SUMMARY EXPLANATION OF RESEARCH

Penn State College of Medicine
Penn State Health

Title of Project: **Project Talk: a cluster, randomized controlled trial to engage underserved communities across the United States in advance care planning**

Principal Investigator: Lauren Jodi Van Scoy, MD

Address: 500 University Drive, Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m., 1-844-432-TALK (8255)

You are being invited to volunteer to participate in a research study. Research studies include only people who voluntarily choose to take part. This summary explains key information about this research. You are urged to ask questions about anything that is unclear to you.

- The purpose of this study is to determine how different types of conversation activities affect people and their decision-making.
- This study is called a randomized-control trial. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will assigned to. There are three conversation tools (1) the Hello Game (2) The Conversation Project Starter Kit, and (3) Table Topics game. **Your community host was randomized to the Table Topics conversation game.** We will compare the information that we gather for the three tools to determine the usefulness of each tool. for having meaningful discussions.
- Anyone who attends this Project Talk event is welcome to be part of the Table Topics game as a part of the event. Everyone will receive some health informational resources. If you choose to participate in the research, you will complete questionnaires about your experience and thoughts related to planning for medical decision-making.
- Six months after the event, researchers will call to conduct a phone interview. During the call, you would complete some follow-up questionnaires. The phone interviews will be audio recorded.
- The expected time to complete these activities is:
    - The Table Topics game — up to 1 hour
    - Research questionnaires: — 20 -30 minutes
    - Follow-up phone interview at 6 months — 20 -30 minutes
- You may opt not to participate in the research and still be part of the group discussion.
- The risks that are associated with being in the research are minimal and may include distress, discomfort discussing end-of life issues, and fatigue.
- There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

- Confidentiality of records are maintained by keeping your name separate from your data – each participant is assigned a number that is kept separate from your name and not linked to your information. Encrypted databases are used to store all data. Audio files are deleted from recorders immediately after the files are uploaded to a secure storage network.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know about the Certificate of Confidentiality.
    - The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.
    - Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.
- The benefits of participating in this study may include you becoming better prepared for medical decision-making. Society will benefit, as this research will provide important information about to help underserved Americans become better prepared for medical decision-making.
- We may use your research information in future studies without your additional informed consent. Before we use or share your information, we will remove any information that shows your identity.
- There are no costs to participate in this study.
- Participants will be compensated for their time with a $25.00 gift card for completing questionnaires and Table Topics game, and an additional $25.00 gift card upon completing the 6-month follow-up phone interview.
- This study is funded by The National Institute on Minority Health and Health Disparities.
- The investigators have no financial relationships or conflicts of interest to disclose.
- This section is about your identifiable health information that will be collected for this research study as explained above.
    - We will use and disclose your information only as described in this summary and in the HMC privacy Notice.
    - If you do not want us to use your identifiable health information, you should not be in this research.
    - Your permission for the use and sharing of your identifiable health information will continue indefinitely.

- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form.
- The PSU Institutional Review Board, the Human Subjects Protection Office and the Research Quality Assurance Office at HMC/PSU, the sponsor (if applicable), FDA (if applicable), and Office for Human Research Protections (if applicable) in the Department of Health and Human Services may need to read your medical and research records if they need to review this study as part of their duties.
- In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have been harmed from participating in this research, you should contact Dr. Lauren Jodi Van Scoy at 717-531-6704. If you have questions regarding your rights as a research subject or concerns regarding your privacy, you may contact the research protection advocate in the HMC Human Subjects Protection Office at 717-531-5687. You may call this number to discuss any problems, concerns or questions; get information or offer input.

You do not have to participate in this research. Taking part in the research study is voluntary. Your decision to participate or to decline the research will not result in any penalty or loss of benefits to which you are entitled.

Tell the researcher your decision regarding whether or not to participate in the research and to allow your information to be used and shared as described above.