

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR CLIENT PARTICIPANTS.

Version 4-14-21

You are being invited to take part in a research study about the Earned Income Tax Credit (EITC) and how EITC can promote a healthy environment in your home.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

We will invite 200 of the clients who use the services of our community health workers (CHWs) to participate in this study.

The 200 clients will answer some survey questions at the time they receive assistance from a CHW regarding EITC submission and again in four months.

A few participants will be invited to also answer some more detailed questions in an interview that will take place within a year after completing both parts of the survey.

By doing this study, we hope to learn if CHWs can help identify clients who might benefit from the EITC and help them submit their taxes. We want to know if screening clients for EITC eligibility and referring them for tax assistance is helpful. We would like to know if the EITC helps our clients in relation to things like stress, depression, income, employment, rent/mortgage, household finances, buying food, and social support.

WHAT ARE THE KEY REASONS I MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We have found that our clients and the partners we work with in the community are interested in helping struggling families, especially families with children. Your participation in this study will help us know if EITC is a good thing for our clients and their families, and in what ways. This information will help us advocate for expanding access to EITC and other resources in our work with other struggling clients and families in the future.

WHAT ARE THE KEY REASONS I MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Some people may not want or be able to participate because they don't have time, or because they don't like the idea of being in a research study.

DO I HAVE TO TAKE PART IN THE STUDY?

No. Participation in this study is voluntary. You can decide to participate or not. You will still be able to get help from the CHW whether or not you decide to participate in the study.

WHAT IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Dr. Janet Page-Reeves, a researcher at the University of New Mexico (UNM). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, you can call her at 505-306-3041 or send an email to jpage-reeves@salud.unm.edu

If you have any questions or concerns about your rights as a participant in this research, contact staff members in the University of New Mexico Health Sciences Center (UNMHSC) Human Research Protections Office (HRPO) between the business hours of 8AM and 5PM, Mountain Time, Monday-Friday at 505-272-1129.

DETAILED CONSENT

HOW CAN I QUALIFY FOR THIS STUDY?

You will qualify if all of the following are true:

- You are a client of one of our CHWs
- You have not filed a claim for EITC in the past year
- You received compensation from work performed in any capacity in the last three years
- You have total annual earned income allowed by EITC guidelines
- You have a valid Social Security number
- You have not been claimed as a dependent on a tax return by someone else
- You understand English or Spanish

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

If you participate:

You will take a survey now and again in four months. Appointments to complete the two surveys will be at the office of our CHW or another location convenient for you, if it is feasible. If in-person meetings are not allowed because of the COVID-19 pandemic, you will meet with the CHW by phone or Zoom. It will probably take 20-30 minutes to answer the survey questions each time.

We may also invite you to do an interview after you have taken the second survey. The interviews will be conducted at one of our partner sites or another location convenient for you, if it is feasible. If in-person meetings are not allowed because of the COVID-19 pandemic, the interviews will be by phone or Zoom. Interviews will last approximately 1 hour.

WHAT WILL I BE ASKED TO DO?

Today you are being asked to sign the consent form or if in-person meetings are not allowed because of the COVID-19 pandemic, you will be asked to provide verbal consent by phone or Zoom.

You will be asked to take a survey now and again in 4 months.

- You will receive a Walmart Card for \$50 for each survey to thank you for participating in this study.
- If the meeting with the CHW is not in-person, we will mail the card to you.

The few participants who are invited to do an interview will also receive an additional \$50 Walmart card.

We will ask you to sign a receipt for the card(s) for our financial record files if we are able to give you the card in-person. If the card is mailed to you, you will not have to sign.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

We do not think that you will experience any negative consequences or effects as a result of participating in this study. However, some people feel anxiety, stress, or inconvenience when they answer questions about themselves or talk about their experiences. In addition, although we go to great lengths to keep everything confidential, there is always the possibility of a loss of privacy. Although we do not anticipate that our data will be stolen or that authorities will request a copy of our data, as a precaution, we go further than just keeping your information stored safely. We also get something called "a Certificate of Confidentiality" that allows us to refuse to release your name and information even if it is requested for some reason by a court of law.

WILL I BENEFIT FROM TAKING PART IN THIS STUDY?

