Principal Investigator: Dr. Samantha Stonbraker
COMIRB No: 20-0123
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Study Title: Information Visualizations to Enhance HIV-Related Communication in Diverse Clinical Settings

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you, go over this complete form with you, and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

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 study because you receive HIV-related services at the Center for Positive Health (CPH).

Up to 82 patients at CPH will participate in the study.

What happens if I join this study?

If you choose to join the study, you will be randomly assigned to either the treatment or control group. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice, so it is completely random which group you will be in. After we complete this informed consent, we will find out which group you are in.

If you are in the treatment group, you will receive information using the new educational method that we are evaluating in this study during your normal visits with your provider and if you are in the control group, you will complete appointments with your provider just like you always do. It is really important to have people in both groups so we know if this new educational method works to help patients or not.

Regardless of the group you are in, we will ask you to complete 4 study visits during the next nine months and today is the first one. At each visit, you will complete a questionnaire. Today you will complete it before you see your provider, then you will complete it after you see your provider at your next three visits (which will take place at approximately 3-, 6-, and 9- month intervals).

Additionally, if you are interested, we may ask you to complete an in-depth interview about your health and your experiences in this study after you complete all 4 of the study visits.

Summary of study visits

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, you will attend your normal visit with your provider. If you are in the treatment group, the provider will use the new educational method during your medical visit and if you are in the control group, your medical visit will be a normal visit.

3-, 6-, and 9-month visits: (Time to complete: 45 minutes)
When you come back for your normal visits at 3-, 6-, and 9- months, we will ask you to complete the same questionnaire and if you are in the treatment group, the provider will use the new educational method during your medical visit and if you are in the control group, your medical visit will be a normal visit.

Optional study activity (45 minutes – 1 hour)

Toward the end of the study, we will ask if you would like to participate in an interview in which we will discuss your health and your participation in the study. This interview will be audio recorded.

Additional considerations

We will randomly select two of your normally scheduled visits with your provider to audio record in order to review how the visit went using the new health education method.

We are asking your permission to look at your medical record so that we can collect some additional data that we may need.

According to current guidelines at Denver Health and your provider's recommendations, you may have the option to choose if you would like to complete your study visits virtually or in-person.

Please note that we will call you to remind you of your appointment before each study visit.

What are the possible discomforts or 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.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the research team to learn more about infographics and how they influence health communication. 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. This information may also be useful to other health care providers and clinics in similar settings.

Are there alternatives?

The alternative is not to participate in this research.

Who is paying for this study?

This research is being paid for by the National Institute of Nursing Research which is part of the National Institutes of Health.

Will I be paid for being in the study? Will I have to pay for anything?

Each time you complete a study visit and questionnaire, you will receive $25. If you choose to participate in the in-depth interview at the end of the study, you will receive $25 for that visit as well. If you complete your study visits virtually, then we can either mail you the gift card or will give it to you at your next visit to Denver Health.

It will not cost you anything to be in the study though you might have unexpected expenses from being in this study, for instance, if you have to arrange for child care while you are here, that will not be covered by the sponsor. Please ask a member of the research team if you have any questions of what will be covered by the sponsor.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

Please feel free to ask any questions that you may have now. If you have questions later, you may call Beatrice Francis, the researcher carrying out this study, at 720-672-0719.

You may have questions about your rights as a participant in this study. You can call Samantha Stonbraker, the Principal Investigator of the study, at 303-724-8281with questions. You can also call the Multiple Institutional Review Board (IRB) at 303-724-1055.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.
These protections apply only to your research records. The protections do not apply to your medical records.
The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

To those connected with the research,
If required by Federal, State or local laws,
If necessary for your medical treatment, with your consent,
For other scientific research conducted in compliance with Federal regulations,
To comply with mandated reporting, such as a possible threat to harm yourself or others,
reports of child abuse, and required communicable disease reporting, or
Under other circumstances with your consent.
A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and the health systems it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Denver Health and Hospital Authority

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate health systems may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Samantha Stonbraker
University of Colorado College of Nursing
13120 E 19th Ave
Aurora, CO 80045
Email: Samantha.Stonbraker@CUAnschutz.edu

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The National Institute of Nursing Research/National Institutes of Health, the organization paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Audio Recordings

Audio recordings from this study will be kept in secure network drives at the University of Colorado Anschutz Medical Campus. Only the research team will have access to the recordings.

Right to access your personal health information

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and demographic Information (age, sex, ethnicity, phone number, level of education, length of time living with HIV etc.)
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to appointments in the clinic, CD4 count, viral load, and current medication regimen

- If you choose to participate in the in-depth interview, anything you say will be audio-recorded
- Two visits will be randomly chosen to be audio recorded, so anything you say in those visits will be part of the recording.

What happens to the data that will be collected from me in this study?

Scientists at the University and the health systems involved in this study are working to improve the health services offered at the Center for Positive Health. The data collected from you during this study are important to this study and to future research. If you join this study:

- Both the investigators and any sponsor of this research may evaluate the data collected from you.
- If any data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures (In-depth interviews)

In this form, you were given the option to agree to additional, optional research procedure, which is the in-depth interview at the end of the study. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

HIPAA Authorization for Optional Additional Study Procedures (Inclusion in database for future recruitment)

We would also like to ask you if we can include your information in a database, so that if any other studies arise, we will be able to contact you to see if you would like to

participate. The only information that we will store in that file is your name and contact information. You will be able to withdraw your information at any time by contacting the researcher listed in this consent form. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Participant

Signature:_____ Date:_____

Print Name:_____

Consent form explained by

Signature: _____ Date:_____

Print Name: _____

Signature:_____ Date:_____

Independent Witness
Print Name:_____