Institutional Review Board Toolkit for Produce Prescription Projects

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Guide to Institutional Review Boards

Purpose

This document is a guide for grantees who are conducting research with the Nutrition Incentive Hub and is about the process of working with Institutional Review Boards.

What are Institutional Review Boards?

Institutional Review Boards (IRBs) are administrative organizations established to protect the rights, privacy, and welfare of human subjects recruited to participate in research activities. Guidelines for every IRB in the United States are established and overseen by the Food and Drug Administration (FDA). According to FDA regulations, an IRB has the authority to approve, disapprove, or require modifications to research protocols that involve human subjects.

What human subjects research does the Nutrition Incentive Hub conduct?

The Nutrition Incentive Hub is charged with providing evaluation and reporting for institutions that launch, modify, or expand Nutrition Incentives or Produce Prescription programs. Specifically, with regard to human subjects research, participant-level core metrics are being collected to contribute to research hypothesizing that program activities increase the consumption of fruits and vegetables and may improve food security and other health outcomes. The information collected from participants is considered human subjects research.

What are human subjects?

A human subject is the terminology used to describe an individual (i.e., participant) who provides data to an investigator during a research study, including programmatic evaluation. Research is as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

What is the goal of IRB review?

The goal of IRB review is to ensure that research is ethical, unbiased, and complies with laws and regulations designed to protect human subjects, including informed consent of participants.

How do I find a local IRB to work with?

IRBs are typically housed within universities, medical institutions, and governmental agencies that conduct human subjects research. It is preferable that you submit documents to an IRB that is geographically close to your research site. Geographic proximity better prepares the IRB to review the proposed research with regard to the rights, privacy, and welfare of human subjects within a local context. If your project includes an employee of a university or clinic, contact this individual to determine if an IRB office exists locally. If you do not have an employee of a university or clinic on your team, contact your nearest university to find a local IRB. If no local IRB is accessible to you, contact the Nutrition Incentive Hub to discuss alternatives and next steps.

Does the research my organization conducts for the Nutrition Incentive Hub require IRB review?

Yes. Any research that includes human subjects with the purpose of contributing to generalizable knowledge and sharing beyond the populations involved requires review from an IRB. The IRB determines the level of review based upon the research described in the documents submitted by the investigator.

What are the different levels of IRB review?

Based upon the research protocol within the documents submitted, the IRB will determine if the research project is exempt, requires expedited review, or should undergo full review.

- Studies that qualify as exempt are determined to present no more than minimal risk to the participant and fit into this federally designated review category (e.g. educational research; surveys, interviews, or observations; benign behavioral interventions; programmatic evaluation).
- Studies that qualify as expedited are determined to present no more than minimal risk to the participant and fit into this federally designated review category (e.g., clinical studies; collection of blood samples; audio or video recordings).
- Studies that qualify as full are determined to present more than minimal risk to the participant and do not qualify for exempt or expedited review.

What is minimal risk?

Defined by the FDA, minimal risk is the probability of physical or mental harm or discomfort that is not greater than those risks ordinarily encountered in daily life or during routine examinations or tests.

What level of IRB review is my research project?

The Nutrition Incentive Hub expects that a majority of the projects conducted will be exempt of expedited due to minimal risks posed to participants. To learn the level of IRB review for your research project, contact the IRB you plan to apply to, describe the research you will conduct, and ask for guidance about what type of application to submit. An IRB application must be submitted at the appropriate level of review for an IRB to approve, disapprove, or request modifications to the research protocol.

I think my research is exempt. Should I submit the required documentation to an IRB?

Yes, you need to submit documentation for an IRB to review. The IRB will then determine if the research is exempt and provide you with a certificate. How do I start an IRB application? Each IRB has slightly different procedures for submission. Visit the website of the IRB to which you plan to submit your application and follow the stated directions.

When do I need to submit an IRB application?

Your IRB application must be submitted and approved before you collect any data from human subjects. In addition, some IRB have timelines for reviewing applications. Please review your local IRB's website to ensure that you submit your application for approval before you need to collect data from human subjects.

What information will be asked on the IRB application?

Generally, all IRB applications ask for the following information: study team; description of the project; application type (i.e., exempt, expedited, full); sponsor or funder; location(s) of research activity; research design; study population; recruitment and screening procedures; benefits and risks to human subjects; study forms (e.g., survey); questions about vulnerable populations; informed consent process; and confidentiality and privacy.

According to my local IRB, COVID-19 is impacting my ability to collect research with human subjects. What do I do?

Each IRB has slightly different procedures for addressing human subjects research in the face of issues presented by COVID-19. Please contact the Nutrition Incentive Hub with information about your particular situation and a team member will help you to navigate the research process within guidelines.

Do I need to complete training for research with human subjects?

Yes, each local IRB requires all members of a research team to complete training about the protection of human subjects in research. Please refer to the CITI Training Guide for detailed information on training.

Who on my research team needs to complete training for research with human subjects?

Each local IRB requires all members of a research team to complete training. Anyone who collects or views the data collected, is required to complete training about the protection of human subjects in research.

My project includes multiple sites. Do I need to apply for more than one IRB approval from more than one institution?

No. You can rely on one local IRB to approve your research project. You must explain the details about how data will be collected at each site. All members of your team that will collect or see data collected need to complete training for research with human subjects and be added to the IRB application. Alternatively, in some instances it is simpler for each site to apply to a separate IRB to approve individual research projects. It is acceptable for each site to apply to a separate IRB to approve individual research projects. Any person who will collect or view human subject's data is required to be included on the IRB application.

My project includes team members from multiple organizations. Do I need to apply for more than one IRB approval from more than one institution?

No. You can rely on one local IRB to approve your research project. However, all members of your team that will collect or work with collected data need to complete training for research with human subjects and be added to the IRB application.

I need help. I am new to research and do not even know where to start.

The Nutrition Incentive Hub is here to help you. Please e-mail Carmen Byker Shanks at cbshanks@centerfornutrition.org, consulting adjunct research scientist, for help with your IRB every step of the way.

I need help. I would like someone to review my IRB application before I submit it.

Make sure your entire research team reviews the application before you submit it. The Nutrition Incentive Hub is also here to help you. Please e-mail Carmen Byker Shanks at cbshanks@centerfornutrition.org, consulting adjunct research scientist, for review of your application.