We anticipate that this project to help clients obtain EITC funds will have a positive impact in the lives of participants in relation to improvements in social isolation, social connectedness, resource knowledge, depression, stress, and empowerment. It is our experience that rather than producing anxiety, it is more likely that participants may find it interesting, rewarding, or empowering to participate in the research or to discuss the issues involved

Furthermore, this research will contribute to our understanding of the best ways we can support our clients, which may be important to you in terms of helping others.

WHAT WILL IT COST ME TO PARTICIPATE?

There are no financial costs associated with taking part in the study. You may incur some expense to travel to appointments if they are conducted in-person.

WHO WILL SEE THE INFORMATION THAT I GIVE?

This type of study is called a “clinical trial.” All clinical trial studies are required to be posted on a specific website online. A description of the study and what we are doing will be available on [ClinicalTrials.gov](https://www.clinicaltrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We will not share your name or contact information with anyone. When we analyze the results of this study, we will share the findings with people through presentations at professional conferences and in written articles, but no one will be able to know that you participated because we will combine the information you provide with that we gather from other participants. After the project is over, we may share the information that we gather with others, but what we share will not contain your name or contact information or be in any way connected to you.

We will keep a record of your name on the consent form (or on the documentation that you provided oral consent, if this happens remotely) and we will use your contact information to schedule your appointment to complete the second survey or to be invited to do an interview.

We will store your consent form (or the list of people who consent orally, if this happens remotely) in a locked cabinet. We will store the information gathered from you in a secure electronic database.

We will do everything we can to protect the privacy of all your personal information, but we cannot guarantee this 100%. All data from this study will be assigned a number and we will not use your name. The UNM HRPO that makes sure we are treating people who participate in research at UNM properly sometimes asks to see our records—not to identify you, personally, but to make sure we are following the rules when we are doing our research.

We will obtain a Certificate of Confidentiality for this project from the National Institutes of Health. This allows researchers to refuse to disclose your identity. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may be required to show your information to other people if the funder wants to evaluate portions of our project or if we become aware that a participant has committed a serious crime. For example, the law may require us to share your information with the responsible agency for the following reasons:

- If you report information about a child being abused.
- If you pose a danger to yourself or someone else.
- If you have a reportable disease or condition.

CAN I CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

Yes, you may do so at any time. If you choose to leave early, the data you have already provided will still be used in the study. Even if you cannot participate, it is helpful to us to keep the information you have already provided in the study unless you notify us in writing by sending a letter to:

Janet Page-Reeves
MSC 09 5065
1 University of New Mexico
Albuquerque New Mexico 87131

Please note that we will not be able to remove information you have provided that has already been used or analyzed or shared before the date that your letter is received.

Occasionally investigators conducting the study need to withdraw a participant. Participants who have been withdrawn will no longer be in the study and will not receive the \$50 Walmart cards associated with completing the surveys. This would only happen:

- If you are disruptive, demonstrate inappropriate behavior, or are perceived as threatening during your conversations or appointments with the CHW. If this were to happen, the CHW may stop the meeting with you and discontinue the survey, and you would not receive the \$50 Walmart card that we are providing to participants who complete that part of the survey. These same rules apply to the interviews we will conduct with a few of the participants.
- If we have to stop the entire project for some unforeseen reason.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will receive a \$50 Walmart card for the first survey and another \$50 Walmart card for the second survey for a total of \$100. If you are invited to do an interview, you will receive another \$50 Walmart card.

FUTURE USE OF MY NAME AND CONTACT INFORMATION

We will not share your personal information with anyone outside of our study.

However, Janet Page-Reeves, the director of this study, will keep your name and contact information on a list called a contact list. That way, if she conducts another study in the future that she thinks you might be interested in or qualify for, we can contact you. **See page 6 below called “subject information to be stored for future research” for more information.**

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF MY PROTECTED HEALTH INFORMATION (PHI).

As part of this study, we will be collecting protected information about you such as your name, your contact information, and answers to questions about you that is “protected” because it is identifiable or “linked” to you.

Protected Health Information (PHI)

By signing this Consent Form, you are allowing the investigators to use your protected health information (PHI) for the purposes of this study. This information includes your name, date of birth, age, and the answers you provide to some of the survey questions.

