

# **Michigan Model for Health: Learning to Enhance and Adapt for Prevention (MI-LEAP)**

NCT04752189

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## Research Informed Consent

Title of Study: Mi-LEAP: Michigan Model for Health: Learning to Enhance and Adapt for Prevention

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### Key Information about this Study

1. This is a research study and is completely voluntary.
2. This study is being completed to help improve health education in schools and will last for the duration of health class. You will complete 2 interviews and short lesson tracking forms.
3. There are a few risks, including answering uncomfortable questions.
4. You may be more engaged in teaching health class and connecting with students.

### Purpose

You are being asked to be in a research study of the Michigan Model for Health: Learning to Enhance and Adapt for Prevention (Mi-LEAP) project because you are at least 18 years old and teach 9th -12th graders in health education. This study is being conducted at your school and through online surveys.

**Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, Wayne State University, in collaboration with your Regional School Health Coordinator, is collecting information through one-on-one dialogue with teachers to better understand the benefits and challenges of different types of health education implementation supports in schools.

### Study Procedures

If you agree to take part in this research study, you will meet with a study interviewer via web conferencing or by phone and discuss your experiences with delivering evidence-based health curricula in your school. The researcher and participant will conduct the interviews in private spaces. We will audiotape interviews to ensure that all information is captured accurately. The interviews will take approximately 45 min total. You will also complete a fidelity tracking form to provide information about what components of the adapted curriculum you used in your classroom and provide a link for your students to complete the student survey. We expect approximately 10-12 teachers and 300 students to participate in this research.

### Benefits

The possible benefits to you for taking part in this research study are your answers may help inform changes to make the process of delivering evidenced-based curricula, health education content, and specifically the Michigan Model for Health<sup>TM</sup>, more efficient and effective in high schools.

### Risks

By taking part in this study, you may experience the following minimal risks: You may feel uncomfortable answering some of the questions. You may choose to skip any question that makes you feel uncomfortable.

The following information must be released/reported to the appropriate authorities if at any time during the study there is concern that:

- child abuse or elder abuse has possibly occurred,
- you have a reportable communicable disease (i.e., certain sexually transmitted diseases or HIV)
- you disclose illegal criminal activities, illegal substance abuse or violence

There may also be risks involved from taking part in this study that are not known to researchers at this time.

### **Study Costs**

Participation in this study will be of no cost to you.

### **Compensation**

For taking part in this research study, you will be paid for your time and inconvenience. You will receive a \$100 gift card for participating in the pre- and post-program interviews, up to \$200 for the fidelity logs for the entire school year and administering pre-/post-test surveys, access to 2-year digital curriculum license for standard MMH curriculum, and trauma-informed practices training.

### **Confidentiality**

This research holds a Certificate of Confidentiality 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. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We will disclose your information for any purpose to which you have consented, as described in this document. This includes sharing your de-identified data with other researchers.

More detailed information about Certificates may be found at the NIH CoC webpage:

<https://humansubjects.nih.gov/coc/index>

### **Voluntary Participation/Withdrawal**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because you did not follow the instructions to take part in the study

The data that you provide may be collected and used by Qualtrics and LearnDash Learning Management System as per its privacy agreement. Additionally, participation in this research is for residents of the United States over the age of 18; if you are not a resident of the United States and/or under the age of 18, please do not complete this survey.

### **Questions**

If you have any questions about this study now or in the future, you may contact Andria Eisman at the following e-mail [aeisman@wayne.edu](mailto:aeisman@wayne.edu). If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

### **Consent to Participate in a Research Study**

To voluntarily agree to take part in this study, you must indicate “yes” in the button below and submit this form. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

- ☐ Yes
- ☐ No