Telephone Consent Example

CONCISE SUMMARY

Food insecurity, or not being able to afford healthy food, makes it harder to manage high blood pressure. The best way to treat food insecurity and improve blood pressure is unknown. This study will compare programs that address food insecurity for people with high blood pressure. We are comparing 8 different versions of the program. The specific version you would be in would be assigned to you at random, like flipping a coin. You can think of the program as being assigned in 3 steps—each one at random. The first step is whether you would receive a $40/month food subsidy versus a box of healthy food delivered to your home. The next step is whether the intervention would last for 6 or 12 months. The final step is whether you would be assigned to work with a community health worker, over the telephone, while receiving the intervention, or not. No matter what version you are in, you would participate in the study for 18 months—this includes both time when you are receiving the intervention and follow-up time after the intervention is over. There will be four telephone-based study visits where you complete a questionnaire. One session will be at the start of the study, a second at 6 months after the start of the study, a 3rd one 12 months after the start of the study, and a 4th one at 18 months after the start of the study.

This is a minimal-risk study. The intervention simply provides healthy food, or money to buy healthy food. Taking part does require a time commitment for study visits calls and working with the community health worker if you are assigned to one. We expect participants in both study groups will have reduced food insecurity and consider this a benefit of taking part in the study.

IRB Study # 21-0992

Hello, my name is_____. I am a (student/faculty member/staff member) from the University of North Carolina at Chapel Hill conducting a research study about food insecurity and high blood pressure. Your participation in this study is completely voluntary. This means that you do not have to participate in this survey unless you want to.

You have already had an eligibility call or completed a eligibility form so I will not repeat those questions. Instead, I will tell you some important information, to help you decide whether you want to participate in this study, and let you ask questions of me.

The purpose of this research study is to look at food insecurity and high blood pressure. We estimate that approximately 1400 people will enroll in this study.

How long will your part in this study last?
You will be in the study for about 18 months.

What will happen if you take part in the study?

After we have finished reviewing this form, you will decide if you would like to join the study. If yes, you will give verbal consent over the phone.

If you decide to participate, you will complete your first questionnaire, over the phone. You will answer questions about things like what you eat, what types of activities you do and other questions about your health. This should take about 20 minutes.

After you complete this questionnaire, a computer program will randomly assign you, like flipping a coin, to receive one of the food insecurity interventions. There are 8 different variations of these, and you will be assigned to one. The programs vary in 3 key ways, and I will describe those to you below. After you are assigned to a program you will receive a call from a member of the study team to tell you which program you are in, give you more details, and go over next steps.

Variation 1: Food Subsidy versus Food Box

The first variation for the programs is whether you will receive a food subsidy or a food box. If you are assigned to the food subsidy group, you will be given $40 that can be spent at any Food Lion supermarket each month, to purchase fruits and vegetables. If you are assigned to the food box, you will receive a home delivery of healthy food every 2 weeks. This will include fresh produce, and shelf-stable foods like oils and spices.

Variation 2: 6 months versus 12 months.

The next variation is about the duration of intervention. If you are assigned to the 6 month group, you will receive the intervention for 6 months, and if you are assigned to the 12 month group, you will receive it for 12 months

Variation 3: Community Health Worker

The last variation is whether you will work with a community health worker or not. Making changes for a healthy lifestyle can be difficult. If you are assigned to a community health worker group, you will work with that person to help. They will offer assistance like advice on following a healthy diet, cooking tips, and connection to other resources in your community that might improve your health. You will have monthly telephone calls with the community health worker, lasting about 45-60 minutes, and a brief follow-up call (about 15 minutes). If you are not assigned to the community health worker group, you will still receive the same food insecurity intervention (food subsidy or food box), but will not work with a community health worker.

Follow-up Telephone Visits

You will have four telephone visits. You will be asked to complete a questionnaire 4 times over the course of the study. Each time should take about 20 minutes. There is a small chance that some of the questions may make you feel uncomfortable. You don't have to answer those questions if you don't want to. In fact you don't have to answer any question that you choose not to answer. And that is fine. We will just skip that question and go on to the next one.

The first will be about after we complete the consent process, the second 6 months after you start the study. The third will be about 12 months after you start the study. The fourth will be about 18 months after you start the study. They will be the same as your first study session. You will be called and asked to answer questions over the phone. This call will take about 20 minutes. You will receive $10 each time you complete one of these follow-up visits. The follow-up visits are the same regardless of what intervention group you are in.

