HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

EARNED INCOME TAX CREDIT ACCESS STUDY

NCT: NCT04901403

DATE: 4/14/2022

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY
4/14/2022

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: EITC Access Study
Principal Investigator: Kathryn Maguire-Jack, MSW, MPA, Ph.D. kmjack@umich.edu
Study Sponsor: Office of Equity and Minority Health, US Department of Health and Human Services

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know:

This project is designed to assess how this home visiting program affects family outcomes. You will be asked to complete a pre-and post-program survey about yourself and your family.

If you choose to participate, you will be asked to take a pre-and post-program survey with a provided iPad or paper copy. At this time, we are only asking you to consent to the pre-program survey.

These surveys will take approximately 15 minutes of your time per survey, totaling one hour.

There is minimal risk to you. During these surveys, you will be asked questions concerning your experiences and attitudes about your mental health, economic hardship, your intimate relationships, raising your children, and your children's emotional and behavioral development, which may be sensitive and cause feelings of discomfort.

There are no direct benefits to you in your participation in this research.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. You do not have to answer any questions that you do not want to answer.

Please take time to read this entire form and ask questions before deciding whether to participate in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this study is to assess the impact of adding a benefits advocacy approach to the home visiting program. We are specifically interested in understanding whether the benefits advocacy approach improves family functioning and reduces economic hardship.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? Participants in the Parents as Teachers home visiting program in the Michigan counties of Kalamazoo, Washtenaw, St. Clair, Calhoun, Sanilac, Wayne, Baraga, Keweenaw, and Houghton may take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

During a regularly scheduled Parents as Teachers visit, you will be asked to take a pre-program survey on a provided iPad or paper copy. Some of the questions asked during this survey may be sensitive for participants because they ask about mental health, economic hardship, intimate relationships, raising children, and children's emotional and behavioral development.

For example,

- "Were you evicted from your home or apartment for not paying the rent or mortgage?"
- "Feeling afraid as if something awful might happen."
- "Left your child some place and did not come back."
- "Didn't stop someone in the house from hurting your child."
- "My partner gave me a sprain, bruise, or small cut because of a fight with me."

4.2 How much of my time will be needed to take part in this study? The pre-program survey will take approximately 15 minutes to complete in one regularly scheduled Parents as Teachers visit. Every 6 months, you will be asked to take a post-program survey at another regularly scheduled Parents as Teachers visit, taking approximately 15 minutes to complete. The total possible survey time is 1 hour over a period of every 6 months for 2 years. After a maximum of 1 hour, participation in the study is over with the completion of a post-program survey.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Because this study collects information about you, the primary risk is a breach of confidentiality. The researchers will try to minimize this by keeping study-related information and data files stored in password-protected folders and presenting reports as aggregate results. Your name will not be identified or linked to your responses in any publication or report from this study. We will not report your individual findings, and your caseworker will not be made aware of your participation in the survey or of your responses. You do not have to answer any questions you do not want to answer. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information," or the Parents as Teachers home visitor. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in research analysis, it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive a $25 electronic retail gift card for each survey you complete for the study.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? Your responses will be kept as confidential as possible – data files will be stored in password-protected folders, and our reports will present aggregate results. Your name will not be identified or linked to your responses in any publication or report from this study. We will not report your individual findings, and your caseworker will not be made aware of your participation in the survey or of your responses.

This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health.

This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We will disclose your information for any purpose to which you have consented, as described in this informed consent document. This includes:

If required by local or state law, we will report to the appropriate authorities in specific cases, such as if we learn of abuse, neglect, or endangerment of any vulnerable person.

Please note that a CoC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates can be found at the NIH CoC webpage**:**
https://humansubjects.nih.gov/coc/index

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

8.3 What will happen to the information collected in this study?
We will keep the information we collect about you during the research for the purposes of determining the effectiveness of the program. Your name and identifying information will be used to link your pre- and post-program surveys. After the linkage has occurred, your name and identifying information will be replaced with an ID number and your name will be removed from all data files. Prior to the linkage, your name and identifying information that can directly identify you will be stored securely and separately from the research information we collected from you.

Your home visitor will ask you every 6 months to complete a post-program survey for a maximum of 2 years.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are and will be presented in aggregate only.

8.4 Will my information be used for future research or shared with others?
Your information may be used in future research studies, but will be reported out in aggregate and no identifying information will be used about you.

8.4.1 Special Requirements
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). 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.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Kathryn Maguire-Jack, MSW, MPA, PhD
Email: kmjack@umich.edu
Phone: 734-764-7805

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By clicking “I consent” and typing your name, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I will give you a copy of this document for your records. If you have any questions about the study after you consent, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Type Legal Name: _____