Resources

Food and Drug Administration. (2019). Institutional Review Boards. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56. Accessed March 26, 2020

Guide to CITI Training for Human Subjects Research

Purpose

This document is a guide for grantees who are conducting research with the GusNIP Nutrition Incentive Hub about the process to obtain a CITI Training Certificate.

About CITI Training

Any research that is conducted with human subjects must be reviewed and approved by an Institutional Review Board (IRB) to ensure that participants are being treated safely and ethically and that there are proper protocols to maintain confidentiality. Each local IRB requires that all team members that collect or see participant data complete human subjects research training. CITI program is an online training designed to provide uniform education to research team members about human subjects research. The learning modules within are followed by tests. The CITI training takes individuals 2 to 6 hours to complete, depending upon the speed at which you learn. At the end, each team member will receive a certificate of completion. The certificate of completion should be sent to the person who will submit your team's IRB application. Each certificate will be submitted with the IRB application. CITI certification must be renewed every 3 years.

Directions

The directions may slightly differ depending upon if CITI changes their platform, but generally follow these steps.

1. Go to the CITI Program website here.
2. Choose Register in the top tool bar
3. Under 'Select Your Organization Affiliation'
    - Type in the local university, health care system, or state government that you are affiliated with. If the organization appears, click on it. This ensures that the modules are FREE for you to take. Agree to the terms of service and, if applicable, that you are an affiliate by using the check boxes.
    - If the organization does not appear and you are not affiliated with a local university, health care system, or state government, choose 'Independent Learner Registration'. Fees apply.
4. Continue through the steps to create your CITI name and password.
5. Choose 'NO' for Continuing Education Credits, unless you choose to do so (this costs money and takes time).
6. Complete all of the information denoted by a red asterisk. You can include your own e-mail address and contact information. Your role in the research is likely 'Co-Investigator.'
7. For the dropdown menu that asks, 'Which course do you plan to take?' Choose 'Basic Human Subjects - Social and Behavioral Focus.'
8. Select 'I do not want to take a laboratory animal welfare course at this time.'
9. Select 'Social and Behavioral Research' (SBE) for the course that you need to begin.
10. On Step 7 of registration, for questions 3 - 9, select the 'No,' 'Not at this time,' 'I am not,' or 'I do not want' options, as appropriate.
11. 'Finalize Registration' and 'View Courses.'

12. Complete the modules by pressing ‘Start Now.’ The modules do not need to be completed all at once, so you can work on them at your own pace and save your progress.
13. Read through the presented content and take the quizzes that follow for the SBE module. Save your progress as needed and return to the CITI homepage to log in and continue the module as many times as needed to complete all sections as quizzes.
14. Once you are finished with all sections and quizzes of the SBE Basic course, you will be presented with a certificate. Create a PDF of your certificate and save it to your files.
15. E-mail the certificate to the person completing the IRB application once you have completed the course.

Guide to the Health Information Portability and Accountability Act (HIPAA)

Purpose

This document is a guide for grantees who are conducting research with the GusNIP Nutrition Incentive Hub about the Health Information Portability and Accountability Act (HIPAA), also known as The Privacy Rule.

About HIPAA

HIPAA sets standards and regulations to protect patients from inappropriate disclosure of Protected Health Information (PHI) that could harm their privacy. HIPAA applies to research that uses, creates, or discloses PHI.

What is PHI?

Protected Health Information (PHI) is any data that is in a patient's medical record that was generated from a health care service and can be used to identify an individual. Identifiers include name, geographic information, dates related to an individual, phone and fax numbers, mailing address, social security number, medical record number, health plan beneficiary numbers, account numbers, certificate or license numbers, vehicle identifiers or serial numbers, device identifiers or serial numbers, URLs, IPs, biometric identifiers, face photographs, any other unique identifying number.

What is not PHI?

Information that is not obtained from a patient's medical record or generated from a health care service, information that does not have any of the unique identifiers described above.

Does HIPAA apply to my research project?

HIPAA applies to research that obtains data from or adds data to a medical record, collects data during health care services, or uses data to make health care decisions.

HIPAA applies to my research project. What should I do next?

If your research involves HIPAA, you must take the following steps:

1. Many local Institutional Review Boards (IRB) require any investigator conducting research where HIPAA applies to take a training. Check with your local IRB.
2. You must include a statement in the informed consent such that the human subject (i.e., participant) can authorize the release of their PHI. Check with your local IRB about the specific language required. An example of the language that may be required is included below.
3. Submit the required HIPAA authorization language to your local IRB with your IRB application package.
4. Make sure all human subjects sign the authorization before collecting data.

I need example HIPAA language to include in my IRB application.

Example HIPAA language is included below for authorization from a human subject:

HIPAA Authorization for Disclosure of Protected Health Information

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record. The people who may request, receive, or use your private health information include the researchers and their staff. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record. By signing this form, you give permission to the research team to anonymously share your information. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it. You do not have to sign this Authorization, but if you do not, you may not join the study. Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies. You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Questions?

Please e-mail Carmen Byker Shanks at cbshanks@centerfornutrition.org for questions about HIPAA and how it relates to your project.

Sample E-mail to a Local Institutional Review Board for Produce Prescription Projects

Purpose

This document provides a sample e-mail inquiry to a local institutional review board (IRB) for Produce Prescription Program grantees collecting any kind of data from individuals (e.g., participant surveys, intercept surveys, focus groups, biomarkers, etc.) as part of their GusNIP grant. It is important to determine the level of review (exempt, expedited, full) required for a research study with human subjects, which includes program evaluation. Some local IRB websites make the type of IRB application clear on their website. In this case, you can skip writing a letter and submit the appropriate application type. If it is not clear, use the sample e-mail below to find out which type of IRB application is appropriate for your grant work. The grantee should complete the appropriate application based upon the IRB's response. IMPORTANT: Save all communication with the IRB to document your due diligence in undergoing IRB approval.

Sample E-mail

Dear Institutional Review Board at [fill in institution name],

I am writing to request the IRB's brief review of my project for help determining which level of review (exempt, expedited, full) is required before submitting a human subjects research application. The following text provides information about key components of the project that will assist you in the determination.

