IRB #: STU00204308

Permission to Take Part in a Human Research Study

Title of Research Study: Improving Health Surveys

Investigator: James Griffith, PhD

Supported By: National Institutes of Health (NIH)

Clinical Trials Number: NCT03584490

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

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 are 18 years of age or older and are willing to complete some questionnaires about your health.

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, and take as much time as you need to make your choice.
- Your medical care will not change in any way if you choose not to take part.

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) 503-6501.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or 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.

Why is this research being done?

This study will help us learn whether routine health questionnaires are valid across groups of people who have different levels of understanding basic health information. Our goal is to improve ways in which health questionnaires are designed and administered across all groups of people.

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How long will the research last?

The study involves a total of 3 visits. We estimate that your first visit will take between 90-120 minutes. Next, you will be asked to come back after 3 months, and then one additional time after 6 months.These two visits will take 60-90 minutes each.

How many people will be studied?

In total, across all study sites, we expect about 1,200 people to participate in this study. The local number of participants we will recruit is 600.

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. Specifically, during your first visit we will ask you to answer some study eligibity questions including language and demographics questions, and then we will ask you to complete questionnaires about your health and different aspects about your personality.

These questionnaires will be presented to you in one of two ways, 1) paper-and-pencil or 2) a talking touchscreen computer that will read text out loud to you. The first visit will take between 90-120 minutes. During your second and third visits, which will last 60-90 minutes each, you will complete the same questionnaires as you did the first time except for the reading and literacy questionnaires.

Lastly, we will conduct a debriefing interview to give you more information about the study and to create an opportunity for you to share with us your thoughts about your participation in this study and, in particular, your impressions about the testing situation itself.

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

You can leave the research at any time and it will not be held against you. We will not share your information for this study, no one will treat you differently, and the care you get from your doctor will not change.

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

You can leave the research at any time and it will not be held against you. We will keep all data collected until the time you change your mind. You can tell us to stop using and sharing health information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect safety, or make sure the research was done properly. If you have any questions, please ask. If you want us to stop, you have tell us in writing. Please address your correspondence to:

James Griffith, PhD
Address: 625 N. Michigan Ave, 27th Floor
Chicago, IL 60611
Phone: 312-503-5345
Email: j-griffith@northwestern.edu

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

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.

Who will see my answers?

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, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record. 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.

Will it cost me anything to be in the study?

No.

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 include the opportunity to experience first hand how a social science study is conducted. Please note that even though your answers will not be used to diagnose or treat any diseases, we will provide you with a list of mental health resources and our contact information in case you need further assistance. Your data will be analyzed in aggregate to understand how different types of questionnaires are influenced by level of health literacy.

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 authorized representatives of the National Institutes of Health (NIH).

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.

Data Sharing

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.

What else do I need to know?

If you agree to take part in this research study, for your time and effort, we will pay you $40 on your first visit, $50 on your second visit, and $60 on your third visit. The routine method of payment would be cash. We will also reimburse you up to $22.50 for transportation costs. We will also contact you via email or phone to confirm and remind you of your appointments.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Billing information
- HIV testing results
- Mental Health information: Any mental health diagnosis, including things like major depressive disorder or panic disorder

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

If you have already been a patient at Northwestern Medicine, we will get some information from your electronic medical record. This information includes your age, date of birth, gender, race, and ethnicity). The research coordinator will ask you some questions to make sure that this information is correct. We will also gather some information from your medical record to understand how many health problems you have had. This is sometimes called “comorbidity”, which means having more than one health problem. From your electronic medical record, we will note whether you have had any of the following illnesses: myocardial infarction, congestive

heart failure, peripheral vascular disease or bypass, cerebrovascular disease or transient ischemic disease, hemiplegia, pulmonary disease/asthma, diabetes, diabetes with end organ damage, renal disease, mild liver disease, severe liver disease, gastric or peptic ulcer, cancer (lymphoma, leukemia, solid tumor), metastatic solid tumor, dementia or Alzheimer's disease, rheumatic or connective tissue disease, HIV or AIDS, hypertension, skin ulcers/cellulitis, depression, and warfarin use. These medical diagnoses will be de-identified (that is, not associated with your name or date of birth) and combined into a single number that summarizes how many health problems that you have had. We will use this information to see whether these health problems are related to your responses on questionnaires. No other information will be retrieved from your medical record. If you do not want us to gather this information from your medical record, you can choose not to be in the study.

This consent expires on 03/01/2021. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

During this study you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous healthcare providers including but not limited to the Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be

tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.
However, Illinois law does not allow the re-release of HIV/AIDS, genetic testing, mental health and developmental disabilities information by the receivers of the information except in precise situations allowed by law.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

At the end of the research study, when all analyses have been completed, all protected health information will be deleted.

Unless you revoke your consent, it will expire at the end of the research study on 3/01/2021.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

James Griffith, PhD
Address: 625 N. Michigan Ave, 27th Floor
Chicago, IL 60611
U.S.A.

Phone: 312-503-5345
Email: j-griffith@northwestern.edu

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

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Optional Elements:
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

The researcher may contact me in the future to see whether I am interested in participating in other research studies.

I agree I disagree

_____ _____

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document upon request.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of witness to consent process Date

_____
Printed name of person witnessing consent process