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

**PROVIDER CONSENT**

(Intervention Group)

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

| | |
|---|---|
| UCSF Research Project Director: | **Elsbeth Kalenderian, DDS, MPH, PhD**<br>Chair, 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-3238 Box 0758 \| San Francisco, CA 94143<br>Tel: 415-502-6504<br>Elsbeth.Kalenderian@ucsf.edu |
| UCSF Study Coordinator: | **Hongchun Liu**<br>Tel: 415-200-6423<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>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 patients' postoperative dental pain using the FollowApp.Care text messaging system that periodically assesses pain in the first seven days following their dental procedures and allows you to securely communicate with them regarding their pain experience.

Members of the study team will explain this study to you. 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 dental provider at either UCSF Dental Center or Willamette Dental Group.

**Why is this study being done?**

The purpose of this study is to optimize the quality of dental pain monitoring and management by implementing mobile phone technology to monitor patients' pain during the critical acute post-operative phase. We believe that by actively tracking these symptoms using mobile phones, we will promptly identify the 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?**
A total of 116 providers across all study sites will be participating this study.

**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:

- You have been randomized to the Intervention Group
- You will be invited to participate in a 1-hour training session where you will be provided with details of the study protocol, including the specified eligible CDT codes, reminders of current evidence-based analgesic prescription recommendations and patient education brochures/ FAQs.
- The training session will include instructions on using the FollowApp.Care system, e.g. case handling and response protocol, and receive a FollowApp.Care training guide. Before the training session, members of the study team will assist you in creating your FollowApp.Care Provider Profile, and setting your notification preferences so that, for example, you could choose to receive notifications by email or text, in real-time or at specified times of the day.
- You and your delegates (and/or the study team staff at UCSF) will invite patients to participate in the study and hand out the information sheet. Those patients interested in participating will be asked to register their mobile phone number on FollowApp.Care (a mobile phone text messaging system). The first text message will contain a link to the information sheet.
- All clinical care procedures will continue as normal and patients will be provided with routine post-op instructions and follow-up care, as well as an additional handout explaining when to expect the FollowApp.Care text notifications and the types of questions that will be asked.
- At 9:00 am on Days 1, 3, 5 and 7 following the procedure, your patients will receive a text notification prompting them to respond to a series of questions about their pain, such as “What is your level of pain right now?”
- When a patient’s survey response meets the pre-defined triggers, a notification will be sent to you through the FollowApp.Care system with a link for you to access the patient’s profile. By clicking the patients’ profile, you will be able to view patient’s demographic information, pain history, and chat history. Using the chat feature, you can also securely communicate with patients to gather more information about their symptoms, answer questions, offer reassurance, remind patients of post-op instructions and notify patients of new analgesic prescriptions or modifications to existing ones.
- On Day 7, your patients will be invited to respond to a questionnaire asking about their postoperative pain experience. During follow-up visits, you may also choose to use the FollowApp.Care responses to discuss the post-op pain experience with your patients.
- At the end of the study, you will be asked to complete a provider satisfaction survey and participate in a focus group session.

**How long will I be in the study?**
The study is expected to last for a period of 12 months.

**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. 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. For more information about risks and side effects, please ask one of the researchers.

**Are there benefits to taking part in the study?**
The information that you provide may help improve our understanding of the utility of text messaging systems for optimizing the quality of post-op pain management. It will allow the developers to improve the system and adapt it to better fit the needs of dental professionals. You will also have the added benefit of being able to chat with your patients using the secure messaging feature of FollowApp.Care, thereby allowing you to make recommendations on how to handle their pain at a much earlier timeframe and at more regular intervals in order to prevent unnecessary suffering.

**What other choices do I have if I do not take part in this study?**
You are free to choose not to participate in the study. 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 practice at your institution 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?**
A stipend of $50 will be given to you if and when you participate in a focus group session at the end of the 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 practice at your institution as 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. Contact 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 at 415-476-1814.

**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.

If you wish to participate in this study, you should sign below.

| | |
|---|---|
| _____ | _____ |
| Date | Participant's Signature for Consent |
| _____ | _____ |
| Date | Person Obtaining Consent |