



MICHIGAN STATE
UNIVERSITY

FURLEY
CHILDREN'S
HOSPITAL

PEDIATRIC PUBLIC HEALTH INITIATIVE

Information sheet

Thank you! Based on your YES responses to the previous questions, it appears that you and your child are eligible to participate in the Flint Tooth FAIRY study! After you complete the entire survey, the study staff will also check to make sure you that you are eligible to participate. You will only receive an incentive (gift card) if you are eligible to participate.

Please read the information below to learn more and see if this study is right for you. If you would like to enroll, please consent to participating after reading the information.

If you have any questions, please call or text us at 810-600-5642, or email us at chm.flinttoothfairy@msu.edu.

Information and Consent for the Tooth FAIRY Study

You are being asked to participate in a research study. Researchers are required to provide a consent form to tell you about the research study, to share that your participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

Study Title: Tooth FAIRY (Flint Assessment of In-utero and at-Risk Young): The application of novel dentition analysis to understand historic lead exposure

Researcher and Title: Mona Hanna-Attisha, MD MPH FAAP Associate Professor, Director of Pediatric Public Health Initiative

Department and Institution: College of Human Medicine, Division of Public Health, Pediatric Public Health Initiative, Michigan State University

Address: 200 East 1st Street, Flint, MI 48502

Sponsor: Robert Wood Johnson Foundation

PURPOSE OF RESEARCH

The study seeks to better understand the impact of exposure to lead in water as it relates to lead uptake in children's teeth. You and your child have been selected as possible participants in this study because your child is in the Flint Registry and you agreed to be contacted about future studies. This study will collect information about where you and your child lived in Flint and use of Flint water through an online survey and will ask for healthy and whole baby teeth (tooth in one piece and without extensive cavities) from your child after they fall out naturally. The teeth will be analyzed for lead and compared to other sources of information, including but not limited to, information about child demographics, outcomes and exposures.

WHAT YOU WILL BE ASKED TO DO

If you decide to participate, you will sign your name on this consent form online. You can call or text 810-600-5642 or email chm.flinttoothfairy@msu.edu to ask questions and if you would like the consent form explained or read to you.

You will then be asked to review a separate HIPAA (Health Insurance Portability and Accountability Act) authorization form to allow the covered entity, the Michigan Department of Health and Human Services (MDHHS), for the Use or Disclosure of Protected Health Information for Research. This form will tell you how your Protected Health Information will be used and to whom it will be given. Federal and state law requires that you give your permission for the use of your Protected Health Information.

You will then be asked to complete an online survey. This survey will take about 30 minutes. It will ask you some basic information about your child (their intake of Flint tap water) and address history (places you and your child have lived or stayed). After you complete the survey, study staff will review your survey to make sure you are eligible to participate. We will contact you with

any questions. If you prefer to do the survey on paper or over the phone, please call or text 810-600-5642 or email: chm.flinttoothfairy@msu.edu and study staff will assist you.

Study staff will also ask you to save and mail in your child's healthy and whole baby teeth after they fall out naturally. We will provide you with instructions, envelopes with prepaid mailing labels and three collection tubes to mail up to three whole and healthy teeth to us. This should take about 15 minutes for each tooth. If you are willing to send us more than three teeth, we would welcome them and we can provide more prepaid mailing supplies.

Your data and your child's data from the Flint Registry and, if applicable, the IRISE (Impact of Resilience, Interventions, Stress, and Environmental Exposure) study, may be combined with data from the Tooth FAIRY study. By signing this consent form, you are giving us permission to use your and your child's data from the Flint Registry and, if you were a participant, from the IRISE study.

POTENTIAL BENEFITS

Although you might not benefit directly, your participation in this study may contribute to the understanding of tap water use recommendations for pregnant women and babies. This study could lead to clearer guidelines, earlier testing for lead and ultimately stricter regulations to protect all children from lead exposure in water. The results from this study may be generalizable to the large number of children in the United States who face similar environmental exposures. Because this type of tooth analysis is not usually done, there are no standard levels to use to understand your child's results. Therefore, we will not be providing your child's teeth results to you, unless specifically requested. Results may not be available until 1 to 2 years after tooth submission.

