

**Title of your research project**

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**Principal Investigator:** *Include name and degree(s)*

**Co-Investigators:** *Include name(s) and degree(s)*

**Study Location:** Tufts University School of Dental Medicine

One Kneeland Street

Boston, MA 02111

**Sponsor:** *If applicable*

**Protocol Version Date:** *Date of Most Recent Revisions*

1. Introduction
   1. Aim/Hypothesis/Objective

*“The objective of this study is to . . .”*

*Clearly state the aim/hypothesis of the study.*

*List and number if there are several (there should be a primary aim/hypothesis and then you may include secondary as well).*

1. Background and Rationale

*Give a brief overview of background information, justification, rationalization, and/or proposal for this study.*

*Use facts, events, and thought processes to connect this section with the aim of the research plan.*

*Support your hypothesis, how this research is going to advance or improve you area of study.*

*Cite sources (list at end of this document in section O).*

1. Research Plan
   1. Experimental Design

*Describe the type of study you are proposing (e.g., randomized controlled trial, blinded, single center, etc.).*

* 1. Sample Size and Statistical Analysis

Sample size

*State the number of subjects needed to be treated in each group to allow for testing for statistical significance. Also, state the number of subjects needed to allow for approximately 15-20% dropout. Cite references that you get your data from for the sample size calculation.*

Statistical analysis

*Describe the statistical methods to be used to test each hypothesis.*

Randomization

*State your randomization plan. Will a computerized randomization scheme be generated? You may need to speak to the statistician about this.*

Blinding

*Who will be blinded (e.g., investigator, subject, both)? How will they be kept blind? Who is responsible for the code? What are the procedures/circumstances for breaking it?*

* 1. Products

*Include any products you are specifically using for this study. State if their use in the study is what they are approved for. Include FDA approval information.*

*If applicable, identify investigational product(s) and control.*

*Include dose and mode of administration for each product.*

|  |  |  |
| --- | --- | --- |
| **Example of Product Descriptions** | | |
| Group | Product 1 | Product 2 |
| Experimental | Description, Manufacturer, etc. . . | Description, Manufacturer, etc. . . |
| Control | Description, Manufacturer, etc. . . | Description, Manufacturer, etc. . . |

* 1. Subject Characteristics
     1. Inclusion Criteria

*List the optimal qualities of a subject*

*Qualities of the diagnosis/study topic*

Sample Language:

At least 18 years of age

* + 1. Exclusion Criteria

*What qualities would prevent a subject from being included?*

*Stages of the diagnosis/study topic that would not be included*

Sample Language:

Subjects who are currently pregnant *(self-reported? Or will a pregnancy test be done?)*

*Non-English speaking subjects (please note: Study related information must be given to a subject or their legally authorized representative in a language understandable to them. The IRB strongly recommends that non-English speakers are not excluded for participated in for benefit studies, and lack of funds is not considered a sufficient rationale for excluding this subject population.)*

* + 1. Subject Withdrawal/Termination Criteria

*Circumstances in which a subject would be withdrawn, would remove themselves from the study, or would be terminated*

*Are subjects allowed to participate in another research study at the same time? Or would this be a reason from termination from your study?*

Sample Language:

Subjects who do not comply with the study procedures, such as…*(Fill in examples)* may be withdrawn from the study.

The study team may terminate subjects if they no longer fulfill inclusion criteria, if an exclusion criterion is met, or if they do not show up for scheduled study visits.

Subjects who experience an unanticipated adverse drug effect will be withdrawn from the study.

Subjects may withdraw from the study at any time.

Subjects may remain patients of TUSDM if they decide to withdraw from the study or are withdrawn by the study team.

Sample language:

The Principal Investigator will determine whether subjects (either withdrawn subjects or subjects completing the study) are in need of additional treatment and/or follow-up observation as a result of participation in this trial. Additional treatment may be needed if (*note circumstances).* Subjects and/or their insurance will be responsible for the cost of any standard of care follow-up visits or additional treatment that is not part of this study.

* 1. Assessment
     1. Risk

*Describe any possible risk, discomforts, or unease that participants might experience, including physical, psychological, social, and economic. State any risks for each procedure and each product used. State whether risk if standard to the procedure or if there are additional risks for participating in the study. Include the risk of loss of confidentiality.*

Sample Language:

There is the risk of loss of confidentiality to the subject by participating in this study. This risk will be kept to a minimum by following procedures listed under confidentiality section.

* + 1. Benefits

*Describe the benefits to the participant.*

*These are not monetary benefits; stipends for participation should be listed separately (section G-7)*

Sample Language:

*If there is no specific benefit to the subject, you may state:* There is no direct medical benefit to the subject for participation in this study.

