

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

NCT04752189
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Documentation of Adolescent Assent Form

(ages 13-17)

Title: Michigan Model for Health™: Learning to Enhance and Adapt for Prevention (Mi-LEAP)
Study Investigator: Andria Eisman

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 two surveys lasting about 15 minutes each.
3. There are a few risks, including answering uncomfortable questions. These risks are similar to other surveys you may have taken in school.
4. You may learn more about yourself and be more engaged in health class

Why am I here?

You are being asked to be in a research study because you are a high school student taking health class this term. Please take time to make your decision. Talk to your family about it and be sure to ask questions about anything you don't understand.

Do I have to be in the study?

You don't have to be in this study if you don't want to or you can stop being in the study at any time. Please discuss your decision with your parents and researcher. No one will be angry if you decide to stop being in the study.

Why are they doing this study?

This study is being done to find out how prevention education about drugs use affects the way you view drug use. This study can help us improve your health education and provide you with more effective skills to prevent drug use.

How long will I be in the study?

You will be in the study for the duration of your normal health class. You will take two 15-minute surveys – one at the beginning of the semester and one at the end. This survey will not be part of your class grade.

Will the study help me?

You may benefit from being in this study because you might learn more about your life and what you have learned in health by answering the questions. You might also learn more about survey studies like this one. Information gained from this study may help other people in the future by improving health education and providing more effective skills to prevent drug use.

Will anything bad happen to me?

There are a few risks for being in this study. Some survey questions could be upsetting. We will ask about your knowledge and opinions about drug use. We will also ask about your potential drug use. If you get upset, you can stop answering the questions. Your teacher will be in the classroom to help.

Do my parents or guardians know about this?

This study information has been given to your parents/guardian and they have not stated that you

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cannot participate in this study. You can talk this over with them before you decide.

What about confidentiality?

Every reasonable effort will be made to keep your records (medical or other) and/or your information confidential, however we do have to let some people look at your study records. Similar to other tests and surveys in school, we ask that you please respect your classmates' privacy and keep your eyes on your own survey. No one on the study team or your teacher will know how you answered the survey questions. Your parents will not see how you answered survey questions. It is possible that a classmate may see your computer, and you might get in trouble or feel embarrassed.

We will keep your records private unless we are required by law to share any information. The law says we have to tell someone if you might hurt yourself or someone else. The study doctor can use the study results as long as you cannot be identified.

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.

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>

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.

What if I have any questions?

For questions about the study please e-mail Andria Eisman at 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.

AGREEMENT TO BE IN THE 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 assent 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

