Tripler Army Medical Center
CONSENT TO PARTICIPATE IN RESEARCH &
AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

PRINCIPAL INVESTIGATOR: **Steven Phung, DMD.**
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KEY INFORMATION FOR PROTOCOL: **Can SAP P_{11-4} Increase the Radiopacity of Incipient Interproximal Carious Lesions on a Radiograph in a Military Population**

You are invited to take part in a research study. Your participation is voluntary. This page gives you key information about the study to help you decide whether to participate. Detailed information follows this page. Ask the researchers questions you have. If you have questions later, the contact information for the research investigator is below.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn about how SAP P_{11}-4 (produced commercially as Curodont products), specifically a product called Curodont Repair Fluoride Plus is used in a military population to treat dental caries (dental caries are developing cavities that are still structurally intact and not too deep). Curodont Repair Fluoride Plus is an FDA fluoride varnish and will be used as approved by the FDA in this study. Your participation in this research will last about 3 months.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)?

The possible benefits to you as a research participant in this study include the use of Curodont Repair Fluoride Plus as a non-invasive treatment that may help remineralize your dental caries and prevent the full development of cavities. There are no reported side effects from using Curodont Repair Fluoride Plus. This may reduce your need for fillings which require the use of drilling and/or needles. You may benefit from the one-on-one oral hygiene instruction and demonstration you receive from a licensed dentist.

In addition, others may benefit in the future from the information learned in this study which may result in the contribution of less invasive dental treatments and reduced time spent at military dental facilities. However, there is no guarantee that you will benefit from being in this research.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICPATE IN THIS STUDY (RISKS AND ALTERNATIVES)?

You might not have the time to participate in this study, which includes an initial visit and 3 follow-up visits over the next 3 months. There are no reported side effects from using Curodont Repair Fluoride Plus.

As part of this study, standard digital X-rays will be taken of your teeth. Radiation exposure from these digital X-rays is same as 1-2 days of naturally occurring background radiation or less than flying in a commercial flight from across the pacific ocean. Therefore, this amount is so small, the risk of any harm to your health is extremely low.

Risk Mitigation and Safety Measures: The radiation exposure from these dental X-rays is considered minimal. To ensure participant's safety and maintain exposures As Low As Reasonably Achievable (ALARA), your standard radiation safety practices should be followed i.e. lead aprons and thyroid collars are no longer recommended standard radiation protection.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
There may also be other risks of taking part in this study that we do not yet know about.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have at Tripler Army Medical Center, Schofield Barracks Dental Clinic if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Steven Phung, DMD. If you have questions, suggestions or concerns about the study, his contact information is: (714) 386-0323, and mailing address: 315 Brannon Rd, Schofield Barracks, HI, 96857.

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research, please contact the Madigan Army Medical Center IRB Office at: 253-968-3524, Department of Clinical Investigation, 9040 Jackson Avenue, Tacoma, WA 98431-1100.

Please tell the researchers if you are taking part in another research study.

If you decide to take part in this research study, you will be asked to sign this document.Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

DETAILED CONSENT:

1. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are an active-duty soldier between the ages of 18-74 and have one or more dental caries between some of your teeth. The purpose of this research study is to learn about the use of a remineralization product called Curodont Repair Fluoride Plus in the military. This is an FDA-approved treatment of developing cavities (dental caries) that are still structurally intact and not too deep. Curodont Repair Fluoride Plus helps to rebuild the tooth structure, preventing the development of a fully formed cavity.

Curodont Repair Fluoride Plus will be applied to your dental caries, by a member of the study team using a process like painting fluoride varnish on your teeth after dental cleaning. You will also receive bitewing X-rays before the treatment, and at 1 week, 1 month, and 3 months after the treatment.

The duration of participation per visit is 20 minutes to 45 minutes for a total of up to 3 hours of study participation, over 3 months.

There will be about 30 people taking part in the study at the Schofield Barracks Dental Clinic, over a period of 3 months.

At the end of this research study and at your last 3-month visit, the clinical results/research results about you will be shared with you. In a private operatory, we will show you your x-rays and see any effects on your caries.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, we will confirm that you will be available for the 3 study follow-up visits (at least 4 months from the start of the treatment). Please let us know about any possible travel or moves (such as TDYs, training, PCS or ETS). You must be 18 years or older to participate. You must also be an active-duty service member. If you use tobacco products, nicotine products, or e-cigarettes, you will not be able to participate in this study.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

First you will read and sign this consent form, and all of your questions will be answered by a member of the study team.

All visits will take place at Schofield Barracks Dental Clinic in a private operatory.

We will collect a baseline measurement of your dental caries by taking a bitewing X-ray before the Curodont treatment, your tooth will be cleaned thoroughly, and then the

Curodont will be applied to each of the caries, a process similar to painting fluoride varnish on your teeth after a dental cleaning. You will be asked not to brush, floss, spit, or rinse for at least 30 minutes afterwards. This first visit, including the consenting process may take 45 minutes or an hour to complete.

We will also schedule your follow-up visits for 1 week, 1 month, and 3 months. For each of these visits you will return to the dental clinic and have bitewing X-ray of your dental caries. Each of these follow-up visits may take 20 to 45 minutes.