* + 1. Alternatives

*What would be the alternative procedure for the patient? List if any.*

*What is the current standard of care at TUSDM for this situation?*

Sample language:

Patients may choose not to participate in the study and to receive the standard of care treatment for *(indication)* at TUSDM at normal clinic fees.

* 1. Study Procedures

*Clearly indicate which procedures are standard of care, which are for research purposes only, and which procedures are standard of care but providing data for the research study.*

*List by visit- specifying the timeframe in between each*

*Specific methods/techniques/materials*

*Laboratory tests, radiographs, etc.*

*Purpose of, amount, and timing of each test.*

*Subject timeline (Table 1 below)*

*Describe specifically what will happen at each visit*

*It is not necessary, but it might be helpful to create a table listing appointment intervals and procedures and length of time for each part*

*Visit 1 (How long will it take?):*

*Clearly outline what will happen at Visit 1. Clearly indicate what procedures are standard of care at TUSDM and which are not. Be very specific about what will occur to the subject.*

Sample language:

The subjects will be asked to read the informed consent form (ICF). Subjects will be given ample time to have any questions answered. If a subject decides to participate, he or she will be asked to sign the ICF. A copy of the ICF will be given to the subject.

Subject will be asked to complete demographic information and a medical history.

An oral exam, including evaluation of oral cavity, soft and hard tissues, will be completed following standard of care procedures in US dentistry using a mouth mirror and dental explorer.

Inclusion/exclusion criteria will be evaluated and eligibility for the study will be determined.

*Visit 2 (if applicable) (How long will it take? How soon can it be after Visit 1?):*

*Clearly state how long after Visit 1 this visit can happen, allowing a window for scheduling. Clearly outline what will happen at Visit 2. Clearly indicate what procedures are standard of care at TUSDM and which are not. Be very specific about what will occur to the subject.*

Sample language:

Medical history will be reviewed and any changes will be noted.

Eligibility and subject withdrawal criteria will be reviewed to ensure the subject still qualifies for the study.

*Visit 3 (if applicable) (How long will it take? How soon can it be after Visit 2?):*

*Clearly state how long after Visit 2 this visit can happen allowing a window for scheduling. Clearly outline what will happen at Visit 3. Clearly indicate what procedures are standard of care and which are not. Be very specific about what will occur to the subject.*

*Visit 4 (if applicable) (How long will it take? How soon can it be after Visit 3?):*

*Clearly state how long after Visit 3 this visit can happen allowing a window for scheduling. Clearly outline what will happen at Visit 4. Clearly indicate what procedures are standard of care at TUSDM and which are not. Be very specific about what will occur to the subject.*

*Include as many visits as needed.*

*Table 1. Subject Timeline (example, fill in all of your procedures)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Example of Subject timeline** | | | | |
| Appointment  Procedures | Visit 1 | Visit 2 | Visit 3 | Visit 4 |
| Informed Consent Form | X |  |  |  |
| Demographics | X |  |  |  |
| Medical History | X | X | X | X |
| Evaluate eligibility and withdrawal criteria | X | X | X | X |
| Oral Mucosal Tissue Examination | X | X | X | X |
| X Assessment |  |  |  |  |
| X Procedure |  |  |  |  |
| X Treatment |  |  |  |  |
| Adverse Event Assessment |  | X | X | X |
| Stipend | X | X | X | X |

* 1. Subject Safety

Sample language:

* + 1. Adverse Event Reporting

Adverse Events

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal physical exam or laboratory finding, symptom, or disease, temporally associated with a subject’s participation in the research.

Adverse events will be recorded in source documents and on case report forms. All adverse events and non-serious situations will be recorded, monitored, and reported to the IRB at time of continuing review or at the study’s termination if this occurs before the study’s next continuing review.

Serious Adverse Events

A serious adverse event is one that results in death, or is life-threatening, or results in hospitalization or prolongation of existing hospitalization, or results in a persistent or significant disability/incapacitation, or results in a congenital anomaly/birth defect, or may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed above.

Serious adverse events will be recorded in source documents and on case report forms. Serious Adverse Events that meet the criteria of an unanticipated problem will be reported to the IRB within 5 business days following the Reportable New Information Policy. Serious Adverse Events not meeting the criteria for an unanticipated problem will be reported to the IRB at time of continuing review or at the study’s termination if this occurs before the study’s next continuing review.

Unanticipated Problems

An unanticipated problem is an incident, experience, or outcome that meets all of the following criteria: 1) The nature, severity, or frequency is unexpected for the subject population or research activities as described in the current IRB approved protocol, supporting documents, and the ICF(s); 2) it is related or possibly related to participation in the research; 3) it suggests the research may place the subject or others at a greater risk of harm then was previously recognized.

