Official Title: Harnessing the Power of Peer Navigation and mHealth to Reduce Health Disparities in Appalachia

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Wake Forest®
School of Medicine

Division of Public Health Sciences
Department of Social Sciences and Health Policy

Harnessing the Power of Peer Navigation and mHealth to Reduce Health Disparities in Appalachia:
Social Network Member
Informed Consent Form to Participate in Research
Scott D. Rhodes, PhD, MPH, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to develop and test the Appalachian Access Project, a program to promote and support the use of needed HIV, STI, and hepatitis C prevention and care services among persons with a spectrum of identities living in rural Appalachia. You are invited to be in this study because you identify as part of this spectrum of identities. They include gay, bisexual, and queer men and other men whose sexual partners include cisgender men and/or transgender persons. They also include transgender persons, including transgender women and men and non-binary persons, whose sexual partners include cisgender men and/or transgender persons. Your participation in this research will last about 2 years.

Participation in this study will involve completing 3 questionnaires and, if selected to do so, participating in 1 in-depth interview. All research studies involve some risks. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Your alternative is to not participate in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study at Wake Forest is Dr. Scott D. Rhodes, Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

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INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you identify as part of a spectrum of identities. These identities include gay, bisexual, and queer men and other men whose sexual partners include cisgender men and/or transgender persons. They also include transgender persons, including transgender women and men and non-binary persons, whose sexual partners include cisgender men and/or transgender persons. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to develop and test the Appalachian Access Project, a program to promote and support the use of needed HIV, STI, and hepatitis C prevention and care services among persons with a spectrum of identities living in rural Appalachia.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 128 individuals will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you choose to participate, you will be asked to do a questionnaire. The questionnaire will be done 3 times, once at the beginning of the study (now), again in 12 months, and again at the end of the study in 24 months. Questions ask about basic demographic information, your health attitudes and behaviors, and your use of local resources.

In addition, a friend of yours will be trained as a peer navigator, known as a "community health leader," to offer formal and informal help, information, and support to others related to HIV, STI, and hepatitis C prevention and care services. If you choose, you may talk to your friend individually or you may attend a more formal group activity. Even if you consent to participate in the completion of the questionnaire, you do not have to talk about HIV, STI, and hepatitis C or local resources with your friend or participate in any health awareness, education, or prevention activities.

You may also be invited to participate in 1 60-minute in-depth interview. Questions will ask about your experiences with the program and ways to improve the program. There are no wrong answers. As part of this interview you will be audio recorded. This is being done because what you have to say is important and to enable study staff to accurately transcribe the interview. You understand that you may request the recording be stopped at any time during the course of the research study. **If you ever want the recorder turned off, just let the researchers know and they will do that.** You can also withdraw your consent to use and disclose the audio recording before it is used. You should also understand that you will not be able to inspect, review, or approve the audio recordings before they are used in this study. The audio recordings will be destroyed once their use in this study is finished.

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How Long Will I Be in the Study?

You will be in the study for about 2 years.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life. However, talking about life experiences and health can sometimes be uncomfortable. **You will never be required to discuss anything that makes you feel uncomfortable.** You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you may consider confidential or private. Efforts, such as coding research records, keeping research records secure, and allowing only authorized people to have access to research records, will be made to keep your information safe.

If you participate in an in-depth interview as part of this research study, everything you say during the interviews is confidential. Nothing you say will be attributed to you or your participation.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope what is learned from this study will benefit you and other people in the future. The benefits of taking part in this study may be: more access to culturally-appropriate materials and increased community awareness about HIV, STIs, and hepatitis C and about local resources.

What Other Choices Are There?

You do not have to participate in this study. This is not a treatment study. Your alternative is to not participate in this study.

What Are the Costs?

There are no costs to you for taking part in this study. All study costs will be paid for by the study.

Will Your Research Records Be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to federal and other regulatory agencies as required.

Audio recordings will be stored in a cabinet in a locked office or on a password protected

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computer and will be retained six years after the study is finished, then destroyed. During study activities, participants may request that recordings be stopped at any time.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Will You Be Paid for Participating?

You will receive $30.00 for the first questionnaire, $60.00 for the second questionnaire, and $80.00 for the third questionnaire. If you participate in an in-depth interview as part of this research study, you will be paid an additional $50.00 for your participation once you complete the interview.

Who is Sponsoring this Study?

This study is being sponsored by the National Institutes of Health (NIH). The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: your demographic information and information about health attitudes and behaviors. We will not collect any information that identifies you.

We will make every effort to keep your Protected Health Information private. We will store

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records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies, and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information will be destroyed. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Scott D. Rhodes that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Scott D. Rhodes
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but

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any information we have already collected can still be used for the purposes of the research study.

By providing your consent you give us permission to use your Protected Health Information for this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first. The investigators also have the right to stop your participation in the study at any time. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Scott D. Rhodes at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this consent form.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in this study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

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