POTENTIAL RISKS

The potential risks of participating in this study are minimal. You do not need to leave your home or meet in-person. You may feel uncomfortable answering some of the questions.

PRIVACY AND CONFIDENTIALITY

Any information gathered about you or your child during this study will be kept confidential to the maximum extent allowable by law. Survey questions will be asked via a HIPAA compliant Qualtrics survey. Qualtrics provides industry standard data security. Any paper copies of surveys will be entered into Qualtrics and locked in a file cabinet in a locked room with 24/7

security in the Pediatric Public Health Initiative Office at Michigan State University in Flint, MI. The study data may be kept permanently.

Tooth collection kits for mailing in teeth will contain the study child's first name and study ID. When teeth are mailed to a laboratory for analysis only a study ID will be used.

The MSU's Human Research Protection Program may see this information in an audit but will also keep this information confidential.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

Participation in this study is voluntary. You and your child have the right to say no. You and your child have the option to skip questions. You or your child may change your mind at any time and withdraw. There will be no penalty for not participating or for withdrawal. You will be told of any significant findings that develop during the study that may influence your willingness to continue to participate in the research.

COSTS AND COMPENSATION FOR BEING IN THE STUDY

There are no costs to you to participate in this study. If you are eligible and complete the survey and mail in 3 whole and healthy baby teeth, you may receive up to \$100. You will receive a \$25 gift card as a thank you for completing the survey. You will receive another \$25 gift card for each whole and healthy baby tooth (tooth in one piece without extensive cavities) that we receive from you in the mail, up to 3 teeth, for up to an additional \$75. Only participants that are verified to be eligible will receive a gift card.

FUTURE RESEARCH

Information that identifies you or your child might be removed from the data. After such removal the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your child. Your data (even with identifiers removed) will not be used for commercial profit. This research will not involve genome sequencing of bio-specimens (teeth). The permission you and your child give us to use your information will not expire.

Data may be shared with a data repository, the Inter-university Consortium for Political and Social Research data at the University of Michigan.

CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues or how to do any part of it, or to report an injury, please contact the researcher Dr. Mona Hanna-Attisha, 200 East 1 Street, Flint, MI 48502, chm.flinttoothfairy@msu.edu, 810-600-5642. If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

Would you like to participate in the Flint Tooth FAIRY study?

Yes

Maybe, but I would like someone from the study team to call me and answer questions or read the consent form to me

No thanks

Please enter a phone number where you can be reached so that someone from our study can contact you.

Consent

Your name

First name

Last name

Your child's name.

If you have more than one eligible child you would like to enroll, please complete a new survey for each child, starting with your youngest eligible child. After you complete the survey for one child, you will need to click the survey link again to start a new consent document and survey.

First name

Last name

I have talked with my child in an age-appropriate way about the Tooth FAIRY study and my child agrees to participate.

Yes

No

What is your e-mail address?

We will use this e-mail to send you a copy of the consent document. We will also send you a \$25 gift card after you successfully complete the survey and we review your eligibility and survey completion. We will also send you a \$25 gift card for each whole and healthy baby tooth you send us, up to 3 for \$75. If you complete the survey and send in at least three whole and healthy teeth, you may receive \$100 in gift cards.

SIGNATURE OF INDIVIDUAL OR LEGAL REPRESENTATIVE

Your signature below means that you voluntarily agree to participate in the Flint Tooth Fairy Study.

×

SIGN HERE

clear

Today's date

I agree to be contacted about future projects or research studies that might be appropriate for me or my child/children.

Yes

No

You will be e-mailed an electronic copy of this form to keep and can also review it on the website, FlintToothFairy.com at any time during the study.

We want to compare the findings from lost teeth to any previous blood lead level results from the Michigan Department of Health and Human Services (MDHHS)

To give approval for us to receive this information, please click "yes" below and you will be taken to the MDHHS form to give your authorization. After completing a brief form, you will be directed to the survey.

If you do not wish to give us permission to receive this information, click "no" and you will be directed to the survey.

Yes, I would like to give approval for MSU to receive blood lead level results

No, I do not wish to give permission