Unanticipated problems will be recorded in source documents and on case report forms. Unanticipated problems will be reported to the IRB within 5 business days after the PI/study team becomes aware of the problem. A Reportable New Information Form will be submitted to the IRB no later than 5 business days after the PI/study team becomes aware of the problem.

Unanticipated Adverse Device Effects (UADEs)

Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

UADEs will be documented in source documents and on case report forms as to onset, severity, duration, management, outcome and relatedness to the test device. UADEs will be reported to the IRB within 5 business days after learning of the effect.

* 1. Subject Participation
     1. Screening

Sample language:

The *PI/CO-I (list who)* will conduct screening examinations to identify subjects who meet the inclusion / exclusion criteria for enrollment into the study.

* + 1. Informed Consent

Sample language:

*PI or his/her* representative will introduce the study.

Consenting will take place in a private clinic bay area and the patient will be given as much time as he/she needs to consider participation. The participant will be invited to include or exclude any associates (e.g., loved ones) in the consent process.

Patients will be asked to read the consent form and given ample opportunity to have their questions answered. To avoid coercion, the consenting investigator will read through the copy of the consent form with the participant section by section, making sure the participant understands each section and has an opportunity to ask questions. If at any time the participant indicates s/he is not interested in participation, the meeting will end.

If after going through the consent form, the participant indicates s/he would like to discuss the study with associates or think about participating, then the meeting will be ended and the participant will be asked to contact the study when s/he makes her decision. If the participant contacts the study in the future for participation, s/he will be invited back to the clinic, and if informed consent is given at that time, study activities will begin then.

If the participant indicates s/he may be interested in participating after going through the consent form with the investigator, and the investigator determines the participant has the capacity to provide informed consent, the participant will be asked to provide informed consent at that time. Written consent will be obtained following “SOP: Written Documentation of Consent (HRP-091).” Patients will certify their willingness to participate in the study by signing and dating the IRB approved informed consent document. The subject will be given a copy of the consent form.

If any new finding requires any change to the informed consent form, the subject will be reconsented.

If excluding non-English speaking subjects:

*Non-English speaking subjects will not be enrolled in the study because study staff at this time are not certified, prepared, or trained to translate or communicate in any language other than English. The study budget does not allow for the payment of translation services at this time. There are no direct benefits to this population by participating in this study.*

* + 1. Study Location

Sample language:

Tufts University School of Dental Medicine

* + 1. Personnel

*List out who specifically will do each procedure – who will obtain consent, who will do the screenings, who will do the procedures, who will maintain the paperwork, each study procedure.*

Sample language:

Ongoing communication with the IRB *(AND sponsor if applicable)* – The PI

Obtaining Informed Consent – The PI or his/her representative

* + 1. Payment for Participation
       1. Compensation

*Amount of subject stipend, when they will receive it. If it is in gift cards, give amount of each gift card and specify where they will be from (e.g., Target, Amazon, etc.).*

* + - 1. Transportation

*Travel reimbursement and transportation costs.*

Sample language:

*If none will be given, state:* No travel reimbursement or transportation costs will be paid.

* + - 1. Payment and Insurance

*Will insurance be billed, if they don’t pay who is responsible?*

*Only routinely performed care are billable to insurance, test performed for research purposes only are not.*

*List the exact cost in the TUSDM clinic for each procedure (even if it is not being billed).*

Sample language:

*If the subject or insurance will not be billed, state:* Neither the subject, nor their insurance company, will be billed for any study procedures.

* + - 1. Provision for Care in Case of Accident or Injury *(if applicable)*

Sample language

In the unlikely event that a study patient becomes ill or is injured as a result of participating in this study and medical care is necessary, such medical care will be provided by a physician chosen by the patient. In the event of a research-related injury, compensation will be determined on a case-by-case basis by *(entity).*

* + 1. Study Results

Sample language:

If interested, study results will be presented to a subject upon their request, either in person or via mail according to their preference, upon completion of the study. A log will be kept of the participants who are interested in receiving study results.

* + 1. Confidentiality

*Describe how confidentiality will be maintained for all study participants, including how identifiable information will be coded, where data will be stored, and who will have access to it.*

*If data will be retained for subjects that are determined to be ineligible, specify how privacy and confidentiality of these potential subjects will be maintained.*

Sample language:

To ensure confidentiality of subject information, each subject enrolled in the study will be assigned a unique alphanumeric code. Subjects’ files will be kept in a secure, locked cabinet in a secure room (*PI’s office*) when the files are not being reviewed. The information will only be shared between the researchers. All HIPAA requirements will be followed. All electronic files will be kept on a password protected computer in a secure, locked office.