- **Title of project**: [fill in title]
- **Funder of project**: United States Department of Agriculture, National Institute of Food and Agriculture, Gus Schumacher Nutrition Incentive Grant Program (GusNIP)
- **Aim of project**: [fill in aim; e.g., This study aims to determine if study participants increase fruit and vegetable consumption after participation in a nutrition incentive program.]
- **Will participants undergo consent?** Yes, through a Consent Form
- **Recruitment procedures**: Beginning in [month], potential participants ages 18 and above who access [name of site or sites] will be asked to participate in [project title] through [name of recruitment tool; e.g., flyers and word of mouth]. Participants will be included in the study if the individual receives a nutrition incentive and are willing to complete study materials. Exclusion criteria will include [fill in any exclusion criteria; e.g., under 18, unable to complete study measures].
- **Number of participants expected for enrollment in the study:** [fill in number]
- **Intervention procedures**: Participants that enroll in the study will be provided with a nutrition incentive. A nutrition incentive is [explain nutrition incentive program at your site(s)]. Participants will receive the nutrition incentive [frequency; e.g., weekly for 6 months] at [location]. Participants will [describe how nutrition incentive is expected to be used].
- **Data collected**: After consent, participants will undergo research measures at [fill in timepoint; e.g., pre at baseline and post at 6 months]. The following measures will

be collected at [site where measures will be collected]: [fill in instruments; e.g., survey and biomarkers]. The survey will be collected by a researcher listed on this protocol and will ask questions about sociodemographics, health, and eating behaviors. [Describe other instruments and the process for collection; e.g., Biomarkers will be collected by a certified clinician [name measures; e.g., weight, height, hemoglobin A1c]. The participant will go to the [site name] and undergo a regular clinical appointment. Height and weight will be collected using a standard stadiometer and scale. Hemoglobin A1c will be collected through a venous blood draw.].

- **Risks to the participant**: The risks to the participant are minimal and not beyond what is encountered in daily life. [If collecting blood, describe risk; e.g., The participant will have no more than 6 mL of blood taken on two occasions. The blood will be taken from the arm via a venous blood draw. The total amount of blood taken for the whole study will be at most 18mL, or 3.6 teaspoons. The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting. Adverse effects will be reported to the principal investigator, IRB, and the participant will be given appropriate care at the site.]
- **Confidentiality**: All efforts to ensure participant confidentiality will be maintained. [Explain data security procedures and how participants' confidentiality will be protected. E.g., The participant's data will be coded and the master code will be kept separate from the data in a locked file, only accessible by researchers on this protocol.
- **Is HIPAA required?** [No, this project only collects survey data.] OR [Yes, this project collects biomarkers which indicate a person's personal health. A HIPAA worksheet will be submitted].

Please let me know if you need any other information about our project to determine the level of IRB application. We look forward to hearing from you as soon as possible if we should apply for exempt, expedited, full review. Thank you for your time.

Sincerely,
[name]

Questions?

Please e-mail Carmen Byker Shanks at cbshanks@centerfornutrition.org for questions about contacting a local IRB.

Template: Assent Form for PPR Projects Which Include Youth

Overview

The purpose of this document is to provide a template and language for an assent form. The assent form will be required if your research study includes youth (<18 years old). All youth will need to be accompanied by a legal guardian (e.g., parent). The legal guardian will also need to complete a consent document and sign the assent document.

Please check with your local Institutional Review Board (IRB) to determine if there is a specific template or boilerplate language required for assent forms. Use the template herein to adapt per the directions of the local IRB.

The assent (for youth) and consent (for legal guardians) forms should be written at no more than the reading level of the youngest eligible age. If this age is less than 12 years old, the reading level should be no more than 5th grade. Once your forms are finalized, check your document's readability score. Instructions for how to check your document readability score are found here.

In this template, the **purple bold font** indicates where you should insert your own program's information. The green font indicates instructions.

Assent Form Template

Header
Include the following information at the top of the assent form:

People in Charge of the Study: **Names of researchers**
Minor Child Assent to Participate in a Research Study

Title of research project

Include the following information below the header of the assent form:

What is a research study?
A research study is a way to find out new information about something. Children or teenagers (youth) like you do not need to be in a research study if they don't want to. We are asking you in this paper if you want to be in this research study.

What is this study about?
You are being asked to be in this research study. The goal of this study is to help to understand if giving people your age more fruits and vegetables can improve health. Your parent or adult caregiver will also be asked to help you during this study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read everything below and ask questions about anything before deciding whether or not to take part. Feel free to leave the room at any time. Use all the time you need to decide if you will take part in this project.

This study will help the research team to:
Understand how eating fruits and vegetables can help improve health
Understand how providing free or low-cost fruits and vegetables can help a family's budget.

Why are you being asked to be in this study?
You are being asked to be in the study because you are a child or teenager between the ages of **age range here**, you can speak and read English, and your family could benefit from help with getting free or low-cost fruits and vegetables.

What will happen at the study visits?

If you are in the study, you will:

- Come to the clinic three times to fill out some paper surveys, have your blood drawn, be weighed, and have your blood pressure taken
- You will be in the study for **duration of study**
- Your family will receive reduced-cost produce (fruit and vegetables) from **name of food retailer or market**

Will any part of the study hurt or cause problems?

You will have **number of blood draws or clinic visits**. You can't eat anything for 12 hours before the blood draw. The blood draw will happen first thing in the morning, at the clinic. After the blood draw you will be given a snack and then you can have breakfast. You may be hungry in the mornings before these three blood draws. You may feel pain when the needle goes into arm to draw blood. A bruise may form at the site.

People sometimes feel embarrassed when they answer personal questions. The survey asks some personal questions. Answering questions about your health might make you feel uncomfortable. Some of these questions are about your weight and eating habits, which may make you uncomfortable or embarrassed.

It is the researchers' job to keep all of your information private. There is always a chance some information will not be kept private, and this is a risk of being in the study.

What do you get for being in the study?

(Only include this section if gift cards are being provided)

If you are in the study, you will be given three different gift cards one for each of the three times you come to the clinic.

- Visit 1 $10
- Visit 2 $10
- Visit 3 $10

If I do not complete all 3 visits. I will only get gift cards for the visits I complete.

What if I have any questions?

You can ask any questions you have now about the study. All of your questions will be answered. If you have a question later, you can ask and get an answer. If you want to, you can call **name of researcher and phone number of researcher**. Or you can call the **name, phone number, and email address** of local Institutional Review Board (IRB).

Do you have to be in this study?

You do not have to be in this study. No one will be mad at you if you say no. If you don't want to be in this study, you just have to tell us. It's up to you.

