University of Illinois at Chicago
Consent/Parental permission and Authorization for Participation in Biomedical Research

Gingival crevicular fluid characterization during orthodontic treatment

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child is also required. When we say "you" in this consent form, we mean you or your child; "we" means the research team.

Why am I being asked?

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: **Assistant Professor Phimon Atsawasuwan**
Department: **Orthodontics**
Address and Contact Information: **Rm #535, College of Dentistry, University of Illinois at Chicago**
Emergency Contact Name and Information: **Dr.Phimon Atsawasuwan Tel: 312-355-4798**
Sponsor: **American Association of Orthodontists Foundation**

You are being asked to be a subject in a research study about "**Gingival crevicular fluid characterization during orthodontic treatment**" conducted by Assistant Professor Phimon Atsawasuwan, Department of Orthodontics, College of Dentistry at the University of Illinois at Chicago (UIC). The purpose of this study is to understand the composition of gingival crevicular fluid (liquid that stays between cervical tooth/root surface and gum at the gum line) when the wire moves teeth during the braces. We will collect gingival crevicular fluid and analyze to identify the unique protein/RNA that is related to tooth movement. We will scan your teeth condition after we collect the fluid at each visit.

You have been asked to participate in the research because you have scheduled an appointment for the orthodontic tooth movement and may be eligible to participate in this study. We ask that you read this form and ask any questions you may have before agreeing to be involved in the research project.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you**

decide to participate, you are free to withdraw at any time without affecting that relationship.
Approximately 100 subjects may be involved in this research at UIC.

What is the purpose of this research?

This research is being done to better understand the composition of gingival crevicular fluid (liquid that stays between cervical tooth/root surface and gum at the gum line) due to the wire moves teeth during the braces. The composition of the proteins and changes in the gingival crevicular fluid may be an indicator for the development of gum disease.

What procedures are involved?

The crevicular fluid collection will be performed at Orthodontic clinic RM#131 and the analysis of the sample for this research will be performed at Rm #535, College of dentistry, University of Illinois at Chicago. The fluid will be collected five times, 2 weeks apart

The collection of fluid will be performed after your teeth are cleaned and absorbent paper strips will be inserted gently in the space between your gum and tooth surface around the gum line and let the paper absorb the fluid. Then the paper will be removed and kept in a storage solution for further analysis.

If you are taking pain medication for post-operative orthodontic treatment, you will only be allowed to take acetaminophen and not ibuprofen or aspirin. This restriction on pain medication would only apply to the study visits when samples are collected.

If you agree to be involved in this research project, we would ask you to let one of researcher in our team collecting your crevicular fluid, your name, medical number and date of birth for research purposes. The information will be coded with a study ID number to protect confidentiality and kept in a locked cabinet.

What are the potential risks and discomforts?

You may experience some mild discomfort from the sample collection, which includes the removal of plaque from the around the gum line. There is also a small risk of loss of confidentiality; others outside the research may become aware you are participating in the research. However, the researchers will take all steps to protect your confidentiality

Are there benefits to taking part in the research?

This study is not being done to improve your condition or health. You will receive no direct benefit from your participation in this research; however, the knowledge gained from this research may help dentists and orthodontist develop ways to prevent complications from braces.

What other options are there?

You have the option to not participate in this study. A decision not to participate will in no way affect the patient's dental procedure or care.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by:

- UIC Office for the Protection of Research Subjects, State of Illinois Auditors

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

By signing this form, you are also authorizing the researchers to use the health information provided by you for the purposes of this research. This includes the information as described within this form and specifically includes name, date of birth, and medical record number.

This authorization does not have an expiration, but you may withdraw your permission for the use of your health information for this study at any time by sending a letter to the following person: Dr. Phimon Atsawasuwan, University of Illinois at Chicago (UIC), College of Dentistry, 801 S Paulina St, Room #247 Chicago, IL 60612. If you cancel this authorization, the investigators may still use and disclose the health information they have already obtained as necessary to maintain the integrity and reliability of research.

What are the costs for participating in this research?

There is no additional cost to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will receive a gift card after you complete the study, you will receive a total of $100 to compensate your travel expense.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC.

Who should I contact if I have questions?

Contact the researchers Assistant Professor Phimon Atsawasuwan at 312-355-4798:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research.

What are my rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

Signature of Subject or Legally Authorized Representative

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate or give permission for my child to participate in the research study and authorize the researcher to use and share my/my child's health information for the research. I will be given a copy of this signed and dated form.

_____ _____

Signature of child (16-17 years old) Date

_____ _____

Signature (18 years and older) Date

_____

Printed Name (18 years and older)

_____ _____

Signature [parent(s)/legal guardian(s) if patient is under 18] Date

_____

Printed Name [parent(s)/legal guardian(s) if patient is under 18]

Signature of Person Obtaining Consent

Date (must be same as subject's)

Printed Name of Person Obtaining Consent