Attachment J: Consent Form to Participate in Clinic Staff Interview

Using Health IT in Practice Redesign: Impact of Health IT on Workflow

Consent to be Interviewed

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

Purpose of the Study

This research is sponsored by Agency for Healthcare Research and Quality (AHRQ), an agency within the U.S. Department of Health and Human Services, and is being led by researchers from RTI International and Vanderbilt University. The purpose of this research is to better understand how health care providers work with computers and with each other. You are being asked to participate in this research because you are a member of the clinical team that provides care to patients in this outpatient clinic.

Study Size and Procedures

This study will include up to 36 health care professionals, including physicians, nurses, clinical assistants, office staff, and up to 64 patients from six primary care clinics.

During the interview, the interviewer will ask questions about your experiences with care coordination, health IT, and workflow and practice patterns. The interview session should last approximately 60 minutes and will be audio-recorded with your permission. Participants will not be asked to refer to themselves by full name or the name of the clinic where they receive care/practice.

You will also be asked to complete a short survey about your experiences and interactions with health IT tools in your clinic. You will have the choice of taking the survey electronically or on paper. The survey should take approximately 30 minutes to complete.

Expected Costs

There are no expected costs to you as a participant in this study.

Potential Risks or Discomforts

There is a risk that the audio tapes of your interview could be lost or stolen. There is also a potential that signed documents might be lost or stolen. We are taking steps to secure these risks by (a) requiring that participants agree not to discuss the interview's proceedings, (b) recording only first names of participants on the recordings, (c) temporarily storing written items and tapes in lockable briefcases and permanently storing them in lockable desks and file cabinets, and (d) assigning a random case and subject number to all audio and print materials. We will destroy the tapes and documents at the earliest opportunity upon completion of our reporting. We will not contact participants after the completion of this session.

This study may cause some inconvenience to you, typically associated with the time involved in the study. There may also be discomfort associated with some of the questions asked.

The discomforts or risks are expected to not exceed those of your employment, and are anticipated to be mostly psychological in nature. For example, anticipated discomforts may include potential feelings of inadequacy or disclosure about your performance. You are not obligated to answer any particular questions asked and may withdraw from the study at any time.

Compensation in Case of Study-Related injury

If you are injured because you are in this study, you can get reasonable, immediate, and necessary medical care for your injury at Vanderbilt University Medical Center without charge to you. There are no plans for the investigators to pay for the costs of care beyond your injury, or to give you money for such injury.

Benefits of the Study

Benefits to science and humankind that might result from this study: This study will help the investigators better understand how the clinic manages patient care and how to better integrate technology into that system to improve and create a more robust system. This will include knowledge about what works, what does not work, and what could be done better to improve the care that patients receive.

Benefits you might get from being in this study: You may find participation in this study to be of educational value. You may also have a better understanding of how your clinic operates and how your team works to provide care.

Compensation

Participants will be offered a gift of $25 at the completion of the interview as a token of appreciation.

Circumstances to Withdraw

The principal investigator may withdraw you from this study if at any time it is deemed that continuing in the study would pose a risk to you or others.

What Happens if You Choose to Withdraw from the Study

Participation is entirely voluntary and will not have any effect on your rights as a patient, the care you receive, or any other benefits to which are you are entitled. You are under no obligation to answer any particular questions posed during the interview or on the survey.

You may withdraw from the study at any time. There is no penalty if you choose to withdraw from the study. If you decide to withdraw from the study, any audiotapes and/or survey responses will be destroyed and not used in any way.

Confidentiality

All efforts, within reason and in accordance with applicable law, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All records collected during this study, including this informed consent document, will be accessible only to key research personnel. All electronic information will be stored on password-protected computers. Additionally all video and print materials will be stored in a locked cabinet and de-identified using a random case and subject number. Finally, only aggregate data will be disseminated, so your data will never be presented singularly; it will be presented with all the others that participate in this study.

During the interview, please use your first name only. Recordings of the sessions are being kept for the purpose of ensuring accuracy. No one other than the research staff will hear the tapes. The tapes will be destroyed after the study's findings are released. By using only first names it becomes more difficult to identify any particular participant in the event a recording is lost or stolen.

Your responses will be kept confidential under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

Privacy

If you or someone else is in danger, or if we are required to do so by law, your information may be shared with the RTI International or Vanderbilt University Institutional Review Boards or the Federal Government Office for Human Research Protections.

Additional information

For additional information about this study, please contact Dr. Jonathan Wald, the study director. He can be reached at 800-334-8571, ext. 2-8116, or via email at jwald@rti.org.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact RTI International's Office of Research Protection at 866-214-2043 or Vanderbilt University Institutional Review Board Office at 615-322-2918 or toll free at 866-224-8273.

Statement of understanding

By signing this document I am stating that I have read (or have had read to me) this informed consent statement and that it has been explained to me verbally. I am also stating that all of my questions have been answered. By signing this document I attest that I understand the contents of this document and freely and voluntarily agree to participate in this study.

Signature: _____ Date: _____

I agree that this interview may be audio recorded. _____

I do not consent for this interview to be audio recorded. _____