Permission to Take Part in a Human Research Study

05/06/2019

IRB Approval Date

Title of research study: *Feasibility of Screening, Brief Intervention, Referral to Treatment with Peer Navigation (SBIRT-PN) for Underserved HIV+ Adults 50+ in Primary Care Settings*

Investigator: Nicole Ennis, PhD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you reported that you are currently using substances such as drug or alcohol.

What should I know about a research study?

- Someone will explain this research study to you.
- 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.

Why is this research being done?

The purpose of this research study is to understand how to provide you the best care through your treatment clinic. Particularly, we want to understand if the treatments that work outside of this clinic can be changed to work within this clinic environment. We also want to understand what may be related to using substances such as alcohol or other drugs.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 6 months. The entire participation time will require about 3 hours to complete over the course of 6 months. This will consist of 3 Sixty-minute meetings with study team members over the course of 6 months.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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

There may be questions that you may find unpleasant or difficult to answer. Questions will include things such as drug use, pain, and depression. You may refuse to answer any question. We will try to answer any questions you have and discuss any concerns you may have about answering a question. If you are unsure of any of the questions, you may ask the interviewer to explain them. More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no direct benefits to you for taking part in this research study. However, you may learn how information about substance misuse and how it could negatively affect your mental and physical health. In addition, you may also learn some and benefit from tips and strategies that decrease substance misuse.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Nicole Ennis, PhD, Principal Investigator, 305-467-2121

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.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 subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about __40___ people here will be in this research study out of __90___ people total.

What happens if I say "yes" to being in this research?

First, we will ask you to give us a sample of your urine in a cup. Your urine sample will be tested for drugs such as marijuana, cocaine, and opiates. After the testing, your urine will be destroyed. We will keep results using a number code. Your name and other identifying information will be kept separate from these results at all times.

You will then be asked to answer some questions looking at your substance use, substance use treatment, medical treatment, mood and pain. We will use the same number code to keep all of your interview responses confidential. Your name and other identifying information will be kept separate from your interview responses at all times.

You will be randomly assigned (much like the flip of a coin) to one of two groups. One group of participants will meet with a study team member to talk about substance use and the other group will not. Those who do not meet with a study team member will be given additional information on paper about substance use. Group assignment will be done by simple randomization. We will put your number in with all the others and then as we pull each number we will flip a coin to decide which group participants will be assigned to (i.e., group 1 or group 2). Next we will flip a coin to decide which group will be assigned to meet with a study team member versus receiving information only.

Those assigned to meet with a study team member will then meet with a study team member to talk about substance use. The study team member will also give you feedback on your answers to the screening questions. Next, the team member will discuss your substance use history and other factors that may be affected by your substance use such as work or family life. Additionally, the study team member will discuss goal-setting and services that may best help you work towards your goals.

Finally, the study team member will put you in contact with a peer navigator, this person will provide 1-3 follow up calls to check in on the action plans you developed while in the session with the study team member.

Mandatory Reporting: Florida law requires that all study staff must report any reports of child abuse, suicidal or homicidal behaviors to the appropriate authorities. These include physical injury to any child not caused by an accident or information that tells staff a person is in danger of physical harm. If

you report that you may harm yourself or others you may be referred for immediate care. If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

What are my responsibilities if I take part in this research?

Note that only half of the individuals who participate will meet a study team member or do anything extra. The other half will be given feedback and information on how to address substance use through a resource treatment guide. We will then contact everyone by phone and ask you to meet with us again both 3 and 6 months after your first meeting with the study team member for an in-person meeting. During this meeting we will ask you about your substance use treatment, mood and physical health. We will also ask about substance misuse and collect another urine sample.

What happens if I say "yes," but I change my mind later?

You can leave the research at any time it will not be held against you.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

- Psychological risks. Participants may find some questions difficult to answer and it may embarrass them or make them uncomfortable. We have trained the people gathering data to explain why the question is being asked if needed and you can refuse to answer any question.
- Privacy risks and Legal Risks. There is the potential that privacy could be breached. However, this is not likely as all data and computer files will be stored in a locked, secure area, and will only be accessed by authorized personnel. Photocopies of original records and computer files will be de-identified and labeled with a unique subject identifier. Therefore, all assessment instruments and related study data will be identified by number only. All research questionnaires will be stored in locked file drawers or on a secure server accessible only to research staff. To provide additional data security a master key linking identifying participant information with the study number will be secured in a different locked file.
- Economic risks. If privacy is breached it could impact your ability to obtain employment. However, this is not likely as all data and computer files will be stored in a locked, secure area, and will only be accessed by authorized personnel.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization and the National Institute on Drug Abuse.

Mandatory Reporting: Florida law requires that all study staff must report any reports of child abuse, suicidal or homicidal behaviors to the appropriate authorities. These include physical injury to any

child not caused by an accident or information that tells staff a person is in danger of physical harm. If you report that you may harm yourself or others you may be referred for immediate care. If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, and the IRB will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential to the extent allowed by law.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include participant is a danger to self or others, has lost cognitive capacity to participate.

What else do I need to know?

This research is being funded by the National Institute on Drug Abuse

If you agree to take part in this research study, we will pay you ___$30 for each assessments which is a total of $90 if all 3 assessments are complete for your time and effort.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	05/06/2019 IRB Approval Date