

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**

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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 whether playing a serious conversation game called Hello is a more effective tool for having conversations about medical decision-making and end-of-life issues, than other advance care planning (ACP) approaches.
- If you chose to participate in the research, you will be asked to complete a brief phone interview two weeks after the event to give your feedback and opinions about study tools and processes as it relates to usability and feasibility in your community. The interview would be audio recorded.
- The expected time to complete the interview is 15 – 20 minutes.
- The alternative for participating in this research is to decline participation.
- 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.
- You will not benefit from taking part in this study. Society will benefit, as this research will provide a better understanding of how to engage underserved Americans and help them 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 the research.
- 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.

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.