* + - 1. Coding

Sample language:

Each will be assigned a subject identification number. Alphanumeric identification numbers will be assigned sequentially. The full subject identification number will consist of the three letters from the subject’s initials and their enrollment number. This will be accessible by study personnel only.

* + - 1. Access

Sample language:

Only study personnel will have access to data. Investigators will permit monitoring, audits, and regulatory inspections and will provide direct access to study related documentation.

* + 1. Data Safety Monitoring Plan:

Sample language:

Study personnel will monitor this trial for all safety related issues to determine whether an unreasonable risk to subjects develops. Quality control measures include routine inspection of case report forms, source documents, data tabulations, and tracking of adverse events.

* + 1. New Findings

Sample language:

The subject will be informed of any significant new findings discovered during the course of this study that might influence the subject’s continuation and participation in the study. Subjects will be told at a study appointment or via telephone of new findings during the study.

*Cost of treatment for any new findings will not be covered by the study.*

If new findings require revisions to the ICF, the subject will be re-consented.

* 1. Collaboration

*If working with another institution, explain the collaboration and attach a copy of their current IRB protocol, consent form, and approval letter.*

* 1. Record Retention

Sample language:

* + 1. Study Records

The Principal Investigator will maintain all study records and documents during the study period. All paper files and documents will be kept in a locked file cabinet, within a locked room *(PI’s Office)*.

*For electronic records, we suggest using Tufts BOX, which is HIPAA compliant, and data would only be accessible to study team members.*

* + 1. Long Term Retention

The investigator will maintain all study records following completion or termination of this study in accordance to state law and institutional policy (at least 7 years after the study is completed or terminated).

* 1. Reporting

Sample language:

Unanticipated problems and adverse events will be reported per the Tufts MC/TUHS IRB Reportable New Information Policy.

The IRB will be notified of any deviations from the protocol in cases of medical emergencies when the change is necessary to eliminate an apparent immediate hazard to the subject

Progress reports on the investigation shall be submitted to the IRB at regular intervals, but in no event less often than yearly, e.g., at continuing review.

* 1. Protocol Deviations

Sample language:

No protocol changes or deviations will be made without prior agreement by the IRB *(AND STUDY SPONSOR, IF STUDY HAS ONE)* unless implemented to prevent an immediate hazard to subjects. All other protocol changes or deviations will be made by a formal amendment subject to IRB approval. All such changes or deviations will be reported to the IRB as they occur and included in the final study report.

* 1. Study Termination

Sample language:

This study may be terminated for the following reasons:

Discovery of unforeseen risk that could jeopardize the dental/physical well-being of subjects.

Enrollment or recall rates that are not likely to produce sufficient data for evaluation of safety and efficacy

Non-compliance with the clinical investigational plan, the Investigator

Agreement, applicable FDA regulations or conditions of approval imposed by the reviewing IRB

Withdrawal of IRB approval

In the event of study termination, the Principal Investigator will determine whether subjects are in need of additional treatment and/or follow-up observation as a result of participation in this trial.

* 1. Subject Recruitment/Advertising

*List out exactly how you will recruit subjects and will advertise. Below are some examples. All recruitment/advertising material must be submitted to the IRB. Dental Research Administration will assist with creating advertising, email text, screening language, etc.*

*For potential subjects who answer advertisements, specify if subject information will be collected and recorded during these calls (e.g. name, telephone number, any screening criteria, etc.).*

Sample language:

Paper flyers will be posted throughout TUSDM. Permission is not required for these posting locations. Flyers will remain posted until enrollment goals are met. Subjects will be recruited through responding to posted study advertisements. These posted advertisements will be visible to faculty, staff, students, and patients.

Investigators may also inform clinic patients about the study.

Investigators may send messages to colleagues via axiUm asking for their help in recruiting eligible subjects.

Likewise, e-mails and/or newsletters that alert the TUSDM community to ongoing studies may include information on this study for recruiting purposes.

Forms of electronic media such as twitter, university websites, facebook etc. may also be used to recruit.

All of the forms of recruitment will be submitted for IRB approval prior to use.

A screening interview/questionnaire or screening script will be used for recruitment.

Screen failure data will be retained by PI. Screening ID number and demographic information will be recorded. Identifiable information will not be recorded in the screening log.

* 1. References/Bibliography

*List references here in a consistent and appropriate style (e.g., MLA, APA, etc.)*

* 1. Appendix

*Attach templates of any medical history, questionnaires, diaries, product information, directions for use, etc.*