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BOSTON UNIVERSITY SCHOOLS OF MEDICINE, PUBLIC HEALTH, DENTAL MEDICINE AND THE BOSTON MEDICAL CENTER

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RESEARCH CONSENT FORM
Analyzing the SSA Disability Evaluation Process (Cognitive Testing)
Title of Project: Analyzing the SSA Disability Determination Process Phase 2
Principal Investigator: Alan Jette, PhD

Background

This study aims to develop a series of computerized adaptive tests to be used in the process of determining disability for the Social Security Administration.

Purpose

The purpose of this study is to improve the testing process of work related functioning for those who apply for disability benefits due to an injury or illness.

What Happens In This Research Study

You will be one of approximately 70 subjects to be asked to participate in this study.

The research will take place at Boston University Medical Center.

As a participant in this study you are being asked to provide feedback on the clarity and meaning of survey items that have been developed by study staff in a one on one interview setting.

Risks and Discomforts

We do not expect that participation will cause you any discomfort. However, 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 participate in this study.

There is a small but important potential loss of confidentiality by taking part in this study, however, all measures possible will be taken to prevent this loss.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand how to better improve assessments used in the Social Security disability determination process

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 receive $20.00 for your participation in this research study.

Confidentiality

The information you provide will be kept confidential and will not be disclosed to anyone but the researchers conducting this study, except as required by law.

Study data such as name, address and telephone number will be kept separately in locked filing cabinets or secure servers at both institutions. The link to codes and names will be destroyed after data collection is complete.

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.

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 Kara Bogusz at 617-638-1995.

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 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