

Mrs. A and Mr. B

NCT02626910

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**Title of the Research Study: Mrs. A and Mr. B****Consent for PWD: URBAN**

Unique Protocol ID: AD-12-11-4567

Principal Investigator: Hillary R. Bogner, MD

University of Pennsylvania

928 Blockley Hall

423 Guardian Drive

Philadelphia, PA 19104-6021

215-746-4181

[Hillary.Bogner@uphs.upenn.edu](mailto:Hillary.Bogner@uphs.upenn.edu)

**Project Manager:** Sister Patrice Colletti, SDS Virtual Ability, Inc.

Email: [sister@virtualability.org](mailto:sister@virtualability.org); voice message: 414-502-7797

You may ask to have this form read to you. We want to be sure you understand all of it. You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Being in the study is voluntary. You can choose whether or not to participate. Either way is fine. Before you make a decision, you will need to know the purpose of the research study. The research team is going to talk with you about the study. They will give you this consent document to read. You do not have to make a decision now. You can take this paper home and share it with friends and family. If you do not understand what is on this paper, do not sign it. Please ask the researcher to explain anything you do not understand. If you decide to participate, you will be asked to sign this form. You will get a copy of it. Keep this paper because it has contact information and answers to questions about the study.

**What is the purpose of the study?**

The purpose of this research is to get your opinion about how health care access and quality may be affecting people with and without disabilities.

**Why was I asked to participate in the study?**

You are being asked to join this study because:

- You are a person 21 years of age or older with a disability or because
- You provide personal care to a person with a disability and will be serving as his or her “proxy.” In this role, you will be sharing his or her likely opinions or experiences because he or she is not able to do so for him or herself.

**How long will I be in the study?**

The study will take place over 3 years. You may be asked to be in one or more focus group sessions. Each focus group session will last no more than 1 ½ hours.

**Where will the study take place?**

Focus group sessions will be in a private space at Agape Community Center, Milwaukee, WI.

**What will I be asked to do?**

First, we will ask you to complete an online survey about your life circumstances, health, and disabilities. You may be asked to participate in one or more focus group sessions. These are discussions with up to 5 or 6 other people from your neighborhood.

In the focus groups, you will be asked about access to healthcare. You will also tell us about the quality of healthcare as you experience it. We also may show you research findings about healthcare and ask you what you think about those findings.

We want everyone in the discussion group to share their ideas. If you need help so you can do that, we will make sure you get it. We are happy to give you the ADA accommodations you might need. Please let us know what you need before the group meets. For example, you might need a sign language interpreter if you are deaf. You might need someone to explain the questions to you. You might need to be in a very quiet room. You might need a guardian or a friend to assist you.

**What are the risks?**

There are no known physical risks with this research study. The research includes the time and effort involved in answering questions about your own healthcare experiences. If you get tired, you can take a break and come back later. You can decide to stop participating at any time. You should not answer any questions that make you uncomfortable.

**How will I benefit from the study?**

There is no direct benefit to you. However, your participation could help us understand ways to improve access to and quality of healthcare. This study could benefit you indirectly. In the future, this may help other people to live healthier and more independent lives.

**What other choices do I have?**

You have two choices. You can be in the study or you can say “no thanks.” If you say “no thanks,” then you will not be in the study.

**What happens if I do not choose to join the research study?**

You may choose to join the study or you may choose not to join the study. Your participation is voluntary. It is up to you. It is perfectly fine if you do not participate. There are no negative consequences should you not choose to participate.

**When is the study over? Can I leave the study before it ends?**

This research study lasts three years. You can stop completing the survey or leave the focus group session at any time.

**How will confidentiality be maintained and my privacy be protected?**

We will do our best to make sure that the personal information you tell us during the focus group discussion(s) will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your records will identify you only by a code number. This protects your privacy. The research analysts will not have your actual name or address. Sister Patrice Colletti will keep a list of everyone's code numbers. The only way the research team would be able to contact you would be through Sister Patrice.

Focus group sessions will be in a private space at Agape Community Center. There will be other people participating in the focus group sessions, too. The information you share can be read or heard by anyone in your focus group session. So, please do not share anything you are not comfortable disclosing in that group. If you have private information you feel you must share with the researchers, please talk with Sister Patrice after the group is done.

The focus group sessions will be transcribed. This means a professional will listen to what is said and type it exactly as you say it. This will help us remember your responses to the questions. The written document is called a transcript or transcription. The transcript will be stored in a secure computer file or in a locked file cabinet. It will be kept private. Your name and all other personal information will be taken out of the transcript. The transcripts will be destroyed at the end of the research project.

Information from the focus group session will be combined from many people. It will be analyzed by a research team and may be published or shared in other ways. If any publications or presentations result from this research, your name will not be included. We might use short quotes from the focus group session chat. Any personally identifying information that you might have provided will be removed from those quotes.

### **What happens if I am injured from being in the study?**

There are no known risks of physical injury from this research study. If a topic upsets you, you may leave the focus group session. Please contact any research team member to discuss your concerns or feelings. See contact information above or at [www.healthcareequitability.org](http://www.healthcareequitability.org). Anything discussed will not be shared outside the research staff team.

### **Will I have to pay for anything?**

You do not have to pay anything to be in this research study.

### **Will I be paid for being in this study?**

If you are invited to participate in a focus group session, you will receive a gift card for \$5 at the end of the focus group session. This is a way for us to say "Thank you for helping!" When you complete the online survey, you will receive another \$5 gift card as our way of saying thank you.

### **Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?**

You have the right to ask questions and have them answered to your satisfaction. If you have complaints or concerns about your rights, you should call the person in charge. Her name is Dr. Hillary Bogner, MD. You can call her at 215-746-4181 or leave a message if she does not answer. You can also call the Director of Regulatory Affairs (University of Pennsylvania) at 215-898-2614 at any time if:

- a. you want to talk to anyone about this research

b. you think you have not been treated fairly, or  
c. you think you have been upset by joining the research,  
They will answer your questions or help you if you have found the process upsetting.

**CONSENT:**

By signing this form, you will be:

- a. Agreeing to participate in this research and
- b. Telling us you understood this form.

If you have any questions or if there is something you do not understand, please ask.  
You will get a copy of this form.

Your Signature (or proxy's signature): \_\_\_\_\_

Your Printed Name (or proxy): \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Person Witnessing Consent: \_\_\_\_\_

Printed Name of Person Witnessing Consent: \_\_\_\_\_

Was accommodation used? If so, specify.