##

## PARTICIPANT INFORMATION SHEET

**FEASIBILITY STUDY OF A MODIFIED FILLING TO TREAT ROOT DECAY**

Invitation to take part

You are being invited to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Please discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of the study?**

This study will try out a new method for the treatment of tooth decay and in particular root decay. Root decay is a condition that affects senior people more often. It occurs as a result of many reasons such as reduced saliva flow due to medications, difficulty in maintaining good oral hygiene in particular around the gum margins and gum recession that progresses with age. Currently the standard of care for such cavities is to use a drill to clean the decayed tooth structure and then place a filling to restore the area and enable normal function and cleaning. Many fillings lack the ability to actually eliminate and inhibit the growth of bacteria, which is to a large extent, responsible for this problem. This study tries out a new way to enhance the antimicrobial property of a common filling material by adding an antimicrobial agent which is commonly found in mouthwashes to help eliminate the responsible microbes for tooth decay. The modified filling will be applied after cleaning the cavity using an atraumatic technique which only involves using hand tools. The main advantage of this is minimum discomfort and hence no injections are needed. To measure the quantity of microbes we will have to take saliva and plaque samples from both teeth and this will be done on the same day of placing the fillings as well as,1,3 and 6 months after.

The main aim of the study is to see how well the modified filling perform for the period of 6 months and what effect will it have on the survival of microbes responsible for tooth decay. A questionnaire will be given to you to evaluate your acceptance of the way the filling was placed and if any issues were experienced during the duration of the study.

**Why have I been chosen?**

You have been chosen because having root decay can lead to tooth loss and possible nerve exposure which could lead to major future dental work. Fixing such cavities early is beneficial to your oral health as well as general wellbeing. Root decay only appear in more senior people so it is unlikely to be found in young and middle aged individuals.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this Information Sheet to keep and be asked to sign a Consent form. If you decide to take part, you are still free to withdraw from the study at any time and without giving your reason. If you decide to withdraw from the study at any time, or decide not to take part in the study, this will not affect you in any way.

**What will my participation in the study involve?**

Your teeth will be examined by a dentist to see if you are suitable to take part in this study. If you are suitable, then the dentist will book you in for 4 appointments to have the fillings placed in the first appointment as well as taking samples and give you a questionnaire to fill out. In the second, third and fourth appointments more samples will be collected and questionnaires will be filled. These appointments will be after 1, 3 and 6 months.

If you agree to take part in the study, you must agree to only use the tooth brush and tooth paste provided and refrain from using any mouthwashes for the duration of the study. Antibiotics will also affect the results of the study so if they are needed, you will have to notify us straight away.

**What do I have to do?**

You must only brush your teeth with the provided tooth paste and tooth brush and refrain from using any mouthwash for the duration of the study. Antibiotics will also affect the results of the study so if they are needed, you will have to notify us straight away. It is also important to attend all appointments on time.

**Explanation of the procedure that is being tested**

This study will test a modified filling material and to see the effect of such material on the microbes that are commonly found in great numbers in decayed teeth. This filling material will be applied to decayed root surfaces using an atraumatic technique which involves only hand tools and no drilling. You will be able to eat and drink as normal and the fillings will not limit you in anyway. The only thing that you will not be able to do for the duration of the study is using antimicrobial mouthwashes.

**What are the potential disadvantages and risks of taking part?**

You may experience slight discomfort during the procedure depending on the side of the cavity.

You may also experience very slight taste alteration which will be temporary if it occurs.

The filling may come out and require replacement. If this happens, you will have to contact us immediately.

You may withdraw from participation in the study at any time and without any disadvantage to yourself.

**EMERGENCY TELEPHONE NUMBER:**

**PROF. PAUL BRUNTON**

Office - Faculty of Dentistry, University of Otago

9.00am – 5.00pm Monday - Friday

**03 479 7039**

**Mobile: 021 2797041**

**What are the possible benefits of taking part?**

We hope that this treatment will help you to eliminate at least one root cavity and it may have an effect in reducing the amount of bacteria in the mouth as a whole.

**What if new information becomes available?**

While you take part in the study new information could become available about your treatment. You will be told if this happens and you will alwayshave the choice of leaving the study at any time. If you leave the study, your normal care will continue. If you continue with the study, you will be asked to sign an updated consent form.

**What happens when the research study stops?**

You will continue to have your fillings and they will not be removed.

**What happens if something goes wrong?**

In the unlikely event that you are harmed by taking part in this research project, this could be covered under the terms of the accident compensation legislation with its limitations. While a claim may be lodged, it is always up to ACC to accept or decline your claim. If you have any questions about ACC, please feel free to ask the researcher for more information before you agree to take part in this study.

If you have any queries or concerns about your rights as a participant in this study, you may wish to contact the local Health and Disability Services Consumer Advocate:

Telephone: (03) 479 0265 or Freephone 0800 377 766 or

Free fax: 0800 2787 7678 (0800 2 SUPPORT) or

Email: advocacy@hdc.org.nz

If there is a specific Maori issue or concern, please contact Prof. John Broughton, Assoc. Dean Maori.

Telephone: (03) 479 7639

Email: john.broughton@otago.ac.nz

**Will taking part in the study be kept confidential?**

If you consent to take part in this research study, your medical records will be inspected by the dentists conducting the study. If you take part, then this is confidential and no one else will know apart from you.

When the project is completed, all personal identifying information will be removed from the paper records and electronic files which represent the data from the project. Paper records will be kept in locked cabinets. Electronic data will be stored on a password secured computer stored at the Faculty of Dentistry. The computers will be contained within locked rooms, in alarm activated area of the respective buildings. Data collected during the duration of this study will be stored for at least 10 years.

**What will happen to the results of the research study?**

If the research study shows a relevant result, then the researchers will publish the results in an appropriate journal within 12 months of the end of the study. All patients who take part in the study will be informed of the results. Any publication will be confidential and the details of individual patients will not be made available to anyone outside the study. You cannot be identified personally from any publication about the study.

**Who is organising and funding the research?**

This study is organised by Prof. Paul Brunton, Dean of the Faculty of Dentistry, Prof. Karl Lyons Head of Department of Oral Rehabilitation. The work on this study has been financed by the Faculty of Dentistry and other grants. None of the dentists conducting this research will be paid for carrying out the research. You will not be paid for taking part in the study.

**Contact for further information**

If you require any further information then please feel free to discuss this with Prof. Paul Brunton at the Faculty of Dentistry, University of Otago, telephone 03 479 7039.

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### CONSENT FORM

**FEASIBILITY STUDY OF A MODIFIED FILLING TO TREAT ROOT DECAY**

**Please tick to indicate consent to the following:**

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| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  |  |  |
| I have been given sufficient time to consider whether or not to participate in this study. |  |  |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. |  |  |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |  |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |  |  |
| I consent to the research staff collecting and processing my information, including information about my health. |  |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. |  |  |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. |  |  |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. |  |  |
| I understand the compensation provisions in case of injury during the study. |  |  |
| I know who to contact if I have any questions about the study in general. |  |  |
| I understand my responsibilities as a study participant. |  |  |
| I wish to receive a summary of the results from the study. |  |  |

**Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |

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