Official Title: Community-Based Participatory English as a Second Language Health Literacy Program to Prevent Lead Exposure in Flint

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HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

General Informed Consent

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: ESL Health Literacy Program to Prevent Lead Exposure

Principal Investigator:

- Emily Feuerherm, Ph.D., Associate Professor of Linguistics at University of Michigan – Flint

Co-Investigators:

- San Juana Olivares, President and CEO of Genesee County Hispanic Latino Collaborative
- Bianca Ramirez, M.A., Staff of Genesee County Hispanic Latino Collaborative

Study Sponsors:

- Michigan Institute of Clinical Health Research (funded by National Institute of Health)
- Flint Truth and Action Partnership Project (funded by the Kellogg Foundation)

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

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please listen and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this study is to improve health literacy by providing a bilingual health literacy course. We will focus on lead poisoning from the Flint water crisis. The program will include an English as second language (ESL) class and a pre- and post-survey.

3. WHO CAN PARTICIPATE IN THE STUDY

Latino / Hispanic residents of greater Flint who are 18 or older and speak Spanish as their first language can participate. You should be able to commit to an 8-week program via zoom.

4. INFORMATION ABOUT STUDY PARTICIPATION

This research study will be conducted virtually by zoom. First, you will see if you qualify for the study and if you agree to participate. Then you will take a survey about your knowledge of health information and health literacy. The survey will take about 40 minutes and can be done in English or Spanish.

Next you will attend the Health and English as a second language Literacy Program (HELP). This is an online educational program that will be held virtually on zoom. The program will cover topics about water safety, lead testing, and nutrition.

At the end of the course you will take the survey again. It will be the same survey as you took before the program. This will end your participation in the study.

Zoom calls will not be recorded.

4.2 How much of my time will be needed to take part in this study?
The HELP program lasts 8 weeks:

- Week 1: Individual enrollment and survey takes about 1 hour
- Week 2-7: Class on Monday evenings from 6-8pm
- Week 8: Individual survey takes about 40 minutes

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

Risks to you: Because this study collects information about you, the primary risk of this research is a loss of confidentiality. The study team will protect your confidentiality and privacy by not sharing identifiable information.

Benefits to you: You might benefit from being in the study by learning more about how to protect yourself and your family from lead. You might also benefit from improved literacy and English fluency.

6. ENDING THE STUDY

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty. The researchers may follow up with you to understand why you stopped attending. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. This information may be used to improve the program. 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 a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

You will receive $20 for enrolling and completing the first survey, $20 for enrolling a friend (one-time compensation), $50 for completing the program (minimum 4 of 6 classes and the final survey). You will also receive a box of fresh produce from Flint Fresh for participating in the program.

8. PROTECTING AND SHARING RESEARCH INFORMATION

You will be given an identification letter and number which we will use to track your progress in the program. You do not need to provide any personal identifiable information to participate in this research study.

We will keep any identifiable information (e.g. name, phone number) for recordkeeping and to follow up with you. This will be stored securely and separately from the research information we collect from you.

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.

8.1.1 Special Protections
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 sharing your de-identified data with other researchers through the repository called Deep Blue. Your information will be labeled with a code, not your name or other information that could be used to directly identify you

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

8.4 Will my information be used for future research or shared with others?

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you.

We will put the information you share with us into a University of Michigan repository called Deep Blue. The repository contains information about many people. Your information will be labeled with a code, not your name or other information that could be used to directly identify you.

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: Emily Feuerherm, PhD.
Email: feuerher@umich.edu
Phone: 916-541-0832

Co-Investigator (For Spanish): San Juana Olivares
Email: sjolivares@gchlc.org
Phone: 810-275-1757

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 to Participate in the Research Study

Do you consent to participate in this research study?