CONSENT FORM
Use of an Occlusal Support Device During the Second Stage of Labor

You are invited to participate in a research study that will evaluate whether wearing a mouth guard during labor helps to shorten the length of time that a woman is in labor before delivering her baby. You were selected as a possible participant because you are pregnant and are a patient at the UMP Women's Health Specialists Clinic. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by *Dr. James Gambucci, DDS, MPH, an Associate Professor in the Department of Developmental and Surgical Sciences at the School of Dentistry at the University of Minnesota.* Delta Dental of Minnesota is funding the study.

This Information and Consent Form may contain words you do not understand. Please ask the study staff or doctors to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study and, if signed, will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Study Purpose

The purpose of the study is to find out if wearing a mouth guard, also called an Occlusal Support Device (OSD), during labor and delivery reduces the length and intensity of the pushing stage of labor. We also want to find out if wearing the OSD reduces labor complications including Caesarian Sections. Based on previous studies, there is evidence to suggest that the use of an OSD will make your pushing more effective and lead to more efficient pushing. This increased effectiveness could lead to less need for Caesarian Sections.

Finally, we want to find out if the use of an OSD can improve the Apgar scores in newborns. Apgar scores are used to determine the health of a newborn child.

Study Procedures

If you agree to participate in this study, we would ask you to do the following: We would ask you to participate in the study for the rest of your pregnancy, your labor, and delivery. Participating in the study will result in 2 visits to a dental clinic compared with people who are not in this study.

The *study procedures* for each visit are listed below. The dental clinic visits are being done for study purposes only. All other data that we are collecting are from your regular prenatal care visits that are considered to be standard of care for pregnant females except we will obtain a urine sample during labor. Half the patients in this study will be assigned randomly to either the study group,

which is the group that will use the mouthguard during pregnancy, or the control group, which is the group that will not do anything different than they would normally do.

It is expected that a total of 500 people will participate in the study, 250 in the study group and 250 in the control group. For people in the control group the study will end at the time of delivery. People in the control group will be asked to complete a questionnaire 6 weeks following delivery, at which time their participation in the study will end. There are no costs associated with study participation.

Initial Visit

At the prenatal appointment where you discuss the study with your care provider and/or the research assistant at the clinic, you will determine whether you are eligible for and interested in participating in the study. This visit will last about 1 hour and will include the following procedures:

- Review of criteria to determine whether you are eligible to take part in the study.
- Signing the consent form. Research staff will first explain the study and procedures to you and answer any questions about the study and consent form. If you agree to be in the study, we will ask you to sign this consent form. You will not be allowed to take part in any of the study until you have signed and dated this consent form and received a copy of the signed and dated form.
- Sign the study HIPAA form. This is will explain our privacy policy related to your private information.
- Complete your medical/pregnancy appointment and discuss any current problems.
- Recording any medicines or treatments that you are taking.
- You will be randomly assigned to either wear a mouth guard during your labor or not. Random assignment means that each person who agrees to be in the study has an equal chance of being in either group. It's like flipping a coin.

Dental Clinic Visit

- If you are randomly assigned to the mouth guard group in the study, you will be contacted to schedule a dental visit to have your mouth and teeth examined to make sure that there is not a dental problem that would prevent you from participating in the study. You will be asked about any dental problems you have been experiencing. You will then have impressions (molds) of your teeth made in order to make your custom mouth guard. You will also be scheduled for a second dental clinic visit to try in the mouth guard to make certain that it fits well so that you'll know how to use it when you go into labor.
- Questions will be asked to make certain that you still want to be in the study.
- Questions will be asked about any changes in your medical and dental histories.

Labor and Delivery event

- If you have not had any major complications during your pregnancy, you will be identified as a study participant when you present in labor.
- Questions will be asked to make certain that you still want to be in the study.
- If you are in the group that will not be using the mouth guard during labor, there will be no change in the normal labor procedures other than providing a urine sample during labor.
- If you are receiving a mouth guard, once your labor and delivery team determines that you are entering the second stage (pushing) of labor, you will be asked to wear the mouth guard.
- If you feel that you do not want to participate in the study (wear the mouth guard), you can let your team know at any time.
- There will be no other changes to the normal labor and delivery procedures.
- You will be asked to wear the mouth guard until the end of delivery.

Risks of Study Participation

A. There are no known risks associated with using the mouth guard during labor.
B. There are no known risks associated with the additional dental appointments, teeth cleaning, and impressions to make the mouth guards.
C. The risks to you and your baby from us collecting and analyzing your medical data are very low. Your samples will be identified only with your study code number.
D. In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away."

Benefits of Study Participation

The benefits to study participation are:

- Potential for shorter second stage (pushing) of labor, based on previous studies
- Potential for better APGAR scores of newborn
- Identification of dental pathology
- Opportunity to obtain a dental home if you do not have one.

Study Costs/Compensation

At the conclusion of this study, all participants will be given a $10 gift card to be used in a major chain store (Target, Walmart, etc.).

Confidentiality

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 confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance."

Protected Health Information (PHI)

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.
The results of this study may also be used for teaching, publications, or for presentation at scientific meetings."

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University, University of Minnesota Physicians or University of Minnesota Health (MHealth). If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are James Gambucci DDS, MPH, Suzanne Darnell MD and Mark Roettger DDS. You may ask any questions you have now, or if you have questions later, you are encouraged to contact the principal investigator, James Gambucci DDS, MPH at 612-625-7448 or gambu001@umn.edu.
This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625- 1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

- You have questions about your rights as a research participant.
- You want to get information or provide input about this research

You will be given a copy of this form to keep for your records.

Conflict of Interest Statement

Dr. Mark Roettger, a Co-Investigator on this project, owns equity in Bite Tech. Bite Tech is the manufacturer of the mouthpiece used in this study. This interest has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject_____

Date_____

Signature of Person Obtaining Consent_____

Date_____