

Permission to Take Part in a Human Research Study

Protocol Title: Evaluation of Project Bread's Flexible Services Program

Principal Investigator: Dr. Eric Rimm

Faculty Advisor (if PI is a student): N/A

Description of Study Population: This consent form is for former Flexible Services clients who participate in a focus group for the study.

Version Date: June 23, 2022

Key Information

The following is a short summary of this study to help you decide whether or not to participate.
More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you completed the Flexible Services Program (FSP) offered by Project Bread. We are interested in hearing about your experience in the program so that we can improve the program in the future.

To be eligible for participation in this study, you must meet the following eligibility criteria:

- Must be a former client of Project Bread's FSP who received services from Project Bread;
- Must have completed the entire Project Bread Flexible Services program within the past three months;
- Must not be currently enrolled in the Project Bread Flexible Services program;
- Must be fluent in English, Spanish, or Portuguese;
- Must be at least 18 years of age.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of Project Bread's research is to determine the impact of Project Bread's Flexible Services Program model on the food security and health of traditionally marginalized populations in Massachusetts. Project Bread has designed an innovative, choice-based nutrition intervention, in collaboration with an Accountable Care Organization for food insecure patients with chronic physical and/or mental health conditions. The intervention provides various goods and services that

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address individual barriers to access food such as financial access, transportation, education, and other skills. Specifically, Project Bread's research aims to:

1. Measure change in food insecurity status among Project Bread's Flexible Services Program clients after they have completed the program.
2. Evaluate the impact of Project Bread's nutrition services.
3. Collect program implementation data from Flexible Services Program Community Health Workers and clients to improve Project Bread's delivery of nutrition services for the Flexible Services Program.

How long will I take part in this research?

We expect the focus group to last between 1-1.5 hours.

What will I be asked to do?

You will be asked to participate in a discussion about your experience with Project Bread's Flexible Services Program. We would like to hear your perspective on how the program went for you, in addition to, any recommendations you may have regarding the implementation of the program.

More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

We don't anticipate any major risks associated with your participation in this study. You may feel uncomfortable answering some of the questions related to Project Bread's Flexible Services Program. You may skip any questions that you are not comfortable answering. Additionally, breach of confidentiality is a potential risk. This risk should be minimal. No participant will be named, and all data will be used in the aggregate so as not to identify participants.

More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

There are no direct benefits to you from your participation in this research. We cannot promise any benefits to others from your participation in this research. However, possible benefits to others may include the improvement of Project Bread's Flexible Services Program and increased knowledge in the public health sector as to the best practices and impact of Project Bread's Flexible Services Program.

What happens if I do not want to be in this research?

Participation in research is voluntary. You can decide to participate, not to participate, or stop participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Your alternative to participating in this research study is not to participate.

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Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. A copy of this form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by contacting the Project Manager at 617-239-2506.

This research has been reviewed by the Harvard Longwood Campus Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Regulatory Affairs and Research Compliance (ORARC) at 617-432-2157 (or toll-free at 1-866-606-0573) or at irb@hspf.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because you have completed Project Bread's Flexible Services Program. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation during the focus group will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?

This study will gather information from 14 Community Health Workers, 60-80 focus group participants, and 150-200 phone survey participants.

What can I expect if I take part in this research?

As a participant, you will be expected to participate in a discussion with 6-7 other individuals who participated in the Flexible Services program. The discussion will last approximately 1-1.5 hours. The focus group conversation will be audio recorded. If the focus group is on Zoom, then the conversation will be video and audio recorded.

What are the risks and possible discomforts?

We don't anticipate any major risks associated with your participation in this study. You may be uncomfortable discussing issues about your food environment, access to resources, and your participation in Project Bread's Flexible Service program. In addition, while we will encourage all focus group participants not to disclose study information outside of the research context, there is no way to guarantee this. You may choose to skip any questions that you do not want to answer, and you may withdraw from the focus group at any time. To mitigate potential risks or discomforts all participants will be given a Resource Sheet with information on local resources and services for housing, nutrition, and financial

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support. Additionally, breach of confidentiality is a potential risk. This risk should be minimal. No participant will be named, and all data will be used in the aggregate so as not to identify participants.

Are there any benefits from being in this research study?

We anticipate no direct benefits to the study participants. However, the information gained during the study will be used to improve Project Bread's Flexible Services program. Results will also be developed into presentations and reports that will be shared and may improve Flexible Services Programs provided by other Accountable Care Organizations and Community Based Organizations. De-identified and aggregated results will also be shared with MassHealth and the Massachusetts state legislatures to inform their decision-making on the continuation, expansion, and funding of the Flexible Services Program in the state.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you decide to withdraw, you may also request that we do not use any of the data collected before your decision to withdraw and our research team will destroy all the data that we collected from you.

Can I still receive services from Project Bread if I choose not to participate in this research?

Yes, you may still receive services from Project Bread if you choose not to participate in this study. Your decision will not change the services you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your eligibility to receive services will not be affected.

Will I be compensated for participating in this research?

You will receive a \$50 Visa gift card for your participation in this study. You may be asked to provide your mailing address to receive the gift card. Your mailing address will not be saved as study data, and we will delete our record of your mailing address after the gift card has been sent. Everyone who completes the focus group, even if they choose to skip questions, will receive the gift card. Gift cards will be sent within 5 business days of the focus group. All enrolled participants will receive the gift card, even if they withdraw and/or choose to skip questions. For in-person focus groups, the gift card will be distributed at the end of the session.

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

Data will be stored in an encrypted Dropbox folder owned by Project Bread. Only the Project Bread research team, the transcription vendor, and those who are responsible for research oversight will have access to the study data. The focus group discussion will be recorded, and notes will be taken. The audio of the call will be transcribed with the participant information de-identified. After the transcription and de-identification is complete, the original recording will be destroyed. The de-identified data and interview transcriptions that are stored on the encrypted Project Bread Dropbox folder will be destroyed after a period of seven years.

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete

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secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of Project Bread.

Under Massachusetts law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, they may be required to report such information to the appropriate authorities.

Your information that is collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled. I understand that if I am returning this form electronically or remotely that all pages must be sent back to the researchers.

I consent to participate in the study.