Duke University Health System

Consent to Participate in a Research Study
ADULT: *Patient Consent Form*
Provider Skill Building for Engagement and Communication in Healthcare – Hypertension Management (REACH – Hypertension)

CONCISE SUMMARY

The purpose of this research study is to see how well a program helps doctors and other primary care providers talk to, listen to, and work with their patients. Joining this research study is voluntary.

Patients will first fill out a survey about their health and demographics. Then, they will audio-record their visit with the doctor. After that, they will fill out another survey about the visit. Your part in the study will be done after you finish the second survey, so it will only take a couple of hours. Patients that complete the audio-recorded visit with their doctor and both surveys will receive $50.

There is a small risk of loss of confidentiality. As described below, we will be careful to protect your information and your privacy. There are no direct benefits to patients, but we hope the information learned from this study will help providers in this study and patients and providers in the future.

If you are interested in learning more about this study, please continue reading below.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. Please feel free to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Sarah Wilson and Dr. Laura Svetkey will conduct the study. The study is funded by a grant from National Institutes of Health (NIH) / National Heart, Lung, and Blood Institute (NHLBI). Portions of Sarah Wilson and Laura Svetkey and their research team's salaries will be paid by this grant.

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Why is this study being done?
The purpose of this study is to teach clinicians how to talk to, listen to, and work with patients effectively.

How many people will take part in this study?
Approximately 20 clinicians and 150 patients from Duke University Medical Center will take part in this study.

What is involved in the study?
If you agree to be in this study, you will be asked to sign and date this consent form. This study includes you completing two surveys and audio recording your doctor's visit. If you agree to join the study, your identity will not be connected to any data collected during this study.

Before your visit with your primary care provider, you will be asked to complete a survey with questions about you. On the day of your appointment with your primary care provider, a member of the study team will meet you in the waiting room. The study team member will walk with you into the exam room and set up a digital tablet to audio record your clinical visit. Once the tablet is set up, the study member will step out of the exam room. At the end of your visit, the study member will come back into the exam room, turn off the recorder, and walk back out to the waiting room with you. In the waiting room, we will ask you to complete a second survey about your clinical visit with your primary care provider. If you do not have time to complete this second survey, we will email you the survey or mail it to your home and ask you to complete it. Some of the questions may make you feel uncomfortable. You do not have to answer any questions that you do not want to answer. Your survey responses will not be shared with your clinician or anyone else besides the research team.

After completing the audio recorded clinical visit with your primary care provider and completing both surveys, you will receive $50 for your participation.

If a relative or friend comes into the exam room with you, anything they say during the appointment will also be audio-recorded. Therefore, we will ask them to agree to the recording on a separate form. Their words will be used in studying how clinicians talk to, listen to, and work with their patients. However, there will

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be no record of who they are and there will be no personal information about them stored anywhere.

We will also ask that you allow for us to access your medical records to obtain information on your medical history, medications, and your medical appointments.

Study participation is voluntary and if you do not sign this consent form, you will continue to receive care. If you decide not to join the study, there will be no penalty or loss of benefits to which you are entitled, and your decision will not affect your access to health care at Duke.

How long will I be in this study?
If you agree to join this study, you will be in the study until you complete the second survey. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

What are the risks of the study?
There are no physical risks with being in this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential. However, this cannot be guaranteed. We will email you a copy of this consent form; however, email is not a secure method of communication. By signing this consent form and providing your email, you agree that we may email you a copy of this consent form. If your encounters are audio recorded with your permission, the recordings will be stored electronically on a password protected, encrypted computer that will be kept in a locked office at Duke University. The recordings will not be shared with anyone outside of the research team. Once the study is complete, the audio recordings will be destroyed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of these questions, and you may take a break at any time during the study. You may stop your participation in this study at any time.

Unforeseeable Risks:
There may be risks that are not yet known.

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Are there benefits to taking part in the study?
If you agree to take part in this study, there are no direct medical benefit to you. We hope the information learned from this study will benefit providers in this study and patients and providers in the future.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those funding, and regulating the study, and those currently collaborating on the study and those who will possibly be collaborating on the study in the future. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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

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research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations. Your name or any other personal information will not be disclosed.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information

We will also ask that you allow for us to access your medical records to obtain information on your medical history and medications and your medical appointments up to one year after your participation is completed

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Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Certificate of Confidentiality:
The National Institutes of Health (NIH) / National Heart, Lung, and Blood Institute (NHLBI) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does

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not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

Will I be paid to be in the study?
For completing the audio recorded clinical visit with your primary care provider and completing both surveys, you will be compensated $50 for your time.

What if I want to withdraw from the study?
If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to join or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

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

Whom should I call if I have questions or problems?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Wilson at 919-971-2406 or Dr. Svetkey at 919-819-0238 either during regular business hours or after hours and on weekends and holidays.

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You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Participant	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time