Signature

If you decide to be in the study, please write your name below.

You can change your mind and stop being part of it at any time. All you have to do is tell one of the people in charge of the study.

You will get a copy of this form to keep.

Child's Printed Name: _____

Child's Signature: _____

Date: _____

Parent/or Legal Guardian of Child Signature: _____

Date: _____

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of Person Obtaining Assent: _____

Date: _____

I give my permission for my contact information (name, address, phone numbers, email addresses) to be kept by the **name of institution performing research study** for future use by the study investigators. They may contact me in the future (up to 15 years from the completion of the study) to ask me to take part in more research.

☐ YES
☐ NO

I choose not to be contacted in the future for additional studies, however I want to participate in this study.

☐ YES
☐ NO

Template: Consent Form for PPR Projects

Overview

The purpose of this document is to provide a template and language for a consent form. Research studies that include human participants (subjects) are required to include informed consent documentation. The purpose of the consent form is to formally document that the research participant understands the research study, how his/her/their data will be used in the study, and what the risks/benefits are to the participant. Research studies that are deemed "exempt" by an Institutional Review Board (IRB) may not require an informed consent form. These studies will require an "information sheet" or statement in lieu of a signed informed consent form.

Please check with your local IRB to determine if there is specific template or boilerplate language required for consent forms. Follow the provided directions first and use the language below to adapt. The details below may not apply to your program but are presented here as examples. Each participant enrolled in your study will need to sign a consent form and should be given a copy of the form to keep. The heading of your consent document should have a version number and date.

In this template, the **purple bold** indicates where you should insert your own program's information.

The consent form should be written at no more than an 8th grade reading level. Once finalized, check your document's readability score by clicking on this link for instructions on how to check your document readability score.

Consent Form Template

Consent Letter: Name of study title here

Dear Participant,

We invite you to participate in a study of the **name of study title here**. The purpose of the current study is to learn about the impacts and experiences of Produce Program participants, so that we can better understand how the program affects one's nutrition and health.

Your participation will involve participating in **number of nutrition education classes over number of months**. You will receive **a frequency and amount of incentive (e.g., weekly amount of $1.00 per family member)** to spend at **name of market outlet/store**. The study will also use assessments including: diet recalls, fruit and vegetable consumption surveys, blood draws, and anthropometric (weight, blood pressure, waist circumference) assessments recorded during your participation in the program. The blood draws will only be used for lipids (triglycerides, cholesterol) and HbA1c and not to test HIV/AIDS. A fingerstick can be used for the HbA1c and does not require fasting. Because the lipid blood lab requires you to not eat or drink anything (except water) for up to 8 hours prior, there is a potential risk of lightheadedness and discomfort at the site of needle stick. It is advised that you drink plenty of water prior to and during the fasting period before you have blood drawn to avoid lightheadedness. Fasting requires that you do not eat or drink anything (except water) during the eight hours prior to having your blood drawn. You will also be asked to participate in the same assessments during and after the program that you completed at the baseline of the program. If you are or were a **name of clinic** patient, we would like to access your medical record information up to date to track long term health changes in order to understand the impact of the **name of program**. A separate HIPAA form will be provided if you agree to allow continued access to your medical records.

Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision to participate or not participate will have no bearing on your ability to receive services from **name of clinic**, or any other services you may be receiving elsewhere. Any individually identifiable information related to your participation in this study will be kept confidential. We will collect your first and last name and all materials linking your identity to the data we collect will be kept in an electronic, password-protected file. No names or identifying information about you will be included in any materials resulting from this research. The audio recording of the interview will be destroyed following transcription for analysis.

The findings from this project may allow us to improve the **name of clinic** Produce Prescription program, and create a successful, beneficial, and ultimately sustainable program for **name of community** residents. The risk associated with this research is

minimal: another participant in the small group interview could share something you said outside the group. To minimize this risk, we will ask all small group participants to treat information as confidential.

If you have any questions about this research project, please contact **name of researcher, phone number, and email address**. Questions or concerns about your rights as a research participant should be directed to The Chairperson, **name of IRB** Board; **phone number IRB**; **email address IRB**.

Research Subject's Consent to Participate in Research
To voluntarily agree to take part in this study, you must sign on the line below. Your signature below indicates that you have read or had read to you this entire consent form and have had all of your questions answered.

Name of Researcher	Signature	Date
Name of Participant	Signature	Date

I give my permission for my contact information (name, address, phone numbers, email addresses) to be kept by the **name of research organization** for future use by the study investigators. They may contact me in the future (up to 15 years from the completion of the study) to ask me to take part in more research.

- ☐ YES
- ☐ NO

I choose not to be contacted in the future for additional studies, however I want to participate in this study.

- ☐ YES
- ☐ NO

Template: Institutional Review Board (IRB) Produce Prescription Application

Overview

The goal of this document is to provide Produce Prescription (PPR) grantees with language to use when completing an IRB. This text should be modified to comply with the local IRB's application and the context of the project.

Checklist

The following section provides a checklist of information you will need to know to complete the IRB application and sample text.

Throughout this document, *all text in italics denotes example text that should be edited based on your specific PPR program.* Text written in **purple lower case** is meant as a placeholder to be replaced with specific information about your specific program. The **green bold** text indicates suggested instructions.

- ☐ Name, contact information, and CITI training certificate for all staff collecting, managing, or viewing data
    - See Guide to CITI Training for Human Subjects Research
- ☐ Title of research project
    - **The title can be what was submitted for the USDA GusNIP grant**
- ☐ Funding
    - This research was funded by the United States Department of Agriculture Gus Schumacher Nutrition Incentive Program, award number **[insert]** / project accession number **[insert]** for **[date]** to **[date]**. *(See sample language at the end of this document, using your own grant and accession numbers).*
- ☐ Description of research methods (purpose, background, specific aims, recruitment, informed consent, data collection)
    - **Purpose:** The purpose of this research is to determine associations between PPR participation and main outcomes of food insecurity, dietary intake, clinical markers of chronic disease management, and other variables related to social determinants of health.
    - **Background:** Obesity recently surpassed tobacco as the number one preventable cause of death in the United States (U.S.),[1] and poor dietary quality contributes to obesity rates and chronic diseases such as cardiovascular disease, hypertension, type 2 diabetes, and some types of cancer.[2–4] Low-income populations carry a disproportionate burden of diet-related diseases, in part due to limited access to healthy food and as a result, consumption rates of fruits and vegetables (FVs) that are below national dietary guidelines.[5,6] Federal food assistance programs, such as the Supplemental Nutrition Assistance Program (SNAP)[7], as well as public and private organizations, have developed initiatives to address affordability-related barriers to healthy eating. One particularly promising effort from the United States Department of Agriculture (USDA), National Institute of Food and Agriculture (NIFA) is the investment in

