Document Coversheet

Study Title:

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KEY INFORMATION FOR SOCIAL NETWORK ANALYSIS TO IDENFITY COMMUNITY HEALTH WORKERS

You are being invited to take part in a research study about social support and self-management of Type 2 Diabetes.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

The purpose of this study is to train influential people in your community to improve self-care among individuals living with Type 2 Diabetes. You will attend a 20 hour (2.5 days) training session, two 30-minute interviews, and will conduct self-management training sessions as part of your Community Health Worker (CHW) role.

By doing this study, we hope to learn how effective it is to use influential individuals in the community to disseminate self-care education. Your participation in this research will last about one year.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may want to volunteer for this study if you are interested in learning how to train others to self-manage their Type 2 Diabetes. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to volunteer for this study if you are uncomfortable talking to others about their health or if you do not wish to become a community health worker. For a complete description of risks, refer to the Detailed Consent/Appendix.

There are no alternative procedures if you decide you do not want to participate in the study. For a complete description of alternate treatment/procedures, refer to the Detailed Consent/Appendix.

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 services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Brittany Smalls, PhD, MHSA of the University of Kentucky, Center for Health Services Research. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is (859) 323-4619 or Brittany.Smalls@uky.edu

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You would not qualify for this study if one of the following applies to you: You are under 18 years of age, you do not live in Leslie County, KY, you cannot speak or understand English, and you cannot provide informed consent for yourself.

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

The research procedures will be conducted at UK's Center of Excellence in Rural Health. You will need to come to a 20 hour training over the span of two and a half days, as well as two 30-minute interviews. The total amount of time you will be asked to volunteer for this study is 23 hours over the next 3 months.

WHAT WILL YOU BE ASKED TO DO?

- First, you will be asked to partake in an informal interview that will help us identify other influential people in your community who could be included in this study like you. You will be asked to provide the first name, last initial and occupation (or job title) of these individuals. You will be provided with a recruitment/referral card to be given to the 3 persons you identified as potential participants so these participants can contact the study principal investigator (PI) if they are interested in taking part in the study.
- You will be asked to attend a training called the Diabetes Empowerment Education Program (DEEP). You will then be asked to provide the Type 2 Diabetes Mellitis (T2DM) self-management sessions from the DEEP training to older adults in your community with Type 2 Diabetes. You will also be asked to participate in two 30-minute interviews with the research team throughout the study.
    - As part of the research, you are training older adults in your community how to manage their Type 2 Diabetes in a healthy way.
    - You will be asked to attend a 20-hour workshop that will prepare you to administer modules to community residents. The self-care sessions will focus on empowering persons living with or at risk for T2DM including self-care skills, knowledge, and strategies to facilitate behavior change. You will be expected to complete training within 3 months of agreeing to serve as a CHW.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- While we do not anticipate any risks, you should know there are always potential risks. Potential risks in this study include a breach of confidentiality, and possible emotional distress when discussing self-management sessions that you have conducted with older adults with Type 2 Diabetes.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, some people have experienced high levels of satisfaction and improved employment prospects when gaining work experience through conducting self-management sessions that benefit their neighbors.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be your responsibility.

Your insurer, Medicare, or Medicaid, may agree to pay for the costs. However, a co-payment or deductible may be needed from you. The amount of this co-payment or deductible may be costly.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. No names (neither participant names nor names provided by participants) will be included in published manuscripts.

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. All information we collect from you will be kept on a locked server at the University Of Kentucky Center for Health Services Research.

All audio files of interviews will be saved on an encrypted device and any information provided will be de-identified by our research team. All files, whether audio or text, will be saved on a password-protected server.

You should know that, in extreme circumstances, we may have to show your information to other people. For example, the law may require us to share your information with a court or agencies if you suspect an older adult you are working with is experiencing abuse or a severe medical event.

Officials of the National Institutes of Health, the University of Kentucky, and The National Institute on Diabetes and Digestive and Kidney Diseases may look at or copy pertinent portions of records that identify you.

Certificates of Confidentiality (CoC):

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of older adult abuse.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The DEEP training program will no longer be provided to you if you are removed from this study, and you will not be compensated for any sessions completed after you are removed. This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

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 Brittany Smalls, PhD at (859) 323-4619 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility. You do not give up your legal rights by signing this form.

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

You will receive monetary compensation for taking part in this study. You will receive $200 for completing the DEEP training program. You will also be compensated $50 for each self-management session provided, and for completing study visits with the research team at 6 and 12 months.

If you earn $600 or more by participating in research, it is potentially reportable for tax purposes.

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

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 200 people to do so. The National Institutes of Health is providing financial support and/or material for this study.

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

Appendix A: Study Visits

WHAT WILL YOU BE ASKED TO DO?

First, you will be asked to partake in an informal interview that will help us identify other influential people in your community who could be included in this study like you.

Then, we will ask you to attend a training session. You will be trained as a community health worker using the Diabetes Empowerment Education Program (DEEP). You will then be asked to provide Type 2 Diabetes self-management sessions to older adults in your community with Type 2 Diabetes.

Month	1	2	3	4	5	6	7	8	9	10	11	12
Training	x	x										
Interview						x						x
Session Delivery			x	x	x	x	x	x	x	x	x	x

INFORMED CONSENT SIGNATURE PAGE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendix A: Study Visits**

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject **Date**

_____

Printed name of research subject

_____ _____

Printed name of [authorized] person obtaining informed consent Date

_____

Signature of Principal Investigator or Sub/Co-Investigator