RESEARCH CONSENT FORM

Title of Project: TO #1 System Redesign in Safety Net Hospitals

Principal Investigator: Carol VanDeusen Lukas EdD

Background

The broad purpose of this study is to better understand how the government and other interested parties can help foster effective and sustainable system redesign in safety net hospitals. In order to achieve this objective, case studies at participating Safety Net hospitals will be conducted to understand the types of resources participating hospitals and health systems have used to support their work on system redesign, the limitations of the existing resources and supports and what opportunities exist for new or enhanced resources.

This study will use qualitative interviews at each of the participating case study sites. Interviews will either be conducted individually or in small groups and will last 45- 60 minutes each. You will only be asked to participate once. There is no obligation to participate beyond one interview. Your participation in this research is completely voluntary, and you can stop the interview at any time.

Purpose

Boston University with funding from the Agency for Healthcare Research and Quality, is conducting research to better understand the awareness, uses and usefulness of available external supports for system redesign in safety net hospitals, to probe the details of the types of system redesign and improvement activities undertaken in each system and their success, and examine the organizational context in which system redesign occurs. Conducting case studies at participating safety net hospitals will allow us to learn directly from the senior medical center leaders, managers and clinical staff who are responsible for implementing system redesign and quality improvement projects at their hospitals. These qualitative interview together with a scan of existing data sources will guide Boston University in the development of recommendations about how safety net leaders can make better use of existing sources of support for redesign and will contain recommendations about developing additional program and tools for supporting system redesign.

What Happens In This Research Study

You will be one of approximately 15 subjects to be asked to participate at this location. A total of 120 subjects at all institutions will be asked to participate in this study.

The research will take place at the following location(s): Boston University Medical Center. You will be asked to participate in an interview lasting 45 – 60 minutes that will explore the hospital's history of improving quality of care and patient safety as well as its

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experience in implementing new quality improvement projects. Particular attention will be paid to the types of resources (e.g. tools, guides, collaboratives, trainings and webinars) used at the hospital to guide both individual quality improvement projects and broader system redesign initiatives.

Each interview will last 45- 60 minutes. You will only be interviewed once.

Risks and Discomforts

There may be questions which solicit your opinion about the strengths and weaknesses of various approaches to and tools and resources for quality improvement. These questions should not put you at risk of criminal or civil liability or be damaging to your financial standing, employment or reputation. If you become tired during the interview, you are free to discontinue the interview at any time or take a break. You can take as many breaks as you need. If you are uncomfortable with recording the interview, we will not record the interview.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare or decision to stay in the study.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the tools and resources available to safety net hospitals interested working on system redesign which in turn, will inform AHRQ and other government and private agencies interested in developing appropriate resources.

Alternatives

Your alternative is to not participate in the study.

Subject Costs and Payments

There are no costs to you for participating in this research study. You will not be paid to participate in this research study.

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Confidentiality

Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications.

The interview will be recorded, with your permission, using a digital audio recorder. We will not link the interview with any identifying information. Any identifying information collected in the interview will be changed for privacy reasons during the review of the notes. All data will be saved in password protected folders on a password protected computer and stored on Boston University's secure network server.

Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at 617-638-7207. If this study is being done outside the United States, you can ask the investigator for contact information for the local Ethics Board.

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact Carol VanDeusen Lukas at 857-364-5685 at any time.

Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If

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you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject (Signature and Printed Name) **Date**

Person Obtaining Consent (Signature and Printed Name) **Date**

Investigator or Designee (Signature and Printed Name) **Date**