nutrition incentive (NI) programs.[8] Nutrition incentive and produce prescription programs aim to increase the purchase of FVs among consumers participating in SNAP by providing incentives at the point-of-purchase. The 2018 Farm Bill solidified support for strengthening these programs as part of the Gus Schumacher Nutrition Incentive Program (GusNIP, formerly known as the Food Insecurity Nutrition Incentive or FINI program).[9] The size and scope of NI programs supported by USDA has grown since FINI in 2014 ($100 million over five years) to GusNIP in 2018 ($250 million over five years)[10,11]. A recent national evaluation found that these programs have broad appeal from a range of stakeholders who view the program as one that can improve food access, reduce food insecurity, decrease health care costs, and stimulate local economies.[12]

The overarching goal of NI programs is to not only increase fruit and vegetable purchases and intake among low-income populations, but also to address food insecurity. Food insecurity is defined as the absence of access to nutritionally adequate and safe food, acquired in socially acceptable ways.[13,14] Given the complexity and diversity of how nutrition incentive and PPR programs operate, and the lack of focus of previous studies on food insecurity, dietary quality, and clinical outcomes, additional research is warranted.

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Specific Aims
Description: The Specific Aims of this project are **(Delete the Example aims and copy/paste the aims that were in your grant proposal)** This study will be conducted in SNAP eligible or food insecure adults aged 18 years or older who are either patients of the **Name of Clinic** or are residents of **Name of Community** and have one or more diet-related illnesses.
Example Language: **Example 1:** *Determine the relationship between PPR participation, and changes in dietary behavior. It is hypothesized that subsidization of fruits and vegetables increase fruit and vegetable consumption during and after the intervention period. It is also hypothesized that overall diet quality and nutrition- related behaviors and attitudes will improve following the intervention period.* **Example 2:** *Determine the relationship between PPR participation, and changes in food security status. It is hypothesized that produce prescription programs improve food security status of food insecure participants during and after the intervention period.* **Example 3:** *Determine the relationship between PPR participation and changes in food purchasing behaviors. It is hypothesized that the produce prescription programs alter food-purchasing behaviors during and after the incentive period.* **Example 4:** *Determine the relationship between PPR participation and changes in clinical outcomes. It is hypothesized that the produce prescription programs will improve clinical outcomes (e.g., blood lipids and HbA1c) in patients with diet-related chronic conditions.* **Example 5** (Qualitative Aim): *What are participant perceptions and experiences with Health and Nutrition* **Example 6** (Qualitative Aim): *What are participants' food purchasing strategies, preferences and in what ways or why do they interact with certain food systems*

Research Design and Methods
Description: This section is where you detail your research design. This includes your primary outcomes/goals, description of intervention and control group (if applicable), when data is collected (e.g., timepoints), and instruments/measures used (e.g., surveys, questionnaires, clinical measures). If applicable you will need to explain how participants are put in either intervention or control group (e.g., randomized).
Example Language: **Example 1:** *This proposed study will implement a non-randomized control trial design utilizing mixed methods in order to compare the effectiveness of two intervention components provided in a produce prescription program. Primary outcomes to assess the effects of the produce prescription program include dietary intake, food security, food purchasing practices, disease management, and serum triglycerides and Hemoglobin A1c (HbA1c) over a 6-month period. The study groups are: 1. The produce prescription program intervention (n=30) which includes nutrition education classes, monthly health screenings, and a weekly subsidy for produce (produce prescription) 2. Nutrition education only (n=15) without health screenings and produce subsidies and 3. A control group only (n=15). Each group will be recruited through purposive sampling with the help of community partnerships in a way that limits intergroup contact. Baseline data will be collected prior to the start of the study for all three groups and will include demographics, dietary recalls, food security status, anthropometrics, and food purchasing practices. For the produce prescription program group the investigators will collect data on fruit and vegetable consumption, anthropometrics, blood pressure, and food purchasing practices once a month. After 3-months of the produce prescription program intervention mid-point assessments for produce prescription program participants will include fruit and vegetable consumption, food security status, interviews and anthropometrics. All study participants will be asked to participate in serum blood draws to assess blood lipids and HbA1c at baseline and 6 months. Redemption and market attendance will be recorded at each market day for the produce prescription program participants. All participants will also participate in the post-intervention assessments which include the same measures used at baseline. Diet quality and fruit and vegetable consumption will be assessed using interviewer-administered 24-hour dietary recalls. Food security status will be assessed using a validated modified 6 item U.S. Household Food Security Survey Module. Food purchasing practices will be assessed with 2 questionnaires: One will assess the items purchased at each Farmer's Market visit, the other will assess typical food purchasing habits in the community.*

Example 2: *Redemption of the produce prescription will also be assessed as a variable of food purchasing practices and program engagement. Blood lipids and HbA1c will be taken through venipuncture or fingerstick techniques by trained nurses or phlebotomists. Lastly anthropometric measurements (e.g., height, weight, BMI, and waist circumference) of each participant will be taken at the clinic.*
Duration and Study Timeline: You will be asked to explain how long any given participant will be in the study. Consider the point from when they are enrolled (completed consent form) and when their follow up data collection is complete. If you have long-term data collection planned, include this in the response. For example, if the produce prescription program and nutrition education classes last 6 months, but you have a follow-up data collection point (e.g., blood draw) planned at 12 months – state the duration of the study for any given participant is 1 year in length, with the intervention period lasting 6 months, and one 12-month data collection follow up point.

