Study Title:	**Health literacy intervention to improve diabetes outcomes among rural primary care patients**
PI (researcher):	**Kristie Hadden**
Institution:	**University of Arkansas for Medical Sciences**
Sponsor:	**National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases**

University of Arkansas for Medical Sciences Informed Consent Form

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can quit the study at any time.**
- **Please take as much time as you need to make your choice.**
- **You can still get your medical care from UAMS even if you are not in the study.**
- **During the study, we will tell you if we learn any new information that might affect whether you wish to stay in the study.**

Why am I being asked to be in this research study?

- We want to learn more about ways of improving diabetes care in rural areas.
- This study will help us learn if easy-to-understand health material and better communication with health professionals are helpful for improving diabetes outcomes for patients in Arkansas.
- We are asking people like you who have type 2 diabetes and an active patient at a UAMS Family Medical Center to help us. A total of 750 people 21 years old and over will be part of this study.

What if I don't understand something?

- This form may have words you do not understand. Research staff will read it with you, if you like.
- You may ask as many questions as you like before you decide whether you want to be in this study.
- You are free to ask questions at any time before, during, or after you are in the study.

What if I say yes, I want to be in this study?

You have qualified for this study because you

- are 21 years of age or older,
- speak English,
- are a patient at a UAMS regional family medical center,
- have type 2 diabetes with recent A1c readings between 7.5 and 10%
- have no visual or hearing problems, and
- are healthy enough to participate.

If you agree to be in the study:

- We will assign you to one of two groups that are the same size. You will receive the same care from your doctor no matter which group you are assigned to, but each group will get different diabetes educational resources.
- We will meet with you three times. The first meeting will be in-person, the second and third may be in-person at a clinic visit or over the phone, to ask you questions about your health and what you know about diabetes.
- The first meeting will take place at the UAMS family medical center during a scheduled appointment and will take about 45-60 minutes to complete.
- At the first meeting, you will be asked questions about your diabetes history, questions about your beliefs about diabetic medications, and questions about how you and your family manage your diabetes. We will also talk about how well you understand health information.
- You can skip any question you do not want to answer.
- We will read the questions out loud and fill out forms for you.
- We will collect information on your Hemoglobin A1c (HbA1c) and LDL cholesterol lab values, along with systolic and diastolic blood pressure values from your medical record. This information will be collected as part of routine clinical care approximately every 3 months, and will be recorded from your medical record at each visit. We will also record your Body Mass Index, height, and weight from your medical record. In addition, we will ask you about missed appointments, emergency department or urgency care visits, and hospitalizations and record this information.

- At the follow-up phone or in-person interview at 3 and 6 months, we will ask similar questions to the first interview. We will ask you questions about diabetes symptoms and medications and about the support that friends and family give you. The follow up interviews will take about 30 minutes to complete.
- If you are assigned to group 1, you will be given diabetes education materials at your regular clinic visit by a nurse.
- If you are assigned to group 2, you will be given diabetes education materials by a health coach who will call you in approximately 2 weeks, then again at week 4 and week 8 and then every month for one year. The phone calls will take about 15 minutes. Your health coach will also check on you at your regular clinic visits about every three months.
- You can continue to contact your providers as usual when you have questions or concerns, regardless of which group you are in. Your care will be the same regardless of which group you are in.

How long will this study take?

The study will take about 12 months to complete, but you may not be interacting with research staff that long.

Who will see the information about me that is collected?

- The UAMS study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will not take your name off of information that we collect from you during the study.
- Some of your private health information will be stored in a computer database at Northwestern University School of Medicine in Chicago, Illinois. This information will include your initials, date of birth, race/ethnicity, diagnosis, and information about your participation in this study. The purpose of storing this information is to assist the Sponsor in creating reports about research and to make sure that research studies are being done correctly. Your information will not be used for any other purpose.
- When we share the results of the study in journals, presentations, or other publications, we will not include your name or any other information that identifies you.

