



Informed Consent to Participate in Research Involving Minimal Risk

Pro # 00034170

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

We are asking you to take part in a research study called:

Effects of a pilot volunteer-based lunch program on feelings of loneliness in elders: a randomized control trial

The person who is in charge of this research study is Brennan Ninesling. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. He is being guided in this research by Lucy Guerra, MD, MPH.

The research will be conducted at your residence.

This study is sponsored by the Arnold P Gold Humanism Society.

Purpose of the study

We want to see if a student lunch visit program can help feelings of loneliness, and we plan to ask you some questions assessing your state of loneliness now and then again in six weeks after the program. We are interested in testing the effectiveness of this program, and we are interested in your feelings whether or not you are assigned a medical student for the next six weeks.

Why are you being asked to take part?

We are asking you to take part in this research study because you are at or above the age of 60, and your score on our previous survey indicated that you may exhibit feelings of loneliness.

Study Procedures:

If you take part in this study, you will be asked to:

- If selected for the intervention group (randomly assigned)
 - Eat lunch once a week for six weeks with the same USF medical student that will bring meals from Meals on Wheels for both you and him/her. Each lunch visit will take about one hour.
 - Answer questions that will take approximately 15 minutes to complete both before and after the program.
- If selected for the control group (randomly assigned)
 - Answer questions that will take approximately 15 minutes to complete both before and after the six-week period.

Total Number of Participants

About 66 individuals will take part in this study at USF.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

Benefits

We are unsure if you will receive any benefits by taking part in this research study.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

Compensation

You will receive no payment or other compensation for taking part in this study.

Costs

It will not cost you anything to take part in the study.

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator, study coordinator, and other research staff.
- Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- Any agency of the federal, state, or local government that regulates this research.

- The USF Institutional Review Board (IRB) and related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an unanticipated problem, call Brennan Ninesling at (678) 896-2728.

If you have questions about your rights as a participant in this study, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

To revoke this form, please write to:

Brennan Ninesling
For IRB Study # 00034170
15610 Morning Drive
Lutz, FL 33559

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies. You will receive a signed copy of this form.

Consent to Take Part in this Research Study

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

Signature of Person obtaining Informed Consent

Date

Printed Name of Person Obtaining Informed Consent