Recruitment
Description: Describe how potential participants will be initially identified. You will be asked to describe, in detail, how you will recruit participants.
Example Language: *Eligibility of potential participants for the intervention and control groups will be determined based on the information retrieved from screening conducted at recruitment meetings organized by program partners including* ***Name of Clinic*** *and other community organizations providing services to targeted low income individuals. Potential participants who attend the recruitment meetings, clinic appointments, or who are approached by a study team member will fill out a screen form which contains all of the necessary items for inclusion. Upon completion of the form, the investigators or site-based collaborators will determine eligibility for the program. If a participant is eligible, a description of the study will be provided and an informed consent meeting will be established. This meeting will allow the participant to enroll and allow investigators to utilize the data collected and medical record information.*
Description: Describe when, where, and how participants will be initially contacted.
Example Language: *Participants will be initially contacted in-person by the clinic staff, community partner leaders and outreach personnel staffed by the* **Name of Clinic***, co-investigators, and community organizations. Clinic staff and community partners will also advertise through recruitment flyers and schedule individual or group enrollment screenings. Clinic recruitment during appointment visits and invite participants to participate in the program. If the client is interested, the clinic staff, community leaders, and/or the researchers will provide information and eligibility requirements.*

Consent Procedures
Description: Describe how, where, when (and by whom) the informed consent will be obtained for research participants.
Example Language: **Example 1:** *Informed consent will be required to participate in the research study, but not the produce prescription program, the unaffiliated clinic produce program itself, or the nutrition education courses. Consent will be provided only after the participant is deemed eligible for the program and prior to the start of the produce prescription intervention or collection of data for the study.* **Example 2:** *After the screening phase for the produce prescription program study is completed the eligible participants will be notified of their eligibility for the program. After this there will be multiple opportunities where the participant will be provided a paper copy of the consent form to participate in the study. A CITI-trained staff member or volunteer will be available to answer questions, and the participant will sign the consent form, while receiving a copy to keep. Either at the site where they were recruited, a pre event, or prior to the first class nutrition education session. The co-investigators or site-based collaborators will hand the participants a paper copy of the consent form which outlines the study benefits, risks, incentives and measures to ensure privacy and confidentiality.* **Example 3:** *All in person points of screening and enrollment will be held at **Name of Clinic,** and partner organizations (**name these organizations**). Any participants recruited from these sites that do not sign a consent form prior to the first nutrition education class they attend will be provided the consent form to complete prior to implementation of the intervention.* **Example 4:** *Any Spanish speaking participants will be provided with a translator to explain the study and the consent form.*

Deception
Description: You will have to describe whether or not your study includes deception. In most cases, your study will not include deception and you will have to explain/justify this. You may have to describe the relationship between the researchers and participants, if applicable. See Example 6 for this language.
Example Language: **Example 1:** *There is no deception associated with this study. Neither the researchers nor the participants will be blinded to their study group. Participants have access to their own data (e.g., survey responses, clinical laboratory values, anthropometric measures) at any time they request.* **Example 2:** *The researcher will not be providing any direct compensation or education as part of the intervention but will be directly collecting data from the participants at multiple time points.* **Example 3:** *The main investigator will be supporting the program partners and the participants during their participation for retention and program success.* **Example 4:** *The supporting investigators will be supporting in collection of data from participants only.* **Example 5:** *The researcher will be directly talking to participants in person, over the phone or by mail to recruit and enroll prior to baseline assessments.* **Example 6:** *Clinic staff and community site leaders who are engaged in research have an established working relationship with participants. These community sites are involved with determining eligibility of clients to receive entrance into the study as well as the clinic's services. They are also involved with registering clients for clinic services, handling medical billing and coverage, as well as making prescription medication available to the clients. Additionally, they are involved with education and volunteer services at the clinic.*

Risks and Benefits
Description: You will have to describe the risk/benefits to participants and include description of safeguards to minimize coercion or undue influence to protect the rights and welfare of the participants.
Example Language: **Example 1:** *The consent form clearly outlines details of the study and what will be asked of the participants and will not influence their ability to participate in the produce prescription program. Participants will also have a chance to ask any questions they may have concerning the study during the initial session.* **Example 2:** *If necessary, a Spanish interpreter will be used to ensure successful communication between the research team and Spanish-speaking participants.*
Description: Describe the nature of the degree of risk associated with participation.
Example Language: *Participants may experience discomfort or stress when asked questions about their food situations, shopping behaviors, or health management. Some participants may feel uncomfortable participating in weight and waist circumference measurements. Because sensitive information about food security status, socioeconomic status, and physical health, participants may also worry about a breach of confidentiality. The blood draws may be uncomfortable or stressful for some participants due the nature of using a fasted venous blood draw for a lipid panel. Lightheadedness is most common risk for a fasted blood draw and participants will be notified in the consent form*
Description: Describe the measure that will be taken to minimize risk.
Example Language: **Example 1:** *We ask personal questions about income, hunger and food insecurity, and the receipt of food-related benefits on the individual survey -- rather than in a group interview context where individuals may not want to disclose this information.* **Example 2:** *Proper measures will be taken to keep the individually identifiable information confidential, only shared with the researchers listed in this IRB application, and only used for the purposes of this research project. If any of the questions make them feel uncomfortable, they are not required to answer them.* **Example 3:** *All fasting blood draw appointments will be held in the morning to minimize length of time participants are fasting during awake hours.*

Description: Direct benefits to participant. Note: you cannot say benefits include gift cards if the participants are to receive a gift card for completing a survey.
Example Language: *Direct benefits to the intervention participants will include an increase in funds to purchase fresh fruits and vegetables, learn nutrition and health skills, improve measures of health, and reduce the burden of diet related diseases. The nutrition education group will receive free nutrition and physical activity lessons*
Description: Benefits to others (e.g., society or other patients).
Example Language: *The results of this study will help better understand how food systems and nutrition education can be better incorporated into health care systems utilized by low- income populations. The results from measuring changes in dietary habits, food security, food purchasing practices, diet related disease management, nutrition knowledge, health outcomes, and participant interviews will also help inform best practices of future research and programs that intend to utilize safety net clinics and food systems*.

