RESEARCH SUBJECT CONSENT AND HEALTH INFORMATION RELEASE FORM

TITLE: Able, Stable, & Well: A Healthy Aging & Falls Prevention Program

INVESTIGATOR: Megan McCarthy, MPH, CPH
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STUDY-RELATED PHONE NUMBER(S):
Name: Megan McCarthy, MPH, CPH
Phone Number: (352) 569-3115
Study Role: Principal Investigator

Name: Brittney McCann, MPH, CPH
Phone Number: (352) 569-3134
Study Role: Co-Investigator; Program Coordinator

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject. If you are a legally authorized guardian, please remember that "you" means the research or study subject.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of this study is to learn things that will benefit our communities in the future.
- The decision to join or not join the research study will not impact your ability to participate in the Able, Stable, & Well Program or affect your ability to use the services of the Florida Department of Health in Sumter County.
- After reading the consent form, you should know exactly how your personal health information will be used and what the purpose of this study is.
- We will take all appropriate measures to protect your information from being released to unauthorized individuals/organizations.
- No identifying information such as name, date of birth, or address, will be used in public publications.
- Should you choose not to allow the use of your health information in this study you will not be able to participate in research. However, this will not impact your ability to use services offered by the Florida Department of Health in Sumter County in the future.
- 12-months after your initial enrollment in ASW all of your personally identifiable information that is held by the ASW program will be destroyed in order to protect your personal health information. After this has occurred you will no longer receive communications from ASW.

- Your information will not be shared with third parties (i.e. agencies or organizations not discussed in this document) without your prior consent.

PURPOSE OF THE STUDY

The Florida Department of Health in Sumter County (DOH-Sumter) is the agency hosting this research project. This research project has the goal of finding out what the long-term and short-term impact of the Able, Stable, & Well Program (ASW) has been. The research also has the goal of putting together an article that will share the experience of DOH-Sumter in running the ASW. It is the hope of Sumter-CHD that by reaching these goals we can give other counties and states a model that they can use to benefit their communities.

PROCEDURES

- You will fill out a fall risk assessment questionnaire.
- This questionnaire will include questions relating to home hazards, individual hazards, and environmental hazards that may contribute to your risk of a fall. This will take approximately 10 minutes.
- Upon submission of this questionnaire, you will receive a personalized report based on your responses that includes a list of actions to take to reduce your fall risk and a list of possible resources to assist you.
- The research team will conduct follow-up surveys and you will be contacted by email after 6 and 12 months to complete surveys online to check on your progress in taking actions to reduce fall risk.
- Data collected from surveys/questionnaires and from your personal record will be used to evaluate the impact of the ASW program. The survey will take approximately 10-15 minutes and will ask questions about contact information, health behaviors, personal perceived risk of falls, medical history, fall history, and other data that maybe important to the research effort.

RISKS AND DISCOMFORTS

- This study involves no greater physical risk than would be expected from normal life.
- This study does involve the risk that personal health information could be re-disclosed by one of the parties to which it was initially disclosed.
- While this study aims to reduce fall risk for participants, unfortunately, we can never eliminate fall risk. Everyone, regardless of age, is at an inherent risk of falling due to environmental or personal factors affecting the individual and their health. The hope is to prevent as many falls as possible through implementing protective measures and decreasing hazards throughout the community. Your participation in this research project will assist ASW in our goal to identify predictors for fall risk and apply these findings towards reducing fall risk throughout the community.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to approve a new consent if this occurs in order to continue contributing to this research.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information will be used in this study?
The research team will use your personal health information in this study. Information to be used includes:

- Name
- Gender
- Race & Ethnicity
- Date of Birth
- Address (including Street number, City, State, and Zip Code)
- Email Address
- Phone number
- Marital status
- Income
- Living arrangement

Who may use and give out information about you?
The research team will have access to your personal health information. The research team includes specially trained research assistants and administrators employed the Florida Department of Health in Sumter County. The primary program researchers can be contacted at:

- Megan McCarthy, MPH, CPH, Phone Number: (352) 569-3115
- Brittney McCann, MPH, CPH, Phone Number: (352) 569-3134

Your information may be given to:

- Florida Department of Health Human Research Protection Program and Institutional Review Board

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right and ethically.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give authorization to use and disclose my health information?
Then you will not be able to be in this research study. You will be able to use the services of the Florida Department of Health in Sumter County in the future.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (terminate) my authorization?
Yes, otherwise authorization will be remain in place until the end of the study.

You may withdraw or revoke your authorization to use and disclose your health information at any time. You do this by sending written notice to the study co-investigator, Brittney McCann, or

to the principal investigator, Megan McCarthy (contact information can be found on page one of this document). If you withdraw or revoke your authorization, you will not be able to stay in this study. The option to withdraw from the research study and/or unenroll from the ASW program can also be accessed via the unenroll link available at the bottom of each email correspondence.

When you withdraw or revoke your authorization, no new health information identifying you will be gathered after that date. De-identified information that has already been gathered may still be used and used in publications.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your authorization. Although normal standards for protecting confidentiality will still apply, HIPAA may no longer protect health information after the initial disclosure for research purposes. The research team takes your privacy and confidentiality seriously.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the research team without your consent for any reason, including, but not limited to:

- if it is in your best interest
- if you do not consent to continue in the study after being told of changes in the research that may affect you

QUESTIONS
Contact Brittney McCann at (352) 569-3134 or Megan McCarthy at (352) 569-3115 for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury, or
- if you have questions, concerns, or complaints about the research.

If you want to talk with someone independent of the research team for questions, concerns, or complaints about the research; questions about your rights; to obtain information; or to offer input, you can contact the Florida Department of Health Institutional Review Board. An Institutional Review Board is a group of people who review research to ensure participants are protected and the research is conducted in an ethical way. You can contact:

Florida Department of Health
Human Research Protection Program and Institutional Review Board (IRB)
4052 Bald Cypress Way, Bin A-24
Tallahassee, Florida 32399-1749
(850) 245-4585
E-mail: Research@flhealth.gov

The Human Research Protection Program (HRPP) provides research consultations and technical assistance concerning applications for review of research by the Institutional Review Board. An Institutional Review Board is a committee that reviews research to ensure it is ethical, and that participants are protected.

HRPP will not be able to answer some study-specific questions. However, you may contact HRPP if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Accepting these terms and completion of the questionnaire implies that you have read the above information and consent to take part in the research.

Please retain a copy of this document for your records.