IRB NUMBER: 18-25477
IRB APPROVAL DATE: 12/27/2019
IRB EXPIRATION DATE: 05/06/2020

# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title:** *Optimizing Acute Post-Operative Dental Pain Management Using New Health Information Technology*

| | |
|---|---|
| Research Project Director: | **Elsbeth Kalenderian, DDS, MPH, PhD**<br>Department of Preventive & Restorative Dental Sciences Leland A. & Gladys K. Barber Distinguished Professor in Dentistry UCSF School of Dentistry<br>707 Parnassus Ave., Room D-1025<br>San Francisco, CA 94143 Tel: 415-502-6504<br>Elsbeth.Kalenderian@ucsf.edu |
| UCSF Study Coordinator: | **Hongchun Liu**<br>Tel: 626-464-9787<br>Email: Hongchun.liu@ucsf.edu |
| Willamette Dental Group/Skourtes Institute Contact: | **Kristen Simmons RDH, BSDH, MHA**<br>Chief Operations Officer<br>Skourtes Institute Board Member<br>Willamette Dental Group<br>Corporate Headquarters<br>6950 NE Campus Way<br>Hillsboro, OR 97124<br>Tel: 503-952-2536<br>Email: ksimmons@willamettedental.com |
| Willamette Dental Group/Skourtes Institute Study Coordinator: | **Joanna Mullins, RDH, MHI**<br>Tel: 503-952-2166<br>Email: jmullins@willamettedental.com |

This is a research study intended to optimize the management of your postoperative dental pain using the FollowApp text messaging system that periodically assesses pain in the first seven days following dental procedures and allows you to securely communicate with your provider regarding your pain experience.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a patient of the UCSF Dental Center or Willamette Dental Group/Skourtes Institute undergoing a procedure and your provider has elected to participate in this study.

**Why is this study being done?**

The purpose of this study is to optimize the quality of dental pain management by implementing an SMS messaging system that allows providers to monitor their patients' pain during the critical acute postoperative phase. We believe that by actively tracking these symptoms using mobile phones, we will promptly identify patients with sub-optimal pain experiences and offer providers an opportunity to intervene (e.g. modify analgesic prescriptions), thereby eliminating needless suffering, reducing the occurrence and/or severity of post-op complications, and enhancing the overall care experience. Our ultimate goal is to achieve the quadruple aim: improve patient experience, improve patient outcomes, improve physician experience and reduce per capita costs.

This research is funded by the Agency for Healthcare Research and Quality (AHRQ). The study researchers have no conflicts of interest to disclose.

**How many people will take part in this study?**

About 6,000 patients will take part in this study across all study sites.

**What will happen if I take part in this research study?**

If you agree to take part in this study, the following procedures will occur:

- We will obtain from your dental record the following information:
    - record number
    - several dates: year of birth, date of procedure, dates of visits
    - information on your dental procedure, post-operative instructions provided to you
    - prescribed medication
    - Information on noted complications
- We will collect this information from your dental record one time one month after your dental procedure.
- Two members of this research team who have each received training in the conduct of this type of research will conduct the chartreview
- Designated staff will assist you with registering your mobile phone number on FollowApp.Care (a mobile phone text messagingsystem).
- You will receive a text message confirming your enrollment in the study.
- On the day of your scheduled procedure, your clinical care will proceed as normal. At the end of the procedure, you will be provided with post-op instructions. You will also receive an additional handout explaining when to expect the FollowApp.Care SMS notifications and the types of questions that will be asked.
- At 9:00 am on Days 1, 3, 5 and 7 following your procedure, you will receive an SMS notification prompting you to respond to a series of questions about your pain, such as "What is your level of pain right now?"
- On Day 7 after your procedure, you will be invited to complete a questionnaire during your follow-up visit or through a link sent via SMS. We may contact you if we do not receive your completed questionnaire within 48-72 hours of sending the link. We will also send you up to three reminders if we are unable to reach you.
- Your provider may also choose to discuss your overall pain experience and responses to the SMS notifications during your follow-up visit.
- **Study location:** All these procedures will be done at the UCSF Dental Center or Willamette Dental Group/Skourtes Institute as part of your regular care. You will be able to respond to SMS notifications using your mobile phones wherever you are.

**How long will I be in the study?**
Participation in the study will take a total of about 40 minutes of your time over the seven-day study period (about 3 – 5 minutes per day). Some additional time might be needed for your provider to follow up with you about any symptoms you may be experiencing.

**Can I stop being in the study?**
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Each SMS notification will have an option to opt out of future notifications. You may also choose to not respond to any of the SMS notifications when prompted. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**What side effects or risks can I expect from being in the study?**
The study was designed to ensure that participants are exposed to minimal risks/discomforts. The study team will maintain strict privacy and data confidentiality. All questions asked would be used to monitor your level of pain in order to improve the quality of care that you receive. SMS notifications will be sent to you at the designated time (9:00 am), and you can choose to respond at any time that is convenient for you that day.

**Are there benefits to taking part in the study?**
If you choose to participate in this study, you will be helping your provider to better understand the degree of pain that you might experience after the dental procedure. You will be contributing to scientific knowledge about the management of post-op pain at the dental office. You will also be able to communicate with your dentist's office directly using the secure messaging feature of FollowApp, giving your provider the opportunity to make recommendations for how to handle your pain at a much earlier timeframe and at more regular intervals.

**What other choices do I have if I do not take part in this study?**
Your other choice will be to receive the usual standard follow-up care after any procedure at the UCSF Dental Center or Willamette Dental Group/Skourtes Institute If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care at UCSF or Willamette Dental Group/Skourtes Institute the way you usually do.

**Will information about me be kept private?**
We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Agency for Healthcare Research And Quality
- Representatives of the University of California

**Will I be paid for taking part in this study?**
You will not be paid for taking part in this study.

**What are my rights if I take part in this study?**
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular

benefits, and you can still get your care from our institution the way you usually do.

**Who can answer my questions about the study?**

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study by contacting Elsbeth Kalenderian, DDS, MPH, PhD at 415.502-6504 or at Elsbeth.Kalenderian@ucsf.edu

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at415-476-1814.

**CONSENT**

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.