**Consent to Participate in a Clinical Research Study**

**Customized oral hygiene therapy**

**Principal Investigators:**

**Jeff CW. Wang, DDS, DMSc (jeffwa@umich.edu)
Martha McComas, RDH, MS**

**Department of Periodontics and Oral Medicine**

**University of Michigan School of Dentistry**

**Invitation to participate in a research study**

We invite you to participate in a research study to enhance personalized oral hygiene instructions as part of a customized oral hygiene therapy.

**Description of subject involvement**

If you agree to be part of the research study, you are consenting to be examined the level of your oral hygiene. You will also learn and reflect on a new oral hygiene intervention customized to your need by the student provider and the instructor. Intraoral photos or video may be taken during our demonstration regarding how to brush the areas of concerns with appropriate devices. The video demonstration can be sent to you for your at-home review. You will also be asked to come for a short follow-up visit to assess your improvement in daily home care on oral hygiene and complete a short survey for both visits.

**Benefits**

You will directly benefit from being in this study because you will learn effective ways to maintain good oral hygiene and promote oral health for health.

**Risks and discomforts**

There is minimal or no risks associated with this study. Although very unlikely, we will end your participation if there is situation of distress or adverse events. Please tell us if you have any injuries or other problems related to your participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

**Compensation**

No monetary compensation.
A free customized oral hygiene therapy video if you consent to have one.

**Confidentiality**

***Authorization to release your protected health information***

Agreeing to be in this study gives researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from your health care record at the University of Michigan School of Dentistry.

We plan to publish the results of this study, but will not include any information that would identify you. There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly, including the University of Michigan, government offices or the study sponsor.

To keep your information safe, the researchers will store your record of your survey in a locked office. And your health record will need authorized individual ID and password to gain access. Also, if you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

**Storage and future use of data**

The researchers will retain the data of the survey for 1 year after conclusion of the project. The researchers will dispose of your data by shredding the paper survey and deleting associated data. Plaque control index will be stored as part of your health record in the system. The data will not be made available to other researchers for other studies following the completion of this research study and will not contain information that could identify you.

**Voluntary nature of the study**

Participating in this study is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time. If you decide to withdraw early,this will not affect or compromise your treatment here in the School of Dentistry clinic.

If significant new knowledge is obtained through the course of the research, which may relate to your willingness to continue participation, you will be informed.

**Contact information**

If you have questions about this research, including questions about scheduling, you may contact your student provider or principle investigators listed above.

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board, 2800 Plymouth Rd., Bldg. 520, Room 1169, Ann Arbor, MI 48109-2800, +1 (734) 936-0933, (866) 936-0933, or (irbhsbs@umich.edu).

eRAM ID: HUM00112606

**Consent**

By signing this document, you are agreeing to be in the study. You will be given a copy of this document for your records and one copy will be kept with the study records. Be sure that questions you have about the study have been answered and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

*I agree to participate in the study.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date