Adverse Effects
Description: You will have to describe potential adverse effects.
Example Language: **Example 1:** *Adverse events may include breach of confidentiality. All data will be deidentified using a unique ID that is not identifiable to the participant. All data will be stored in a locked filing cabinet in a locked office either at the clinic (medical chart security protocol) or researchers office.* **Example 2:** *Adverse event may include lightheadedness from fasting. Participants will not be required to do the blood draw for a lipid panel if they choose not to. They will be provided details of the risks involved in the consent form, such as lightheadedness and discomfort at site of needle stick, and will also be instructed to drink water up to the point of the blood draw to avoid this risk* **Example 3:** *All adverse effects will be reported to the IRB within 24 hours of researcher becoming aware of the situation (note: the length of time between hearing of an adverse event and reporting it will be specific to your local IRB).*

Blood Sampling Collection
Description: If you are collecting clinical data for the purpose of evaluating your PPR, you will need language in your IRB about clinical data collection. You will be asked to state how much blood is collected (if you are collecting HbA1c, lipids, etc.) and how frequently. All of the following in this section in italics is sample language. If you are only using fingerstick for HbA1c:
Example Language: *Blood sample collection is based on fingerstick point-of-care collection. The HbA1c fingerstick only requires a minimum of 1 microliter and a max of 2 microliters from finger capillary. Participants will have fingerstick A1c tested two times over the course of three months (baseline and 3-month follow up).* **Note:** HbA1c should not be collected more frequently than every 3 months.
Description: If you are using venipuncture blood draw, you can check with the language used at the lab or clinic where blood is drawn/processed but in general:
Example Language: *For the lipid panel (LDL, HDL, Total Cholesterol, Triglycerides) the recommended amount of blood is 1 mL, and our collaborating laboratory (***Name***) requests 0.5 mL sample.*
Description: You will likely have to describe specific blood sampling procedures.
Example Language: *For the HbA1c collection at either the community site or the participating clinic the staff member will handle any sterile items with sterile nitrile gloves and ensure the sterile items are sealed and not contaminated prior to use. The staff member will then prepare the patient draw site with a sealed alcohol pad and allow the area to dry. Lastly, the staff will perform a finger-stick capillary puncture using a sterile single-use lancet appropriately sized to the patient. The Point-of-Service HgA1c study requires 1 microliter/one drop of finger-stick capillary blood. Should a lipid panel be needed, venipuncture will be performed by a trained staff member in accordance with OSHA and bloodborne pathogen guidelines. Using similar sterile techniques, the staff member will select and prepare an appropriate site for puncture. A single use, disposable venipuncture needle ranging from 25 gauge to 21 gauge depending on the specific needs of the participant will be used. The blood will be collected into a sterile color-coded Vacutainer tube. All specimens should be labeled at the time of collection with at least two patient identifiers. The patient's name (full last name, then full first name or initial) or a unique ID code is always required. The second patient identifier may be one of the following: 1. Date of birth (month/date/year) 2. Other unique patient identifier that is also on the test requisition, e.g. hospital or office ID code or file number 3.* **Name of Lab** *requisition number or specimen barcode label.*

Description: If blood is drawn at one site and processed at another.
Example Language: A **Name of Lab** *courier collects all blood tubes from the* **Name of Clinic** *each afternoon and transports them to the testing laboratory. Test results are faxed to the Clinic usually within 24 hours. Bio-hazardous trash and sharps are disposed of in an OSHA approved container, is stored in a secure area and disposed of monthly by a certified service.*
Description: To describe personnel who will perform blood draws.
Example Language: *Only clinic staff trained to collect blood samples through fingerstick and venipuncture techniques will perform these tests. The staff trained to perform these tests all have either a BS Nursing or are Nurse Practitioners and are trained in the OSHA standards of collecting and safe handling of blood. Some participants will be referred to the local* ***Name of Lab*** *laboratory for their lab draws and will undergo collection by their trained and qualified phlebotomy staff.*
Description: If participants are asked to fast prior to blood draw (if collecting fasting blood glucose (FBG) or triglycerides (TG), this may be needed.
Example Language: *Consent to participate in the blood collection will be obtained prior to requesting the participant to be fasted. The language will be part of the consent form to participate/enroll in the study, which will be signed upon recruitment into the program. Instructions of how to avoid the risk of lightheadedness during the fasting will also be included in the consent form.*
Description: To describe why it is important that blood is drawn for this study.
Example Language: *We hope to demonstrate that a combined intervention of nutrition education, physical activity, and subsidized fresh fruits and vegetables will reduce the risk of cardiovascular disease and diabetes. By collecting the blood values at baseline and post intervention we will have clinic-based evidence for these health outcomes.*
Description: To describe the plan for disposition of any unused blood.
Example Language: *All blood samples will be used for only one analysis at each time point and will not be retained for future analysis. The equipment and samples used for analysis will be discarded in appropriate sharps containers at the clinic, community site, or* ***Name of Lab*****.**

Age of Participants
Description: You will be asked to describe your participants.
Example Language: **Example 1:** *All participants will be >18 years of age* **Example 2:** *We will enroll up* ***to # participants in the study***

Inclusion and exclusion criteria
Description: You will be asked to describe who can and cannot be included in the study.
Example Language: Example 1: *All participants will be >18 years of age and have at least one of the following diet-related diagnoses: hypertension, obesity, prediabetes, diabetes or cardiovascular disease.* **Example 2:** *All participants will be considered low income as designated by household income and the federal poverty line, or currently receiving SNAP benefits, or eligible for SNAP benefits by other means-tested mechanisms (e.g., participation in WIC or Head Start)* **Example 3:** *All participants will be enrolled patients at* ***Name of Clinic*****.** **Example 4:** *Participants will be excluded if they have active substance abuse or a planned move during the duration of the study period.*
Description: You may have to provide justification of inclusion of "vulnerable populations" which may include "economically / educationally disadvantaged"
Example Language: *In this study, we seek to examine the impact of fruit and vegetable prescription program on food purchasing behaviors, food security, and disease management in low-income patients. This population will be the focus of our study because the* **Name of Community/City** *area has high rates of poverty and food insecurity, which are associated with reduced chronic disease management and poor dietary behaviors. The program intervention seeks to support these targeted individuals by providing monetary incentives to perform health screenings, attend nutrition classes and purchase fresh produce.*
Description: If you plan to include non-English speakers or people with disabilities, (or any other special group) – you will need to consider all accommodations necessary and mention this in the protocol.
Example Language: *Spanish-language surveys and consent forms for Spanish-speaking audiences.*