In addition to researchers and staff members at UNMHSC there is a chance that your health information would have to be shared outside of the research study. Examples of this include health oversight activities and public health measures, and safety monitors.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your PHI for this study shall not expire unless you cancel this authorization. Your PHI will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Janet Page-Reeves

MSC 09 5065
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used before the date that your withdrawal is received.

WHO CAN I CALL IF I HAVE QUESTIONS ABOUT THIS STUDY?

If you have any questions or concerns at any time about the research study, Dr. Janet Page-Reeves will be glad to answer them at 505-306-3041. If you would like to speak with someone other than Dr. Page-Reeves, you may call the UNMHSC HRPO at (505) 272-1129.

WHO CAN I CALL IF I HAVE QUESTIONS ABOUT MY RIGHTS AS A RESEARCH PARTICIPANT?

If you have questions regarding your rights as a research participant, you may call the UNMHSC HRPO at (505) 272-1129. The HRPO is a group of people from UNM and the community who are not involved in this project. They look out for the interests of people who participate in research projects at UNM. For more information, you may also check out the HRPO website at <https://hsc.unm.edu/research/hrpo/>

INFORMED CONSENT SIGNATURE PAGE

By signing below, you are agreeing to participate in this study. This consent form includes the following:

- First page with key information
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

Signature of research participant

Date

Printed name of research participant

Signature of researcher

Date

Printed name of researcher

The University of New Mexico Health Sciences Center

ADDITIONAL INFORMATION

Participant Information to be Stored for Future Research

WHAT INFORMATION THAT I PROVIDE WILL BE STORED?

- We will store your name and contact information in a contact list
- We will also store the information that we gather from you in the form of answers to survey questions and interviews so that we can use it as part of this study. We will not store any information that can be directly connected to you after the study is over.

WHAT IS A CONTACT LIST AND WHAT IS THE PURPOSE OF THIS LIST?

- It is a list of people's names who participated in the study and their contact information.
- **The purpose of this contact list** is to be able to contact people to see if they want to participate in another study that we do in the future.
- We will invite all 200 participants of this study to be in our contact list.

WHAT IS THE OTHER INFORMATION THAT WILL BE STORED?

- As indicated above, answers you gave us to survey questions and interviews will be stored.
- **This information will not include your name and will be made anonymous when it is stored** so it will no longer be connected to you.

WHERE WILL INFORMATION BE STORED AND FOR HOW LONG?

- The contact list will be stored in the office of Dr. Janet Page-Reeves, the project director at UNM.
- The answers to questions from surveys and interviews that you provide will be stored in a secure UNM database until we are done using it for our research..
- We will keep this list and the other information for 6 years after the study is over and then the list and any connection to you will be destroyed.

HOW WILL THE CONTACT LIST INFORMATION BE SHARED WITH OTHER INVESTIGATORS?

- We will not share this contact list with anyone else.
- Only Dr. Page-Reeves will be able to use it to invite people to participate in future studies.

HOW WILL THE OTHER INFORMATION BE SHARED WITH OTHER INVESTIGATORS?

- We will not give or share data from this study with other researchers.
- We will use the data from this study to write papers and to give professional presentations about the research, but we will not use your name or include any way to identify you.
- Information you provide will be stored on a UNM password-protected computer. After 6 years, this information will be destroyed.

HOW IS MY PRIVACY AND CONFIDENTIALITY PROTECTED?

- We will take careful steps to keep your information confidential. Dr. Page-Reeves will store the contact list on a UNM password-protected computer and only study team members will have access to it.

- There is a risk that someone might get access to the information stored in the contact list. In spite of the security measures and safeguards we will use, we cannot absolutely guarantee that your identity as a research participant will never become known.
- We will obtain a “Certificate of Confidentiality” to increase the security of our data.

DOES TAKING PART IN THE CONTACT LIST COST ANYTHING?

- There will be no financial costs to you for your name and contact information to be in the contact list.

WHAT IF I CHOOSE NOT TO PARTICIPATE OR CHANGE MY MIND AND WANT TO WITHDRAW FROM TAKING PART IN THE CONTACT LIST?

