*RESEARCH PROJECT DESCRIPTION*

# Implementation of Saliva-Check Mutans bacterial identification kit as educational aid for patients during pre-natal dental visits

TO _____
[Full Name of Volunteer]

My name is Dr. Joshua Thomson. I am a faculty member in the Division of Integrated Biomedical Sciences at the University of Detroit Mercy School of Dentistry.

I have asked you to agree to be a volunteer in some research aimed at determining the educational benefit of using a rapid test that measures the level of a bacterium that can cause dental disease. Before I can accept your consent, I want to make known to you the following information relating to the project.

1. **Explanation of the Purpose.** The purpose of this project is to use a salivary bacterial identification test as an educational aid for pregnant women that receive dental health services. The kit measures the level of the bacterium *Streptococcus mutans*, which is linked to cavities. We hope this kit will help educate patients about the importance of proper oral hygiene to reduce levels of this bacterium, thus decreasing transmission of the bacterium to children, reducing their risk of early childhood tooth decay.

2. **Explanation of the Procedures.** As part of this study, you will be asked a few questions about your understanding of bacteria and dental diseases, as well as your oral hygiene practices. Then you will be asked to provide a stimulated saliva sample. You will be asked to chew on a piece of paraffin wax (the base of chewing gum) to stimulate saliva flow and dislodge bacteria attached to oral surfaces. Then, you will be asked to spit that saliva into a container for processing. This will occur at the first appointment at the health clinic and the follow-up appointment after birth. After the tests are done, any remaining saliva will be immediately discarded. There will not be any other tests done with your saliva.

3. **Expected Risks.** There are no attendant discomforts or risks reasonably to be expected.

4. **Expected Benefits.** Results of this test may help inform the health-care provider and patient of the current risk of tooth decay. This test is not always used in dental health screenings, but will give additional information about the patient's caries-risk and oral health status. In the long term, there could be benefits to science and dental practice, if important educational correlations are discovered.

5. **Confidentiality.** Upon collecting saliva samples, your sample will be tested and the results will be recorded in 15 minutes. The results will be kept by the clinic and after the last testing

post-partum, results will be sent to me at Detroit Mercy Dental with no patient identifiers, only a coded number, for analysis. **NOTE: In certain cases, the FDA may inspect the records, the sponsor may inspect the records, and/or the IRB may inspect the records.**

6. **Offer To Answer Questions.** I hereby offer to answer any questions you might wish to ask concerning the procedures used in this research at this time. Furthermore, I may be reached during the hours of 9:00 AM until 5:00 PM at 810-650-9836 or by e-mail at thomsojo@udmercy.edu. If I am not available, you can also contact Dr. David Fischer with questions at fischedd@udmercy.edu. If you have questions concerning your rights as a volunteer, you may contact Dr. Elizabeth M. Hill, Chair, University of Detroit Mercy Institutional Review Board, 313.578.0405 or hillelm@udmercy.edu.

7. **Freedom To Withdraw Consent.** If you consent to be a volunteer in this research project, you are nonetheless free to withdraw your consent and decide to not provide a saliva sample without prejudice to you. You should also understand that the investigator has the right to withdraw you from the research project if for some reason they decide not to collect your saliva, such as poor health (suspected bacterial or viral infection).

8. **Compensation.** There is no financial compensation for participation in this study.

9. **Additional Costs.** There are no additional costs for you to participate in this study.

10. **Significant New Findings**. If any significant new findings are developed during the course of this research which may relate to the volunteer's willingness to continue participation, such new findings will be provided to the volunteer.

11. **Future Data Use**. Samples will be tested on-site of collection and destroyed appropriately after use.

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## INSTITUTIONAL REVIEW BOARD

# *ACKNOWLEDGMENT AND CONSENT*

I, _____
(Prospective Volunteer's Full Name)

of _____, hereby state:
(Street address, City, State, Zip Code)

1. I have read all of the statements above pertaining to the research project entitled "Implementation of Saliva-Check Mutans bacterial identification kit as educational aid for patients during pre-natal dental visits" and I understand them.

2. I have been given the opportunity to ask any questions I wish concerning this research project and any questions I have asked have been answered to my satisfaction.

3. I understand a full copy, with signatures, of this document will be provided to me.

4. I hereby consent to be a volunteer in this research project.

_____ _____
Full Signature of Prospective Volunteer Date

As the investigator in the research project entitled "Implementation of Saliva-Check Mutans bacterial identification kit as educational aid for patients during pre-natal dental visits". I hereby state to the best of my knowledge and belief that all of the statements made in the above consent form are true and that in consenting the prospective volunteer exercised free power of choice without undue inducement or any element of force, fraud, deceit, duress, or any other form of constraint or coercion. In addition to the participation by the volunteer being voluntary, the volunteer has been advised that he or she may decide to not participate at any time without penalty.

_____ _____
Full Signature of Investigator Date