DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Communication Coaching in Cardiology: Clinician Consent Form

CONCISE SUMMARY

The purpose of this research study is to measure the effectiveness of an intervention to improve cardiology clinician's communication skills. Clinician participants will complete a survey at the beginning and the end of the study and agree to allow their patients to be enrolled and have their clinical encounter audio-recorded. Clinician participants will be randomly assigned to one of two groups: the control or the intervention. If you are assigned to the intervention, you will receive 1 informational coaching session followed by 2 tailored coaching sessions to improve communication. You will also be asked to obtain verbal consent from up to 6 patients and audio-record those clinical encounters to help guide the coaching sessions. Total study duration is about 5 months.

There is a risk of loss of confidentiality. There is a possible benefit of improving your communication skills with patients.

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

You are being asked to take part in this research study because you are a clinician in the Department of Cardiology who sees patients at Duke University Medical Center. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you 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.

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

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Kathryn Pollak's and her research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to teach clinicians how to talk to patients more effectively. We will look at how clinicians communicate with diverse populations, including gender and race.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 50 clinicians and 670 patients from Duke University Medical Center.

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 and ask you to complete a survey about how you communicate with patients. Then, we will enroll four of your patients to complete a survey and audio-record their clinical encounter with you. Then, you will be randomly

assigned (like a flip of a coin to receive either 1) the control arm or 2) a tailored coaching intervention arm.

After randomization, if you are assigned to the coaching arm, you will attend one session with a study coach that includes teaching communication. Also included in the intervention is two one-on-one coaching sessions to improve communication. You will be asked to obtain verbal consent from two patients to audio-record their clinical encounter with you. The coach will listen to these audio-recordings to tailor the intervention and provide feedback. You will meet with the coach in-person or via video conference to provide feedback and set communication goals. Once feedback is provided, you will be asked to audio-record another two clinical encounters with patients' verbal consent. The coach will again listen to the audio-recordings and meet with you for a second feedback session. During the feedback sessions, coaches will debrief about the encounters, answer questions, and discuss difficult patient interactions. After all coaching sessions have been completed, we will ask you to complete one more survey.

If you are assigned to the control arm, you will not receive any training.

After the intervention period, we will ask you to complete a survey about communication and provide feedback on the study and coaching intervention. Then we will enroll six more of your patients to complete a survey and audio-record their clinical encounter with you.

If there is a learner observing you, we will ask that you do not permit learners (e.g. medical students or visiting clinicians) to observe recorded encounters. We need to be able to capture your usual communication practices.

At beginning of the study and again at the end of the study, we may also access aggregate data already collected by your clinic as part of usual practice. These data include your patient satisfaction (HCAP) scores, average length of stay of your patients, and your readmission rates.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study for approximately 5 months, depending on how long it takes to enroll patients and collect the pre- and post-intervention audio recordings.

Participation is voluntary. 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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, you might learn more effective ways to communicate with your patients. 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. Identifiable individual-level data about your communication will not be shared with anyone outside of the study team. Your personal information may also be given out if required by law. Clinicians randomized to the intervention group, audio recordings will be sent to DataGain, Inc. for de-identified transcription.

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 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. This means that you 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.

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.

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.

WHAT ARE THE COSTS TO YOU?
There is no cost to you for participating in this study.

WHAT ABOUT COMPENSATION?
You will receive up to $200 for completing all aspects of the study.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, 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 participate 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 or your standing in your practice. If you leave your practice prior to completing the study, we will ask to audio record visits with patients at your new practice. If you do decide to withdraw, we ask that you contact Dr. Pollak in writing and let her know that you are withdrawing from the study. Her mailing address is 2424 Erwin Road, Suite 602, Durham, NC 27705.

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

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 DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. Pollak at 919-681-4757 during regular business hours and at (919) 602-2485 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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 Subject	Date	Time