- There are people who make sure the study is run the right way. These people may see information from the study about you. They are:
  - ✓ National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board
  - ✓ Other institutional oversight offices
- State law requires we tell the authorities if we learn
  - ✓ about possible child or adult abuse
  - ✓ that you might hurt yourself or someone else

Where and how long will my information and samples be kept?

- We will code your information and keep the code in a locked file.
- Only the research team will have access to the code for your information.
- We will put information about you from the study in your medical record as required by UAMS.

What if I say no, I do not want to be in this study?

- Nothing bad will happen.
- You can still get the same medical care at UAMS.

What happens if I say yes, but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen.
- You can still get the same medical care at UAMS.
- If you decide to stop being in the study, call Dr. Kristie Hadden at 501-686-2594 or 501-993-3178.

Can I be taken out of the study even if I want to continue?

Yes, the Principal Investigator can take you out of the study if:

- It is not in your best interest to continue.
- The study is stopped for any reason.

If I stop being in the study, what will happen to any information collected from me in the study?

- We will not be able to take your information out of the study after it has started.

Will my information from the study be used for anything else, including future research?

- No. Your information will be used only in this study.

Will it cost me anything to be in the study?

The study will not cost you anything. You or your insurance company will be responsible for your regular medical care as usual.

Will I be paid?

Yes. We will give you a $30 Wal-Mart gift card after the first in-person meeting. This is to thank you for your time. You will get another $30 Wal-Mart gift card after the follow-up phone call or in-person meeting at 3 months, then again at 6 months. If you receive a follow-up phone call instead of a face-to-face meeting, you can get your gift card the next time you come into clinic. If you change your mind and decide not to be in the study, you will only be paid for the parts you completed. If you complete the study, you will receive a total of $90 in Wal-Mart gift cards.

Will being in this study help me in any way?

Being in the study may or may not help you, but may help people with diabetes in the future. What we learn may help in the following ways:

- Patients who are in the study may have better understanding about their diabetes and self-care.
- Taking part in this study may help scientists to better understand how to improve diabetes patient education.

What are the risks of being in this study?

The risks are:

- The risks for this study are no more than what happens in everyday life.
- Someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.
- The questions could make you sad or upset.

What if I get sick or hurt while I'm in this study*?*

- We don't expect you to, but if you get hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care and/or follow-up care.
- This treatment may be billed to you or your insurance company in the normal manner. Normally, no other form of payment is available.

What are the alternatives to being in this study?

You do not have to be in this study. If you do not want to be in this study, you can still get treatment and education for your diabetes.

What if new information comes up about the study?

- We want you to know about anything that may change your mind about being in the study.
- The researcher will let you know by
  - ✓ calling you
  - ✓ sending you a letter
  - ✓ telling you at a follow up visit

Where can I find more information about this clinical trial?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time.

What if I have questions?

- Please call the Principal Investigator of the study Dr. Kristie Hadden at 501-686-2594 or 501-993-3178 if you
  - ✓ have any questions about this study
  - ✓ have questions about your rights
  - ✓ feel you have been injured in any way by being in this study
- You can also call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if you
  - ✓ have questions about this study
  - ✓ have questions about your rights
  - ✓ can't reach the study team
  - ✓ need to speak to someone not directly involved with this study

What should I do if I want to be in the study?

Sign this form. We will give you a copy of this form to keep.

By signing the document I am saying:

- I understand that joining this study is voluntary.
- I agree to be in the study.
- Someone talked with me about the information in this document and answered all my questions.

I know that:

- I can stop any and all parts of the study at any time and nothing bad will happen to me.
- I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- My decision will not change my medical care at UAMS.
- I do not give up any of my rights by signing this form.

Study Title:	**Health literacy intervention to improve diabetes outcomes among rural primary care patients**
PI (researcher):	**Kristie Hadden**
Institution:	**University of Arkansas for Medical Sciences**
Sponsor:	**National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases**

I agree to be part of this study:

_____ _____
Your name (please print) Your signature

_____
Date

If someone is signing this form for the subject, explain why:

_____ _____
Name of legally responsible person (please print) Signature of legally responsible person

Relationship to you: _____

_____ _____
Name of person obtaining consent (please print) Signature of person obtaining consent

_____
Date