Stipends/Incentives/Participant Compensation
Description: Different IRBs use different terms here, it may be "stipend" and it may be "participant incentives" or "Respondent compensation"—These are all synonyms, but your IRB may be specific as to which you should use.
Example Language: **Example 1:** *Participants will be provided with 6 free monthly nutrition education classes through **Name of Educational Curriculum/Program** and free biometric screening provided by **Name of Clinic** staff. Upon enrollment, participants will receive a **Frequency** monetary subsidy worth **Dollar Amount** per household member to redeem for fruits and vegetables at the **Name of Market** each week.* **Example 2:** *Participants will also receive items to help them cook, like plastic cutting boards, measuring cups, tote bags, and recipes. Free transportation will be provided to participants to and from the **Name of Market**. For participating in follow up interviews, surveys and assessments previous intervention participants will receive a gift card of **Denomination Gift Card** **to** **Name of Market.***

- ☐ Consent statement
  - Click here for the Consent Statement Link
  - Note, your local IRB may have template or "boilerplate" language that needs to be included in this consent statement.
  - Likely you will need to include a phone number for the IRB on the consent template so participants know whom to contact should they have questions or concerns about the research.
- ☐ Assent form (if children are eligible for this study)
  - Click here for the Assent form Link
- ☐ Copy of survey
  - You will need to include a copy of all surveys or questionnaires in the IRB submission for their approval.
  - GusNIP Nutrition Incentive Hub has core metrics available for your use
    - Click Here for Core Metrics Link
- ☐ Copy of moderator guide (if there is a qualitative [focus group or interview] component)
  - You will need to include a copy of the moderator guide in the IRB submission for their review and approval.
- ☐ Copy of all recruitment materials
  - Flyers, scripted language that may be posted on social media (e.g., Facebook), or mailed recruitment letters
  - Copy of screening form for eligibility
    - Or screening script if verbal eligibility screening (e.g., over the phone)
- ☐ Use of Protected Health Information (HIPAA)
  - Click here for HIPAA Document Link
  - If you are going to access data from the electronic health record (EHR) and/or use chart abstraction to collect any data, you will need to complete a HIPAA request. Following are some of the questions you may be asked to answer in this "use of protected health information" request.

        - PHI (Protected Health Information) to be accessed/recorded
            - Names, street address, city, county, zip code, birth date, telephone numbers, electronic mail (email) addresses, height, weight, BMI, health diagnoses, medications, blood pressure, blood glucose, A1c, blood lipid panel, and insurance status.
        - Source and location of records to be reviewed: **Name of Clinic**
        - Description of how records will be reviewed and identified
            - These records will be identified through personal identifiers such as name and date of birth. The approved researchers and investigators will search the records for only the needed information.
        - Description of who will identify records to be reviewed and who will conduct chart review
            - Either the approved researcher from the clinic or the co-investigator will access the records of the patients who are consented to participate and signed the HIPAA form. The approved researcher and co-investigator will record only the needed data of each patient into an electronic file that is only on a secured flash drive and backed up on a secured external hard drive. Any information extracted from the medical records will be coded to the participants' unique id and not stored on computer hard drives.
- ☐ Data management
    - Copy and paste this section from the grant application. This should include details on how paper surveys are stored, where they're stored, etc. It should also include details on how data is transferred from site to researcher office (for example, if the clinic and researcher office are in separate locations, how do clinical metrics get transferred to the researcher?)
- ☐ Data analysis
    - Copy and paste this section from the grant application. This section should include collaboration with Gretchen Swanson Center for Nutrition (GSCN), which serves as GusNIP NTAE, for analysis.
    - Data will be analyzed by an outside evaluator. De-identified data will be provided to this collaborative evaluator. Impact analyses will be led by the GusNIP NTAE per grant specifications. Generally, frequencies will be calculated to examine participant demographics and general response patterns. Inferential statistics (e.g., regression analyses) will be used to compare fruit and vegetable consumption and food security among users participating in the program for > 1 month versus 'new users' (i.e., control).
    - Find information regarding Reporting and Evaluation Resources available through the GusNIP NTAE Nutrition Incentive Hub.

Qualitative Methods
Description: If you plan to include qualitative interviews or focus groups in your protocol, you need to describe the recruitment, procedures, data collection, and data analysis plan of the qualitative data. Here is example language you can use.
Example Language: *Recruitment: A subset of the participants enrolled in the produce prescription program will be recruited for in depth 1:1 interviews (or focus groups). Recruitment will occur at the clinical sites.*
Description: Privacy and Confidentiality
Example Language: *In the case of focus groups, it's impossible to guarantee confidentiality. However, state that at the start of each focus group the researcher will ask all participants to keep what they discuss private and use discretion when sharing their experience in the focus group with others*.
Description: Focus Group Procedures
Example Language: *Participants will be recruited by staff at the clinical site. They will be asked to call the researcher at listed phone number to RSVP to attend the focus group interview. The focus group interview will last ~90 minutes in length and will be comprised of 5-8 participants, all of whom are produce prescription recipients. The location of the focus groups will be at the clinic. The focus group will be led by a trained qualitative researcher, who will use a moderator guide to facilitate the focus group. There will be a note-taker present. Focus groups will be audio recorded, and de-identified upon transcription. For example, all identifying names will be replaced with NAME in the transcript, and the audio recordings will be destroyed after data analysis is complete. Data analysis will be conducted in collaboration with the Nutrition Incentive Hub R&E team. All focus group participants will receive a $20.00 gift card for their participation.*

Description: Individual interviews
Example Language: *Participants will be asked to complete a short (~30 minute) interview with a research at the same date and time of their clinical visit. On select days, researchers will be on site at the clinic to facilitate interviews. If any produce prescription recipient is interested in engaging in a one-time 1:1 interview, they will be directed to the researcher. If the researcher is in another interview when a participant is interested in participating, the flyer will include research phone number to schedule a telephone or in-person interview at a later date. The interviews will be led by a trained qualitative researcher, who will use a moderator guide to facilitate the focus group. Interviews will be audio recorded, and de-identified upon transcription. For example, all identifying names will be replaced with **NA** in the transcript, and the audio recordings will be destroyed after data analysis is complete. Data analysis will be conducted in collaboration with the Nutrition Incentive Hub R&E team. All interviewees will receive a $20.00 gift card for their participation.*
Description: You will need to include a copy of your moderator guide (questions you plan to ask during the focus groups or interviews) for your IRB approval
Example Language: **Example 1:** Tell me about your experience using the produce prescription program at (**Name of Clinic**). **Example 2:** If we could improve the produce prescription program, what would the improved program look like?

If you have questions about qualitative data collection or analysis, please contact Sarah Stotz, Adjunct Research Scientist, at sstotz@centerfornutrition.org.

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