

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

NCT04752189
8/15/2021

Parent Information

Michigan Model for Health: Learning to Enhance & Adapt for Prevention (MI-LEAP)

Andria Eisman, PhD, MPH

Key Information about this Study

1. This is a research study and your child's participation 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. Your child will complete two surveys lasting about 15 minutes each.
3. There are a few risks, including answering uncomfortable questions. These risks are similar to other surveys your child may have taken in school.
4. Your child may learn more about him/herself and be more engaged in health class.

Purpose

You are being asked to allow your child to be in a research study at their school that is being conducted by Andria Eisman in Community Health, Division of Kinesiology, Health, and Sport Studies Division at the Wayne State University College of Education to investigate the relative benefits of an enhanced Michigan Model for Health™ curriculum and implementations supports to prevent the use of alcohol tobacco and other drugs among youth.

Your child has been selected because he or she attends a Michigan high school participating in this study. Additionally, the health teachers at his or her high school use the Michigan Model for Health™ curriculum.

Study Procedures

If you decide to allow your child to take part in the study, your child will be asked to complete a survey from Wayne State University about their learning experiences during their high school health class and about health behaviors and perceptions, including alcohol, tobacco or other drug use. This survey is similar to other surveys they may have taken in class including the Michigan Profile for Healthy Youth MiPHY and MMH summative evaluations. We expect approximately 10-12 teachers and 300 students to participate in this research.

Benefits

The possible benefits to your child for taking part in this study are your child might learn more about their life and what they have learned in health by answering the questions. They might also learn more about survey studies like this one. Additionally, information from this study may benefit other people now or in the future.

Risks

By taking part in this study, your child may experience that some survey questions could be upsetting. We will ask about your child's knowledge and opinions about drug use. If they get upset, they may stop answering the questions. The teacher will be in the classroom to help. The Wayne State University study team will do everything we can to keep survey answers private. In the very rare event that privacy protections fail, they might feel embarrassed.

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

Costs

Submission/Revision Date: 8/15/2021

Protocol Version: #1

Parent Information: MI-LEAP

There are no costs to you or your child to participate in this study.

Compensation

You or your child will not be paid for taking part in this study.

Confidentiality

All information collected about your child during the course of this study will be kept confidential to the extent permitted by law.

- All information collected about your child during the course of this study will be kept without any identifiers.
- All reports about the survey results will use group averages and percentages. The study team will safely manage your child's survey data. The survey forms will be destroyed after the answers are stored in computer files. All computer files with survey answers will be stored on password-protected computers. The researchers plan to keep this study data for up to 10 years for future studies about youth programs.

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

Your child's participation in this study is voluntary. You may decide that your child can take part in this study and then change your mind. You are free to withdraw your child at any time. Your decision about enrolling your child in the study will not change any present or future relationships with Wayne State University or its affiliates, your child's school, your child's teacher, your child's grades or other services you or your child are entitled to receive.

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. 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.

Parent Information: MI-LEAP

Request to Opt-Out in a Research Study

To request that your child be recused from this study, you must sign on the line below. If you choose to have your child take part in this study, you may enroll them at any time. You are not giving up any of your or your child's 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. By signing this document, you are indicating that you **DO NOT** want your child to participate in the study. You will be given a copy of this consent form.

Print the Name of the Participant

Date of Birth

Signature of Parent/ Legally Authorized Guardian

Date

Printed Name of Parent Authorized Guardian

Time