UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	The FIRE Trial: Reducing patient memory recall in the burning mouth patient population
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Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study here is being conducted to test the effectiveness of a phone app and/or text-based notifications at collecting real-time data, such as pain symptoms, in burning mouth syndrome patients. If you agree to join the study, you will be asked to complete questionnaires during the in-person visits and download an app onto your smartphone and/or provide your phone number to receive text reminders. Your participation will last for about 12 weeks and is voluntary.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you have had a diagnosis of burning mouth syndrome for more than 3 months. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or your Oral Medicine specialist. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study.

What is the purpose of this research study?

Burning mouth syndrome is not well understood, and the daily impact of this condition on this population has yet to be examined.

The purpose of this study is to collect real-time data, such as pain symptoms and exercise habits, to investigate the factors that influence burning mouth symptoms. You have been invited to take part in this study because you have been diagnosed with burning mouth syndrome and have been under the care of an Oral Medicine specialist.

How many other people will be in the study and how long will I be in the study?

This study will enroll a total of 50 participants.

If you agree to enroll, we will ask you to participate in two in-person visits and ask you to respond to daily surveys over the course of 12 weeks.

What am I being asked to do?

Screening/Baseline Visit (Visit 1):

- We will determine whether or not you are eligible to participate in the study.
- You will be asked to read and sign this informed consent form. An electronic version of the informed consent form can also be made available to you to review the document thoroughly at your own pace in the privacy of your own home).
- We will collect demographic information and review your medical history.
- We will help you download the app onto your smartphone or set you up to receive text reminders to fill out a web-based survey. By signing and agreeing to the consent form, you agree to receive text messages with the ability to opt-out (message and data rates may apply). Together, we will go over how to use the app, and/or receive text notifications, take online surveys, and answer any additional questions.
- We will ask you to complete a series of questionnaires.
- We will collect a sample of your saliva for banking for future analysis.

12 weeks study time period:

- You will receive up to three, random daily notifications from your smartphone to answer a series of questions. In total, the questions in the survey will take approximately less than 1 minute to answer.

Final Visit (Visit 2):

The final visit will occur approximately 12 weeks after Visit 1.

- We will ask you to complete an exit survey and questionnaires.
- We will collect a sample of your saliva for banking for future analysis

What are the possible risks or discomforts?

Questionnaires and Social History: There are minimal risks associated with completing questionnaires. You may feel emotional distress when answering questions about your health condition and daily activities, if you find these topics distressing. There is also the risk of negative effects socially and professionally if the responses to these questions are made public. To help prevent this risk, all information collected in this study will be held to high confidentiality standards.

There are minimal risks associated with the saliva collection. However, this procedure may be inconvenient or unpleasant for you to complete.

Confidentiality: As with all research studies, there is a potential for a breach of confidentiality as a result of unintended release of research records. Any breach could have negative social or professional effects, given the sensitive nature of some data, including drug and alcohol use.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What may happen to my information and samples collected on this study?

Saliva samples will be used to analyze biomarkers; we plan to perform future analyses with other biomarkers and will bank the saliva for future analyses. Samples collected as part of the study will be coded. The sample will be assigned a unique identifier that is separately linked to your record.

Collection of Identifiable Specimens

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens

Your identifiable (coded) information and samples will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study.

The following identifiers will be retained with your information and samples: only the unique code will accompany data/specimens during storage and sharing. Your information and samples may be stored and used for future research purposes for an indefinite amount of time. There are no plans to tell you about any of the specific research that will be done. We may share your identifiable information and samples with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies.

We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by coding information and samples.

You will likely not directly benefit from future research with your information and samples. Research with your identifiable information and samples may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information and samples, or have changed your mind, you can contact Dr. Eugene Ko at 215-573-5441. If you change your mind, should you wish to withdraw their samples from the biobank, you will be instructed to contact the corresponding PI in writing (either through mail or email). Any data already generated from use of the stored sample will be retained, but no future tests will be performed on the sample. The sample will be discarded according to the laboratory's policies and procedures and will be recorded as such in the laboratory records.

What are the possible benefits of the study?

Except for a more frequent monitoring of your pain symptoms, there is no direct benefit expected from participation in this study. However, it is hoped that the knowledge gained will help us to better understand burning mouth syndrome, and lead to future interventional studies.

What other choices do I have if I do not participate?

Participation in this research study is voluntary, and you do not have to participate to receive ongoing care for your condition from your Oral Medicine specialist. If you choose not to participate in this study, your Oral Medicine specialist will continue to manage your burning mouth symptoms.

Will I have to pay for anything?

You will not be charged for any study-related procedures during your participation in this study

What happens if I am injured from being in the study?

We recommend participants exercise judgment in safety when answering survey questions on your smartphone. For example, filling out a survey while driving is not safe. The notifications are reminders for you to take the survey within a reasonable time, and do not necessarily mean you must answer the survey immediately. There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form. If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

Will I be paid for being in this study?

Visit 1: Participants who attend will be compensated $25, including participants who are found not to be eligible.

12-week study period: If you are eligible for the study, you will be compensated for your time at a rate of $10 for every week that you respond to at least 50% of the app prompts. For example, for four weeks, the maximum amount you can be compensated if you respond to at least 50% of app prompts can be $40. If you respond to at least 50% of the app prompts for all 12 weeks will receive an additional $20 compensation (a maximum of $140 total during the 12 weeks).

Visit 2: Participants who attend Visit 2 will be compensated $25.

Table 1. Summary of compensation

Visit 1	$25
Week 1	$10
Week 2	$10
Week 3	$10
Week 4	$10
Week 5	$10
Week 6	$10
Week 7	$10
Week 8	$10
Week 9	$10
Week 10	$10
Week 11	$10
Week 12	$10
If you respond to 50% of the app prompts for all 12 weeks	$20
Visit 2	$25

Total maximum compensation for full participation in the study is $190.

Your compensation will be given to you via a Greenphire ClinCard, this is a reloadable pre-paid card. We will give you separate instructions on how to use the card. Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by the Principal Investigator, without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. However, we may continue to collect information from your medical records unless you specifically withdraw authorization as noted below.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be 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. All data collected during this study will be kept in a password-protected, electronic database. This database is only accessible to personnel who directly work on this study.

For this study we may need to contact you via text message or email to provide you information about scheduling, appointment notes or to send you information about your participation in the study. Text message and email communications are often not secure and may be seen by others as a result. By signing below, you accept this risk. If you wish for us to use a different means to communicate with you during the course of this trial, please discuss this with the research team and alternative methods can be arranged. If you are unable to attend a study visit for safety reasons, study staff may call to collect study data or send questionnaires to be completed.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that

require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team.

Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Will I receive the results of research testing that may be relevant to my health?

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?

The following information will be used or shared in connection with this study:

- Name, address, telephone number, date of birth
- Social Security number
- Medical, family, and social history
- Results from physical examinations, tests or procedures
- Information in your medical record regarding medications and treatment

Why is my information being used?

Your information is used by the research team to contact you during the study.
Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- see if the research was done right
- evaluate and manage research functions

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- Other authorized personnel at Penn Dental and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Who, outside of the School of Dental Medicine, might receive my information?

Collaborators within the University of Pennsylvania

Oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections
- The Office of Biotechnology Activities and their committees overseeing gene therapy research
- The study data and safety monitoring board

Once your personal health information is disclosed to others outside the School of Dental Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Dental Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Dental Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study. You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By signing this document you are permitting Penn Dental and the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study. By signing and agreeing to the consent form, you also agree to receive text messages with the ability to opt-out (message and data rates may apply).

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date