# Document Coversheet

Study Title: Clinic to Community Navigation to Improve Diabetes Outcomes

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**WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?**

You are being invited to take part in a research study about taking care of your diabetes. You are being asked to take part in this study because you are an adult (age 18+); Appalachian resident, with no plans to relocate out of the area in the next 18 months, you are willing and capable of participating, and you either have been told that you have type 2 diabetes or/and you have blood Hb1A1C levels of at least 6.5%. If you volunteer to take part in this study, you will be one of about 1300 people to do so.

**WHO IS DOING THE STUDY?**

The person in charge of this study is Nancy Schoenberg (*Principal Investigator, PI*) of University of Kentucky, Department of Behavioral Science. There may be other people on the research team assisting at different times during the study.

**WHAT IS THE PURPOSE OF THIS STUDY?**

By doing this study, we hope to learn the best way to help people with diabetes manage their health.

**ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?**

You should not take part in this study if you plan to move out of the area in the next eighteen months, as we will try to contact you every three to six months of this project.

**WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?**

There are three parts to this project: (1) screening for eligibility; (2) a series of interviews; and (3) a program. The screening procedure will be conducted at a community location, like your home or a church. To determine eligibility, you will be asked several questions and your blood sugar will be tested by a brief finger prick. You will be notified immediately about your A1C. We would like to provide the screening results to your primary care doctor, with your permission. If you are eligible to participate, you will be contacted for an interview which will last one hour. The interview will be conducted in a community setting that you chose—a church, home or our project office in Whitesburg, KY.

We also will invite you to participate in one of three possible programs. If you are asked to participate in the Diabetes self-management group classes, you will need to come to a community location (a church or the Faith Moves Mountain office on Main Street in Whitesburg KY) for the meetings. You will be asked to attend six 2 hour sessions every week. If you are asked to participate in Patient Navigation, you will have a face to face meeting with our navigator--this may take place at your home, church, our office, or other designated locations. You will also receive several telephone calls. This program is expected to last several hours. We will check your clinic attendance with your main diabetes care provider. The third program combines the Diabetes self-management groups plus the Patient Navigation. This will include the six educational sessions, face to face meeting, and the telephone calls.

**WHAT WILL YOU BE ASKED TO DO?**

If you are eligible to join the project, you will be will be asked to answer 60 minutes of questions by an interviewer. These interviews will be repeated three times, once at month 3 and then again at month 6 and again at month 9. The project team will decide which program your church or organization is asked to join. This placement will happen by chance— your church or community organization will be randomly drawn from a list.

If you are asked to join the Diabetes self-management group classes, you will attend six meetings where you will learn about taking care of your diabetes. At each of these meetings, you will focus on a different topic—checking blood sugar, talking with your doctor, eating rights, and so on. If you are asked to participate in the group diabetes self-management program, you will attend six 2 hour sessions. If you are asked to participate in Patient Navigation, you will have a face to face meeting with our navigator--this may take place at your home, church, our office, or other designated locations. You will also receive several telephone calls. This program is expected to last several hours. The third program combines the Diabetes self-management groups plus the Patient Navigation. This will include the six educational sessions, face to face meeting, and the telephone calls.

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

There are very few risks or discomforts involved in this study. You may experience some discomfort when you have a finger prick for the blood sugar test. Blood draw related risks may include: pain,bruising, soreness, bleeding, possible fainting and infection. The only other risk involves that potential that some of the information you provide might be viewed by study personnel.

**WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

There is no guarantee that you will get any benefit from taking part in this study. However, some people have experienced an improvement in their diabetes self-management. Your willingness to take part, however, may, in the future, help doctors better understand and/or treat others who have your condition.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

**IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

If you do not want to be in the study, there are no other choices except not to take part in the study.

**WHAT WILL IT COST YOU TO PARTICIPATE?**

There are no costs associated with your participation in this study. If you are asked to attend program classes, there may be travel costs if you are asked to travel to a church or our project office in Letcher County for the sessions.

**WHO WILL SEE THE INFORMATION THAT YOU GIVE?**

We will make every effort to keep confidential all research records that identify you to the extent allowed by law. If you agree, we will share the results of your health screenings (blood sugar, blood pressure, etc.) with your doctor. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will have to collect your social security number once to process your payment, but you may still participate if you do not wish to provide your social security number.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. We will store all of the data we collect from you on a computer that is password protected. Only the project leaders will have access to the passwords and your identification code numbers. Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still en route to us.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you pose a danger to yourself or someone else. Also, officials from the University of Kentucky may look at or copy pertinent portions of records that identify you.

**CAN YOUR TAKING PART IN THE STUDY END EARLY?**

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. The individuals conducting the study may need to withdraw you from the study if you cannot participate regularly or if any problems arise.

**ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?**

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

**WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?**

If you believe you are hurt or if you get sick because of something that is due to the study, you should call the investigator, Nancy Schoenberg, Ph.D. at 859-323-8175 or Van Breeding, MD at 606-633-4871.

**WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?**

You will receive $35 for each of the three surveys that you complete.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?**

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Nancy Schoenberg, Ph.D. at 859-323-8175. If you have any

questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity between the business hours of 8am and 5pm EST, Mon-Fri at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

**WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?**

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

**AUTHORIZATION TO CONTACT HEALTH CARE PROVIDER**

Do you give permission for the project staff to contact your main diabetes care provider to provide information about your health screening results and to verify your clinic attendance?

☐ **Yes** ☐ **No** _____**Initials**

**POTENTIAL FUTURE USE**

**Contacting Research Subjects for Future Studies**

Do you give your permission to be contacted in the future by Nancy Schoenberg regarding your willingness to participate in future research studies about how to prevent, detect, or treat diabetes?

☐ **Yes** ☐ **No** _____**Initials**

**WHAT ELSE DO YOU NEED TO KNOW?**

There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case the data will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

**AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION**

Researchers are required by to protect your health information through the privacy law, HIPAA (Health Insurance Portability and Accountability Act). Below, we describe how researchers may use your health information.

**Your health information that may be accessed, used and/or released includes:**

- Your medical appointment dates
- Information in a medical record
- Lab tests, or certain health information indicating or relating to a particular condition

**The Researchers may use and share your health information with:**

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.

The researchers agree to only share your health information with the people listed in this document.

**After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:**

- You will send a written letter to: Nancy Schoenberg, nesch@uky.edu or 125 Medical Behavioral Science Office Building, University of Kentucky Lexington KY 40536-0086 to inform *her* of your decision.
- Researchers may use and release your health information **already** collected for this research study.

The use and sharing of your information has no time limit.

**If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.**

**You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.**

_____ _____
Signature of person agreeing to take part in the study Date

_____
Printed name of person agreeing to take part in the study

_____ _____
Name of [authorized] person obtaining informed consent Date