects:** 130

**Research Purpose:** The purpose of this study is to understand if a mobile health intervention from the emergency department can improve adolescent sexual health.

## Contacts

| Contact | Title | Contact Information |
|---|---|---|
| Lauren Chernick | Principal Investigator | Phone: 212-305-6628 |

## Information on Research

### Introduction

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:
- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

The principal investigator (the lead researcher for this project) Dr. Lauren Chernick or a trained researcher will discuss the study with you. If at any time you have questions about the study, please ask. Take all the time you need to decide whether you want to take part in this research study.

## What information is on this form?

We are asking you to take part in a research study. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (researchers) would like to use and share information about you. Please take the time to read this form and ask questions.

## Why is this study being done?

We are doing this research study to find out how a personalized and interactive app followed by text messages can affect the reproductive health choices of adolescent male patients. We also want to learn if it is feasible to deliver the app in the emergency department, if you like it, and if it changes the choices males make. You are being asked to take part in this texting study because you are a male patient.

## What will I be asked to do if I choose to be in this study?

If you agree to be in this study, you will be selected to be in one of two groups. One group will interact with the app and then receive weekly text messages over the next 12 weeks and the other group will not. At any point, you can "opt out" and can stop receiving messages. Message and data rates may apply. In other words, when you get our texts, the only cost to you is whatever your wireless provider charges you to send and receive text messages. If you have an unlimited text messaging plan, then you don't have to worry.

Today, we will collect information about you, including demographics, prior use of medical care, and sexual behaviors. In 12 weeks, we will review your Columbia University Medical Center and/or NewYork-Presbyterian Hospital electronic medical records and collect information, such as if you saw a doctor. We will also contact you for follow up in four ways: phone call, text message, email, and direct messaging via Instagram. You can refuse any of these methods.

All participants who complete 12 week follow up will be offered to receive condoms by mail. Those participants will be contacted at 16 weeks to collect feedback and if the condoms were received.

# Risks

We think that the only risk in participating in this study is to your confidentiality. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. However, this project does not involve collecting health information that may be considered sensitive. Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number, email, or social media information or any other direct identifiers unless disclosure of the information is required by law or you have authorized the disclosure. Your phone number will be shared with a secure mobile platform company, who has committed to keep your number confidential.

# Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do

everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your information will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your medical record number and home address to the code number will be kept in a secure computer and only the investigator and authorized study staff will have access to the file. Your information collected as part of this research, even if identifiers are removed, may be used or distributed for future research studies. The following individuals and/or agencies will be able to look at, copy, use, and share your research information:

- The investigator, Columbia University Medical Center and NewYork-Presbyterian Hospital study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University, including the Institutional Review Board ('IRB')
- The Office of Human Research Protections ('OHRP')
- The National Institute of Health (NIH)
- Our data and safety monitoring board

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring US government agency from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Your authorization to use and share your health information will expire when the research is completed. Once your health information has been disclosed to a third party (for example, a mobile platform company participating in a study), federal privacy laws may no longer protect it from further disclosure. You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Dr. Lauren Chernick. However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

## Benefits

You will not receive any direct benefit from participating in this study. The possible personal benefits of taking part in

this study include learning about preventing partner pregnancy and infections.

## Compensation

We will give you a $10 gift card to pay you for your time. You will also be entered into a raffle to receive a $100 gift card if you complete follow up. You may also have the option to receive a one-time delivery of condoms to your home in a discrete package. All participants who complete follow up will be offered a delivery of free condoms.

## Voluntary Participation

Taking part in this study is voluntary and your choice. You can decide not to take part in or 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 NewYork-Presbyterian Hospital. You may also choose to not provide your email or social media information for follow up.

## Additional Information

**Contact**

You may call Dr. Lauren Chernick at telephone (212) 305-9825 if you have any questions or concerns about this research study. If you have any questions about your rights, you may contact the Institutional Review Board at Columbia University, by phone 212-305-5883 or by email at irboffice@columbia.edu.

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. More information about taking part in research studies can be found on the Columbia IRB website at:http://www.cumc.columbia.edu/dept/irb.

## Statement of Consent

Statement of consent and HIPAA authorization

I have read this consent form and HIPAA authorization. The research study has been explained to me. I agree to be in the research study described above. A copy of this information sheet will be provided to me. Another copy will be placed in my medical record. By agreeing to this consent and HIPAA authorization form, I have not given up any of the legal rights that I would have if I were not a participant in the study.