Official Title: Information Visualizations to Facilitate HIV-related Patient-provider Communication in New York City (Info Viz: HIV-NYC)

Unique Protocol ID: AAAS4611

Registration Identifier: NCT04102540

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Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAS4611
Principal Investigator: Rebecca Schnall (rb897)
IRB Protocol Title: Information visualization to facilitate clinician-patient communication in HIV care in New York City: Info Viz HIV – NYC

General Information

Participation Duration: 6 months
Anticipated Number of Subjects: 30 patient participants
Research Purpose: The purpose of this research is to evaluate a new method to teach patients about HIV in a clinical setting. We are asking you to participate in this research because you receive HIV-related services at NYP-CHP.

Contacts

Contact	Title	Contact Information
Samantha Stonbraker	Investigator	Phone: 720-880-8194 Email: slb2201@cumc.columbia.edu

Information on Research

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 and HIPAA authorization 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 risks of participation
- any potential benefits of participation
- options other than taking part in this study that you have

First, we will review this form in detail. If you have any questions while we go through it, please ask. Take all the time you need to decide whether you want to take part in this research study.

After we go over this form together, if you decide you would like to participate in this study, we will both sign the form and then you will get a copy to take home with you. If you want to participate but you cannot sign your name, you can just put your fingerprint on this form, which will tell us that you understood everything that I said and that you agree to participate.

If you agree to participate in this study, we will ask you to complete a questionnaire today as well as during your regularly scheduled clinic appointments at 3 and 6 months. Additionally, if you are interested, we will ask you to complete an in-depth interview about your health and your experiences in this study. That is a total of up to 4 study visits in the next 6 months. We will ask for your permission to place reminder calls to you prior to each study visit.

Summary of all of the visits in the study

Initial visit: (Time to complete: 1 hour)
During today's visit, we will complete a questionnaire together and I will ask you for some additional contact information to help us get in touch with you during the study. After that, we will talk about HIV using infographics, which are a new way to provide patient education.

3 and 6 month visits: (Time to complete: 45 minutes)
When you come back for your normal visits at 3 and 6 months, we will ask you to complete additional study visits where we will complete the same questionnaire and you will receive health education in this new way.

Other study activities:
We will randomly select up to two of our study visits to audio record in order to review how the visit went using the new health education method. Then, toward the end of the study, we will ask if you would like to participate in a 45-minute to one hour interview in which we will discuss your health and your participation in the study. This interview will also be audio recorded. We are also asking your permission to look at your medical record so that we can collect some additional data that we may need.

Risks

There are very minimal risks to participating in this study.

One risk is that you may feel discomfort with some of the questions that are asked while you participate. If there are questions that make you feel uncomfortable, then you do not have to answer them, that is not a problem.

Another risk is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know your information. I want to assure you that the study team is well trained on how to save your data securely and we will do everything possible to keep your information safe.

Benefits

There are some potential benefits from taking part in this study. You will receive health information in a new way, we think this could help you learn more about HIV and how to manage it. Additionally, your participation may help us learn how to better provide services to the people who come to this clinic.

Alternative Procedures

You may choose not to take part in this research study.

Confidentiality

Any information collected during this study that can identify you 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.

For the audio recordings, only the study team will have access to them and they will be stored in an encrypted password protected computer that is kept in a locked office space. We will send them to a secure service who will transcribe them.

Your data, which will come from your responses in questionnaires, the chart review and in-depth interviews 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 name to the code number will be kept in an encrypted data file that is only accessible through a password-protected computer. Only the investigator and study staff will have access to the file.

It is a possibility that the information you provide us could be used in future research studies without additional consent. If this is the case, we would be certain to remove any information that could identify you prior to its use.

The following individuals and/or agencies will be able to look at and copy your research records

- The investigator, Columbia University Medical Center study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University including the Institutional Review Board ('IRB') who are there to make sure that research participants, such as yourself, are protected.
- The Office of Human Research Protections ('OHRP')
- Persons or organizations working with or owned by the National Institutes of Health
- A secure transcript service that makes professional transcripts will be used to transcribe audio recordings
- Other regulatory agencies responsible for ensuring research participants are protected

This study will be registered with Clinicaltrials.gov, an organization that monitors research studies. Data regarding the study and the results that we obtain will be posted on that website. But nothing that we ever post will have any identifying information.

Once your health information has been disclosed to a third party (for example, a pharmaceutical 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, Rebecca Schnall at rb897@cumc.columbia.edu

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.

Your authorization to use and share your health information will expire when the research is completed.

Certificate of Confidentiality

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. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). 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. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. 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.

Compensation

For your participation in this study, you will receive $25 in the form of a pay card for each time you complete an interview or questionnaire. If you choose to withdraw from the study before it is completed, then you will only receive the compensation for the visits that you have completed.

Additional Costs

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

Voluntary Participation

Taking part in this study is your choice. You can decide not to take part in it or choose to withdraw from the study at any time. Your choice will not affect the treatment you receive at NYP-CHP.

Additional Information

Audio recording

We are asking you to allow us to include audio recordings of you and study team members during study visits.

The recording(s) will be used in order to verify that study team members are using the materials for the study correctly. The recordings will include any information that you and the study team member mention during your study visits. Otherwise, there will not be any other information that will link you to this recording. Like all of the data in this study, we will do everything we can to keep your information confidential. All audio recordings will be stored on a secure computer that is protected by a password.

If you agree to participate in an in-depth interview, we will audio record that interview so we can go back and re-listen to it and to create a paper copy. The recordings will not have any identifying information and will only be linked to you through a code to which only the study team will have access.

We will destroy all of the audio recordings as soon as data analysis is complete.

Confirm understanding

To confirm that you understand everything that we are asking you to do in this study, I am going to read a few statements. When I read each statement, can you please tell me if it is true or false?

1. True or false: If you participate in this study, you will complete up to 4 study visits in the next 6 months. Some of those visits will be recorded.

2. True or false: As a study participant, you will receive reminder phone calls prior to your study visits.

3. True or false: Your participation in this study is completely voluntary, you do not have to participate if you do not want to.

Contact Information

You may call Samantha Stonbraker at telephone # 212-305-5092 if you have any questions or concerns about this research study.

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the Institutional Review Board listed below.

Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
irboffice@columbia.edu

Future Research

If you agree that your data can be used in future research, please initial here: _____

If you agree that we can contact you to participate in future studies, please initial here: _____

Statement of consent and HIPAA Authorization

I have read the consent and HIPAA authorization 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. If I cannot sign, I will place my fingerprint on the line below. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent and HIPAA authorization form to keep for my records.

Signatures

Participant Signature Lines

Print Name_____

Signature or fingerprint _____

Date _____

Researcher/Witness Signature Lines

Print Name_____

Signature _____

Date _____