

Permission to Take Part in a Human Research Study**Protocol Title: St. Louis Baby Teeth—Later Life Health****Principal Investigator: Marc G. Weisskopf, PhD, ScD****Description of Study Population: St. Louis Baby Teeth participants who donated teeth to Washington University (St. Louis) in the 1950s and 1960s****Version Date: May 19, 2022****Key Information**

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you and your parents donated at least one of your baby teeth to Washington University in St. Louis in the 1950s or 1960s. It is your choice whether or not to participate in this new study. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

What should I know about a research study?

- Someone on our research team is available to explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends, and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to explore how exposure to different factors in early life impact later life health. We can use your previously donated teeth to assess some characteristics of your early development. Answering a questionnaire about your health and behaviors and completing a cognitive test (which measures mental functions like memory, language, and the ability to recognize objects) may help us see how these early-life exposures relate to later-life health.

How long will I take part in this research?

We expect the survey to take no longer than 30 minutes to complete.

We expect the cognitive test to take no longer than 30 minutes to complete.

More detailed information about the study procedures can be found under the “*What can I expect if I take part in this research?*” section.

Is there any way being in this study could be bad for me?

The only risks of participation are the disclosure of confidential information, which we will make every effort to prevent, and possible emotional distress from talking about your health history.

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The survey includes questions about mental health and drug and alcohol use, which may make some people uncomfortable.

You are free to skip any question you wish.

More detailed information about the risks of this study can be found under the “*What are the risks and possible discomforts?*” section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better scientific understanding of how different factors in early-life relate to later-life health.

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. You can download a copy of this form to keep or, upon request, we can mail you a copy of this form for your record.

Who can I talk to?

The research team will answer any questions you have before you decide if you want to participate; please visit [hsph.me/SLBT](https://hsph.harvard.edu/SLBT) to access our FAQ for answers to the most common questions, or you can contact us at slbt@hsph.harvard.edu. If you do not have access to the internet, you can call us on our study line at 617-432-0041.

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the head of the research team, Dr. Marc Weisskopf, at 617-384-8872 or mweissko@hsph.harvard.edu.

This research has been reviewed by the Harvard Longwood Campus Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Regulatory Affairs and Research Compliance (ORARC) at 617-432-2157 (or toll-free at 1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary

You are invited to take part in this research because you and your parents donated one of your baby teeth to Washington University in St. Louis in the 1950s or 1960s. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

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How many people will take part in this research?

We will invite about 60,000 people to take part in this research.

What can I expect if I take part in this research?

As a participant, you will be expected to complete a survey of your health and behaviors and a cognitive test. Each part is expected to take about 30 minutes for a total of one hour.

What are the risks and possible discomforts?

The only risks of participation are the disclosure of confidential information, which we will make every effort to prevent, and possible emotional distress from talking about your health history. The survey includes questions about mental health and drug and alcohol use, which may make some people uncomfortable. You are free to skip any question you wish.

Are there any benefits from being in this research study?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better scientific understanding of how different factors in early-life relate to later-life health.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. With your permission, we will use the data you provided us (if you completed the survey and cognitive test). It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why.

Will I be compensated for participating in this research?

You will not be compensated for completing the survey or cognitive test.

What will I have to pay for if I participate in this research?

It will not cost you anything to participate in this research.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

The researchers are fully trained in the protection of human subject participants. All participants will be assigned a unique study ID that will be used in place of identifying information, and all study data will be kept in password-protected files on password-protected computers.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of the organizations involved in this research, including the sponsor (the National Institutes of Health).

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Permission to Take Part in a Human Research Study**What else do I need to know?**

This research is being funded by the National Institutes of Health and the Superfund Research Program.