Once you have completed your 3-month visit your participation in this study will be over.

4. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There are other options for treating dental caries. Alternative treatments and/or procedures that may be available to you include fluoride varnish, prescription strength fluoride toothpaste, silver diamine fluoride, MI Paste (another type of remineralization product), cavity filling, or no treatment. You should talk with your personal dentist about these options.

Choosing not to take part in this research study is also an option.

5. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

6. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

7. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study): Steven Phung, DMD

8. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data): As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

9. SOURCE OF FUNDING: Dental Health Activity Hawaii

10. LOCATION OF THE RESEARCH: Schofield Barracks Dental Clinic

11. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS: None

12. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by staff from Tripler Army Medical Center, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: coded data, removal of personal information, computer password protection, locking of drawers and offices.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

The study team will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data

13. AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR THIS RESEARCH:

You are being asked for permission to use and disclose your protected health information (PHI) for this research study. Protected health information is defined as individually identifiable health information.

The Health Insurance Portability & Accountability Act of 1996, Public Law 104-191 (also known as HIPAA), establishes privacy standards to protect your health information.

This law requires the researchers to obtain your authorization (by signing this document) before they use or disclose your protected health information for research purposes in the study listed above.

WHAT PERSONAL IDENTIFIERS AND/OR PROTECTED HEALTH INFORMATION (PHI) MAY BE USED AND DISCLOSED IN THIS RESEARCH?

The identifiers and/or PHI collected, used, or disclosed are below:

• *Names* • *Dates (except year) directly related to an individual such as birth date* • *Phone numbers* • *DoD ID numbers*	• *Medical history* • *Imaging results* • *Radiographs*

HOW WILL YOUR PROTECTED HEALTH INFORMATION BE USED OR DISCLOSED IN THIS RESEARCH?

Your name, date of birth and DoD ID will be used to review your medical records. Your phone number will be used to contact you for visit reminders. Your imaging results/radiographs will be used for data analysis.

The use and disclosure of your protected health information is necessary in order to be able to conduct the research described. Records of your participation in this research may only be disclosed in accordance with state and federal law, including the Privacy Act (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (45 CFR 160 & 164).

Note: Protected health information of military service members may be used or disclosed without your authorization to military command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

By signing this document, you give your permission for information gained from your participation in this research to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

WITH WHOM MAY YOUR PROTECTED HEALTH INFORMATION BE SHARED THROUGH THIS RESEARCH?

- Tripler Army Medical Center or Department of Defense representatives
- The Madigan Army Medical Center Institutional Review Board
- State and Federal Government representatives, when required by law (such as the Food and Drug Administration (FDA))

Those listed above who are covered entities under HIPAA agree to safeguard your protected health information by using and disclosing it only as permitted by you in this Authorization or as directed by state and federal law.

You need to be aware that some parties receiving your protected health information may not have the same obligations to safeguard your protected health information and may re-disclose your protected health information to parties not named above. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

You do not have to sign this document. If you decide not to sign this document:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You will not be allowed to participate in the research.

After signing this document, you can change your mind and:

- Notify the Principal Investigator in writing that you have withdrawn your permission to disclose or use your protected health information (revoke the Authorization).
- Send your written letter to Steven Phung, DMD, 315 Brannon Rd, Schofield Barracks, HI, 96857 to inform him of your decision. Your revocation is not effective until your letter is received.
- Researchers may continue to use and disclose your PHI that was obtained before your revocation became effective to the extent that the researchers have taken action in reliance on your earlier authorization. Researchers may also continue to use or disclose your PHI as necessary to maintain the integrity or reliability of the current research, as, for example, to account for your withdrawal from the study, to conduct misconduct investigations, or to report adverse events.
- If you withdraw the Authorization, you will not be allowed to continue to participate in the research.

If you have not already received a copy of the brochure entitled “Military Health System Notice of Privacy Practices,” you may request one, or it is available on-line at: https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/HIPAA-Compliance-within-the-MHS/Notice-of-Privacy-Practices

If you have any questions or concerns about your privacy rights, you should contact the TAMC HIPAA Privacy Officer, 808-433-2237.

This Authorization does not have an expiration date.

14. INCIDENTAL FINDINGS

There is a possibility that while reviewing your bitewing x-rays we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." It could be a cavity on a different tooth or a defect in a previous filling or crown you had previously done.

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor, or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

15. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

16. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the study Principal Investigator, Dr. Steven Phung, or another research team member in writing.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your dentist to discuss treatment for your condition. You could request treatment for your condition with another dental provider.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the Principal Investigator as discussed in the HIPAA Authorization section of this form.

The Principal Investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

17. WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

CONTACT INFORMATION:

Principal Investigator (PI): The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Steven Phung, DMD
Phone: (714) 386-0323
Mailing Address: 315 Brannon Rd Schofield Barracks, HI, 96857

Tripler Army Medical Center (TAMC) Human Research Protection Program (HRPP) Office: The Human Research Protection Program Office staff and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study. Please contact the TAMC HRPP Office at: 808-433-7486, 1 Jarrett White Road, Tripler AMC, HI 96859-5000, or by email at: dha.tripler.Tripler-AMC.mbx.dart-hrpp@health.mil.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

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