Consent to Participate in Research

Title of Research Study: Improving Health Surveys

Principal Investigator: ***James W Griffith, PhD***

Supported By: National Institutes of Health (NIH)

Collaborating Institutions: Boston University Medical Center

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to help us learn whether routine health questionnaires are valid over the phone and people who have different levels of familiarity with basic health information
- You will be asked to complete health questionnaires over the phone with a research coordinator. At the end of the phone call, the research coordinator will ask you a few questions about how things have changed since your last call and how you felt about the questionnaires.
- We expect that you will be in this research study for about 6 months and you will complete three phone calls.
- The primary potential risk of participation is the loss of private information; however, there are procedures in place to minimize this risk. You may also stop participation at any time or skip any questions, if you feel uncomfortable.
- The main benefit of being in this study is helping us learn more about asking health questionnaires over the phone.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have already participated in the Health Literacy research study; and you are 18 years of age or older and are also willing to complete some questionnaires about your health.

How many people will be in this study?

In total, across all study sites, we expect about 1,224 people to participate in this study. The local number of participants we will recruit is 612.

What should I know about participating in a research study?

- Someone will explain the 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.

- You do not have to answer any question you do not want to answer.
- Your medical care will not change in any way if you choose not to take part

What happens if I say, "Yes, I want to be in this research"?

If you agree to participate in this research, you will be asked to part take in research activities a total of 3 times. You will complete some questionnaires about your health.

These questionnaires will be completed over the phone with a research coordinator. The first call will take between 60-90 minutes. During your second and third calls, which will last 60 minutes each, you will complete the same questionnaires as you did the first time.

Lastly, we will conduct a debriefing interview give you an opportunity to share with us your thoughts about your participation in this study and your impressions about the questionnaires. If you are 45 years of age or older, we may also ask you a few questions about colon cancer screening at one of your calls to see if you have had any screening tests completed by your doctor.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to society include improving how healthcare providers communicate with patients. Please note the questionnaires used in this study will not be used to diagnose or treat any conditions and results will not be returned to participants. If you request, we will email or mail you a list of mental health resources in case you need further assistance.

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

There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. You may also stop participation at any time or skip any questions, if you feel uncomfortable.

What happens if I do not want to be in this research, or I change my mind later?

Participation in this research study is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with Northwestern University/Northwestern Memorial Healthcare.

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

If you decide to withdraw from this study, the researchers will ask you if information already collected from you can be used.

How will the researchers protect my information?

The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. Your survey answers and health information will be stored in a secure, encrypted database.

In this study, we will ask you some questions about depression. If we think that you are at risk for harming yourself, or harming another person, we may have to share information in order to make sure that you and others are protected. This might include calling 911 and asking for emergency services. We may also need to share information if we learn of a child or elderly person that is being abused. Outside of these exceptions, we will make every effort to protect your confidentiality and privacy.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

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

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information including research study 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 authorized representatives of the National Institutes of Health (NIH). When we share the results of the study in scientific journals, poster presentations, and paper presentations, we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

How might the information collected in this study be shared in the future?

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Will I be paid or given anything for taking part in this study?

If you agree to take part in this research study, we will pay you for your time and effort. You will receive $40 for your first call, $50 for your second call, and $60 for your third call. You will be paid after each call that you complete. The routine method of payment would be an e-gift card, unless you do not use an email address, in that case a gift card will be mailed to you within 4 to 6 weeks after the call.

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 (312) 503-1469.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may contact the IRB by phone at (312) 503-9338 or by email at irb@northwestern.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 participant.
- You want to get information or provide input about this research.

Verbal consent:

Do you wish to participate? Record participant's response: Yes No

Study ID number: _____

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Printed Name of Person Obtaining Consent Date