Qualitative Interviews
A subset of study participants will be selected to complete telephone interviews about their experience with the program. These are completely optional and whether you do them or not will not affect your participation in the rest of the study. These interviews will be recorded so we can analyze them, but information from them would only be published in aggregate, not in a way that could identify you. These interviews would take about 30 minutes, and you would receive $20 for completing one.

What are the possible benefits from being in this study?
Research is done to gain new knowledge. By being in this study you may have more access to healthier foods and better blood pressure control. These are not guaranteed benefits.

What are the possible risks or discomforts involved from being in this study?
There are few risks and discomforts involved with being in this study.

- Overall we think there is very little risk to you from the food, money to buy food, or dietary advice given as part of the program.
- People may have allergic reactions to foods. For known allergies, food vendors will have up to date food allergy training as required in NC, and we will work with the food vendors to ensure potential allergens are appropriately labeled. Please check labels for potential allergens, and not consume foods with those allergens. It is possible that you might have a food allergy that you are unaware of. Overall, we think this risk would be no greater for having taken part in the study than if you did not take part.
- You may choose to lose weight as part of this program. If you do not eat enough, you could lose weight too fast.
- Doing more physical activity is not the main focus of this study. However, we do recommend you do moderate physical activity. Those who increase their level of physical activity may experience minor muscle pain. This is common, affecting more than 50 in a 100 people. Minor muscle pain will go away. This type of activity rarely, less than 1 in a 100, causes serious health problems such as chest pain.
- Changing how you eat could lead to lower blood pressure. Blood pressure that is too low can cause dizziness and even falls. It is very rare that this could be a serious risk, (less than 1 in a 100 people). Typically, the blood pressure is lowered slowly. This will allow your doctor time to observe the lower blood pressure and reduce any blood pressure medicine you may be taking.
- In all studies, there is a very slight chance of loss of privacy. This means the risk that others may see your study information. As we describe in more detail below, we will

do all we can to make sure this does not happen.

Also, there may be other risks we did not list here, including uncommon or previously unknown risks. You should report to the research team any problems that may be due to this study.

How will information about you be protected?

The results of your study surveys and interviews will be stored with your study ID number and your first and last initial. We call this coded data. No one other than study staff will be able to connect your name and study ID as we will follow standard procedures to protect the privacy of research data.

For this study, we also need to access your electronic health record data, held at UNC. This will enable us to look at your blood pressure, medications, and similar information important for the study. To do this, after we complete this consent form, we will also read you a HIPAA authorization form that enables us to look at this information. If you do not wish to provide this authorization, you will not be able to participate in the study.

Your study information will only be shared among study team members. Team members are at both UNC and Blue Cross Blue Shield of North Carolina. All will have undergone training about protecting information safely and respecting the rights of research participants.

Your name, contact information and any food allergies will be shared with vendors that manage food box or subsidy delivery. These third parties are not affiliated with UNC and that once the specified information is disclosed to the third parties it is possible that they may use the information according to their own policies and/or procedures.

We may use your coded data, as described above, in future research without additional consent. However, in some cases, the Institutional Review Board (called IRB and described below) may require that you be re-contacted and asked for your consent/permission to use your data in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought.

When writing reports or publishing articles participants will not be identified by name. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by agents of the University or research sponsors for purposes such as quality control or safety.

What if we learn about new findings or information during the study?

You will be given any new information gained during the study that might affect your willingness to continue participating.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by Blue Cross Blue Shield-NC (The Sponsor). This means that the research team is being paid by the sponsor for doing the study. In addition, external site principal investigator, Lori Taylor the Senior Program Manager on the Driver's of Health Team of Blue Cross Blue Shield of NC and co-investigator Brant Morefield the Director of Healthcare Research Evaluation and Improvement with Blue Cross Blue Shield of NC will evaluate the effectiveness of food insecurity intervention (food subsidy vs. health food delivery).

If you would like more information, please ask the researchers listed in the first page of this form.

Blue Cross NC wants to help members gain access to healthy food to better understand how it may improve overall health and how Blue NC should improve benefits in the future. Your decision to participate or not will have no impact on your insurance coverage or care provided.

Study Withdrawal:
Changes that preclude us from collecting data, such as changes in healthcare provider or health insurance may result in withdrawal from study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee called the Institutional Review Board or IRB. This committee works to protect your rights and welfare. If you have questions or concerns about your rights, would like more information or have suggestions please contact them. You can call the Institutional Review Board at 919-966-3113 or you can email IRB_subjects@unc.edu.

Are there any other questions I can answer for you?
{If No, proceed below}

Do you voluntarily agree to participate in this research study?

Yes {Proceed below}
No {Say: "That is OK. Thank you for your time.", and continue to HIPPA Authorization form}}