PARENTAL CONSENT FOR PARTICIPATION IN RESEARCH STUDY

STUDY TITLE:	Caries History of an Insured Population of Children
PRINCIPAL INVESTIGATOR:	Joyce Galligan, R.N., D.D.S. Principal Investigator for Research Institution
TITLE:	Caries in Insured Children
DEPARTMENT:	Herman Ostrow School of Dentistry of USC, University of Southern California Division of Periodontology, Diagnostic Sciences & Dental Hygiene
COLLABORATOR:	Mitch Couret, D.D.S.
24-HOUR TELEPHONE NUMBER:	Toll free (800) 537-1715 x1244 (Ask for study line) Direct local phone: (603) 223-1244

We invite you to take part in a research study. . Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your dentist. You may find some of the language difficult to understand. If so, please ask questions or call our 24-hour telephone number or contact us by e-mail and we will answer your questions. If you decide to participate, you will be asked to sign this form.

The University of Southern California is contracted by Proactive Oral Solutions, Inc., which received funding for this study from DDPNH. They provide funding to cover the costs of conducting this study.

WHY IS THIS STUDY BEING DONE?

This study is about tooth decay. We would like to find out if saliva (spit) can be used to validate a test that indicates a child's risk for developing cavities.

You are invited to participate in this research study because your child is between 3 and 17 years of age with current or previous dental benefit coverage through Delta Dental Plan of New Hampshire, Inc. (DDPNH). About 1000 male and female participants will take part in this study.

WHAT IS INVOLVED IN THIS STUDY?

If you allow your child to participate, you will be asked to ***read and complete the following forms:***

1. Parental Consent form – which explains all about the study; you will need to sign this form.
2. HIPAA Authorization form – gives written permission to DDPNH to release only your child's dental health information (in a coded format to preserve confidentiality) to members of a research team for research purposes. Your child's identity will not be disclosed.
3. Assent – Even if you allow your child to participate in the study, children who are 7-17 years of age have the right to choose whether they wish to participate or not. Your child will be asked to read this form, be given the opportunity to ask questions, and then print and sign their name and enter the date if they voluntarily agree to participate.
4. Medical History Questionnaire – We request this information to see if any medical condition affects your child's oral health. The questionnaire will be coded and de-identified to preserve the anonymity of your child and the privacy of their information. Please complete and place this form in the postage paid envelope and seal afterwards. This information is transmitted directly to USC and is not available to DDPNH.
5. Saliva Collection Information form—This form is completed by the parent following sample collection.

Your child will collect their saliva as follows:

1. Rinse mouth with water and relax for 5 minutes.
2. Collect a volume of saliva by drooling into a funnel connected to a test tube.

The total amount of time required to complete all of the above procedures is approximately 20 minutes. This is a one-time only collection.

Information About Saliva Samples Collected as Part of This Research:
Excess sample obtained from saliva collections will be frozen and kept at the Research Institution until the study is completed. No cell lines will be used. No genetic testing will be conducted.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are no known risks or discomforts associated with this study.

WILL YOUR CHILD'S INFORMATION BE KEPT PRIVATE?

The investigator and the Institutional Review Board (IRB) will keep your child's records for this study private as far as the law allows. The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your child's name.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

Your child will receive no direct benefit by participating in the research study. However, his/her participation in the study may help us learn how to identify an individual's level of risk for developing cavities through a simple saliva test.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to allow your child to participate in this study.

ARE THERE ANY PAYMENTS TO YOUR CHILD FOR TAKING PART IN THE STUDY?

Your child will receive a one-time payment in the form of a $15 gift card to Toys R Us for participating in this study.

Possible Commercial Products

All saliva samples are important to this research study. Your child's sample will be owned by the University of Southern California or by Proactive Oral Solutions, Inc. If a commercial product is developed from this research project, the commercial product will be owned by the University of Southern California or Proactive Oral Solutions, Inc. You will not profit financially from such a product.

WHAT HAPPENS IF YOUR CHILD GETS INJURED OR NEEDS EMERGENCY CARE?

This protocol is less than minimal risk, so it is unlikely that your child will get hurt or sick from taking part in the study. Normally, you or your child will not receive any compensation for being hurt or sick, and you will be responsible for paying for any care.

WHAT ARE YOUR CHILD'S RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOUR CHILD DECIDES NOT TO PARTICIPATE?

Your child's participation in this research study is voluntary. Your decision whether or not to allow your child to take part will not affect current or future care or payment determinations by DDPNH. You are not giving up any legal claims or rights. If you decide to allow your child to

take part in this study, you can change your mind and stop him/her from being in the study at any time.

DO THE INVESTIGATORS OR THE INSTITUTION HAVE A CONFLICT OF INTEREST?

Dr. Galligan is the principal investigator for the University of Southern California, and Dr. Couret is the collaborator, principal investigator and contact person for DDPNH. The University of Southern California is contracted by Proactive Oral Solutions, Inc., which received funding for this research study from DDPNH. Neither Dr. Galligan nor Dr. Couret has any affiliation with Proactive Oral Solutions, and they have no financial interest in the project. Patricia Denny is the study coordinator for this research study conducted by the University of Southern California, and she is affiliated with Proactive Oral Solutions. The University of Southern California will receive royalties from future sales associated with the technology developed during this research.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Mitch Couret, D.D.S. at (800) 537-1715 x1244 or direct local phone (603) 223-1244 or study@nedelta.com or Joyce M. Galligan, R.N., D.D.S. at (213) 740-7165 or galligan@usc.edu with any questions, concerns, or complaints about the research or your child's participation in this study. If you feel your child has been hurt by taking part in this study, please contact Mitch Couret, D.D.S. at (800) 537-1715 x1244 or direct local phone (603) 223-1244 or study@nedelta.com or Joyce M. Galligan, R.N., D.D.S. at (213) 740-7165 or galligan@usc.edu. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM. PST (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your child's rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Health Sciences Institutional Review Board at the LAC+USC Medical Center, General Hospital Suite 4700, 1200 North State Street, Los Angeles, CA 90033.

You will get a copy of this consent form.

AGREEMENT:

I have read the information provided above. I have been given a chance to ask questions, and all my questions were answered. I am signing in order to allow my child to take part in this study.

Name of Parent/Legal Guardian of Participant	Signature	Date Signed and Time

Name of Child

Name of Person Obtaining Informed Consent	Signature	Date Signed and Time