CONSENT FORM

TITLE OF RESEARCH:	Living Well (Improving Medication Adherence in the Alabama Black Belt)-AIM 2
IRB PROTOCOL NO.:	X160301010
INVESTIGATOR:	Andrea Cherrington, MD MPH
SPONSOR:	Patient Centered Outcomes Research Institute (PCORI)
SPONSOR PROTOCOL NO.:	AD-1306-03565

Purpose of the Research

We are asking you to take part in a research study. This research study will test if Peer Advisors can help patients with diabetes better care for his or her diabetes to improve blood sugar levels, blood pressure, and quality of life. Peer advisors come from the same community as participants and have been trained to help people with diabetes. This study will enroll 500 participants. 250 participants will work with a peer advisor for 6 months and 250 participants in the general education group will receive health education videos. Which program you receive will depend on a random assignment process.

Explanation of Procedures

If you agree to participate in this study, you will be asked to take part in a telephone interview with a UAB study research assistants that will last approximately 45-60 minutes. During this call, you will be asked questions about you, your diabetes, your overall health, and topics related to your health such as your doctor, health care access, health knowledge, and current health behaviors. You do not have to answer any questions that you don't want to or that make your feel uncomfortable.

After the telephone interview, you will be asked to complete an in-person data collection visit that will last approximately 45-60 minutes. The data collection will be scheduled within 30 days of completing the telephone interview. The data collection visit will be conducted at a location in your community or in you home, depending of your preference. During the in person data collection visit, trained UAB study research assistants will conduct the following activities:

1. Test your blood sugar levels and your cholesterol levels by drawing blood from your finger
2. Measure your blood pressure 2 times
3. Measure your weight and height.
4. Make a list of all of your medications, including the doses and the frequency that you take the medicines.
5. Give you a health report card that provides you with the results of your blood sugar levels, cholesterol levels, blood pressure, and your weight.

Wearing a loose fitting shirt is recommended to the in-person data collection visit so that we are able to measure your blood pressure. We ask that you do not to not drink any caffeine (from coffee, tea, or soda), do not eat or do any heavy physical activity, smoke, ingest alcohol for 30 minutes prior to the in person data collection visit.

After the in-person data collection visit, you will start your 6-month program. You will receive one of two programs. Which program you receive will be determined by chance.

The first program is called the General Health Program. If you receive this program, you will receive health education videos. The videos cover the following topics: Dementia and Alzheimer's, Breast Cancer, Colorectal Cancer, Osteoporosis and Fall Prevention, Eye Health, Oral Health, Foot Care, and Driving Safety. The videos last between 15 to 30 minutes. If you are in this program, UAB study staff will call you on the phone 3 times during months 1, 3, and 5 to make sure the program is going well and to answer any questions you may have. These calls will last around 5 minutes. You will also receive post cards from UAB staff during months 2, 4, 6, and for holidays.

The second program is called the Living Well Program. In this program, you will be matched with a peer advisor. The peer advisor you are matched to depends on yours and peer advisor's availability. Your peer advisor will contact you on the phone within 2 weeks. You will watch videos that cover the following topics: diabetes basics, healthy eating, physical activity, stress reduction, and diabetes, cholesterol, blood pressure medications. The videos last between 20 to 40 minutes. You will then talk with your peer advisor on the phone using your study activity goal. During the phone calls with your peer advisor, you will set health goals and talk about the content covered in the videos. You will speak weekly for the first 8 weeks, bi-weekly for 1 month, and 1-3 times for month for the final 3 months. For the first 3 months, the calls with your peer advisor will last between 30-45 minutes. For the months 3-6, the calls with your peer advisor will last between 10-15 minutes. The total number of times and your peer advisor speak will be determined by you and your peer advisor but you will talk with your peer advisor around 13-16 times. If you are in this program, UAB study staff will call you on the phone 2 times during months 2 and 5 to make sure the program is going well and to answer any questions you may have. These calls will last around 5 minutes. You may also receive postcards from UAB staff for holidays. Finally, if you are in this program, you have the choice to use a study telephone. This phone will be yours to use for the 6 months when you are talking with your peer advisor. We ask that you only use the phone to talk with your peer advisor. You will need to return the phone to UAB after you finish the study. If you would like to use a study phone, the phone will be provided to you during the in person data collection visit. You will return the phone to UAB at the second in person data collection visit.

After 6 months, all participants in both programs will be asked to participate in a second in person data collection visit and a telephone interview. During month 6, UAB study staff will call you by telephone to schedule the in person visit and the telephone interview. The same information and tests will be collected during the second in person data collection visit as we

collected in the first in person visit. We will measure your blood sugar levels, cholesterol levels, two blood pressure measurements, and your weight and height. We will make another list of your medications, doses, and frequency. You will also receive a health report card with your measurements. At the second telephone interview, we will ask you many of the same questions that we asked at the first interview. The in person data collection visit and phone interview will each take 45-60 minutes.

Risks and Discomforts

The risks in this study are minimal. There is a potential for loss of confidentiality. You may experience discomfort or pain during the blood test and may experience temporary redness and soreness on your finger. It is possible that your numbers may be high or low when we test them. A doctor or nurse will be available by phone to help you address any concerns you may have.

If you are working with a peer advisor, it is possible that the peer advisor may not always know the right answer. The study investigators will be helping the peer advisors and meeting with them weekly. Peer advisors are trained by study investigators. So the chance of the peer advisor giving you the wrong information is very small. If any time you have concerns, you can contact Dr. Cherrington.

You will be assigned to a program by chance, which may prove to be less effective than the other study group or available information.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand how to treat diabetes better in the future. You will receive a "health report card" at the data collection visits that tells your blood sugar number, cholesterol number, blood pressure, and weight.

Alternatives

The alternative to this study is not to participate and continue your routine diabetes treatment.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of PCORI and the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out.

Some of your sessions with your peer advisors may be audio recorded. A study investigator will listen to these recordings to make sure that the peer advisor is conducting the sessions correctly. The recordings will be kept in a secure place, a locked cabinet in a locked office suite at UAB until they are listened to. The recordings will be erased after they are listened to.

A description of this clinical trial will be available on http://www.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.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with UAB.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation in Research

You receive a portable DVD player and $20 for participating in this study. You will receive the DVD player at the first in person data collection visit. You will receive a $20 VISA card at the second in person data collection visit.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research, you may contact one of the studies investigators. For UAB, contact Dr. Andrea Cherrington. She will be glad to answer any of your questions. Dr. Cherrington's number is 205-996-2885.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of Person Obtaining Informed Consent Date

Reviewed by:

Signature of Principal Investigator Reviewing Consent Document Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Living Well (Improving Medication Adherence in the Alabama Black Belt)-AIM 2
UAB IRB Protocol Number: X160301010
Principal Investigator: Andrea Cherrington, MD MPH
Sponsor: PCORI

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____