Taking part in the contact list is optional and voluntary. You may withdraw your permission to continue taking part in the list at any time. To do so, you must send a written withdraw request to Dr. Page-Reeves at JPage-Reeves@salud.unm.edu. She will destroy your information that has been stored.

FUTURE USE AUTHORIZATION

Yes, I choose to participate in the optional contact list. _____ Initials

No, I choose not to participate in the optional contact list. _____ Initials

The University of New Mexico Health Sciences Center Consent and Authorization to Participate in a Research Study

Your organization is participating in a training on [DATE HERE] about the Earned Income Tax Credit (EITC) being provided by the Office for Community Health at the University of New Mexico (UNM), and your organization has indicated that you will be attending the training. Researchers at UNM are inviting participants to take part in a brief 2-PART survey to evaluate the training. Each part of the survey should take 5 to 10 minutes to complete. If you agree to take the survey, you will enter PART ONE of the survey using the link below and complete it online before the day of the training. If you fill out PART ONE of the survey, you will receive a link to complete PART TWO of the survey following the training.

WILL I BE PAID TO TAKE THE SURVEY?

If you are a UNM employee, UNM policy does not allow for you to receive any payment for participating in a study related to your work.

If you are not a UNM employee and you complete both parts of the survey, you will receive a \$25 electronic Amazon card to thank you for taking the time to answer the survey questions.

DO I HAVE TO TAKE THE SURVEY?

Your organization has indicated that they want you to attend the training as part of the work being done in the community, but you do not have to take this survey in order to attend the training. Your participation in the survey is completely voluntary. If you do participate in the survey, you are free to skip any questions or discontinue at any time.

WHEN WILL THE SURVEYS HAPPEN?

If you choose to participate in the survey, you will enter PART ONE of the survey using the link below and complete it online before the day of the training. Answers submitted after the training has started will not be considered. If you fill out PART ONE of the survey, you will receive a link to complete PART TWO of the survey following the training.

WILL ANYONE KNOW THAT I TOOK THE SURVEY OR HOW I ANSWER THE QUESTIONS?

Only the project's 2-person Data Management Team will know that you took the survey and what you responded to the questions. This is because they will use your email address to provide you with the link to the second part of the survey and to provide you with your \$25 Amazon card if/when you complete both parts of the survey. They will also need to connect your responses to the first part of the survey to your responses to the second part of the survey in order for the research team to compare them. However, they will share your responses with the rest of the research team anonymously (i.e., without your name). The Amazon cards will be issued electronically and the list of recipients will not be shared with the study team or your organization. The Data Management Team will not disclose or identify individuals who complete the surveys by name or other identifying information in the analysis. All of your responses will be de-identified and results will be aggregated for reporting. Please be aware, while we make every effort to safeguard your data once received on our servers via our REDCap data system, given the nature of online surveys, as with anything involving the Internet, we can never absolutely guarantee the confidentiality of the data while it is being transmitted to us.

This type of study is called a "clinical trial." All clinical trial studies are required to be posted on a specific website online. A description of the study and what we are doing will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The survey is brief but your responses will be valuable. Researchers at UNM are interested in knowing if this training helps frontline health workers (community health workers [CHWs] and medical assistants [MAs]) and staff understand the EITC, how to screen clients for EITC, where to refer clients for free tax preparation assistance, and how EITC relates to the health and wellbeing of your clients and their families. As a CHW, MA, or staff member of an organization that serves the needs of individuals and families with many social needs, this information will be very valuable.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

>

Some people do not like to answer survey questions or participate in research. We have tried to make the survey brief to be convenient. Some people feel uncomfortable answering questions about themselves or their experiences. We designed the questions to evaluate the training and they are not questions of a personal nature.

WHAT IF I HAVE QUESTIONS ABOUT THIS RESEARCH OR ABOUT THE SURVEY?

If you have questions about the study, please contact me at the email or phone number listed below. If you have questions regarding your legal rights as a research subject, you may call the UNM Human Research Protections Office at (505) 272-1129.

Thank you in advance for your assistance with this important project. **By clicking on the link below, you will be consenting to participate in the above described research study.**

Sincerely,

Janet Page-Reeves, PhD., Office for Community Health, University of New Mexico Health Sciences Center

PHONE: 505-306-3041

E-MAIL: JPage-Reeves@salud.unm.edu