

 **Title of your research project**

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Principal Investigator: List name and degree (students may not be PI)

Co-Investigator(s): List names and degrees, include your statistician

Tufts University School of Dental Medicine
1 Kneeland St.
Boston, MA 02111

Date:

1. **Introduction**

Provide a concise and objective introduction (2-3 paragraphs). Give background information regarding your study; include information regarding other studies as applicable. Only include information pertaining directly to the study. Cite your references.

1. **Research Aims/Hypothesis**

Clearly state the aim/hypothesis of the study. If there are several, list and number them.

1. **Significance**

State the significance of the study. State how your survey results will be significant to the appropriate population (e.g., faculty, students, patients).

1. **Materials and Methods**

Explain in detail how your research will be conducted.

We will pre-test the survey questions for validity and reliability. Pre-Testing Methodology for survey is presented below:

Content Validity: To test for content validity, three to five XXX (who have experience XXX) will be given the same surveys. Each XXX will be given the opportunity to rate each question individually using the five point Likert scale (1=very important, 2=important, 3=moderately important, 4=of little importance, and 5=not important). In addition, they will be asked to rate whether the questions should be included in the survey (0=no, 1=unsure, 2=yes).

Inclusion Criteria for Content Validity

Exclusion Criteria for Content Validity

Face Validity: To test for face validity, three to five XXX will review the survey to ensure that questions are easily understood, simple, useful and necessary. These individuals will not be asked to complete the questionnaires, but will be asked to offer their opinions on each question. They will be asked whether they were comfortable answering the questions, had any trouble with the questions, and if they have any additional feedback.

Inclusion Criteria for Face Validity

Exclusion Criteria for Face Validity

Where additional comments from the content reviewers are offered, the investigator will manually record those for possible edits in the items.

Test-retest Reliability: Three additional XXX will be given the survey, twice approximately 1 week apart. The results will compare the data for consistency by calculating correlation coefficients.

If any edits are needed for the survey, they will be made and the updated survey will be submitted to the IRB for review prior to the full distribution of the survey.

Survey

State how you will distribute your survey.
State if it is paper based or electronic. If electronic, will you send it out more than once? If so, how many times and how often? Will you use Qualtrics?
State how you will contact possible subjects.
State how many people you will give the survey to.
State what your inclusion/exclusion criteria are.

How long will it take to complete the survey (minutes)?

1. **Recruitment**

State how you will find your subjects.

Will you advertise with flyers? Will you tell people by word of mouth? Will you send an email? Will you tell people at a class?

*Face Validity Recruitment*

*Content Validity Recruitment*

*Survey Recruitment*

*Any recruitment material (flyers, emails, etc.) must be submitted to the IRB along with this protocol. In addition, for surveys an information sheet regarding the study must be given to each participant. Dental Research Administration will help with formatting this information sheet. In many survey studies it can be used instead of an informed consent form.*

1. **Risk**

If no identifying information will be collected you may state, “This study poses minimal risk to subjects as no identifying information will be collected. Risk will be kept to a minimum by following the procedures under section VIII. Confidentiality.”

If you are collecting identifiable information that will later be deleted you may state, “This study poses minimal risk to subjects as identifying information will be removed from the data set once analysis is complete. Risk will be kept to a minimum by following the procedures under section VIII. Confidentiality.”

If you are including students, faculty, or patients use the following appropriate language: “Participation or the refusal to participate will have no effect on a patient’s care/student’s academic standing/faculty’s employment status.”

*Some of this language will be specific to your study; Dental Research Administration will assist with this.*

1. **Location of Research Activities**

Tufts University School of Dental Medicine,
If there will be any other locations, list them here.

1. **Confidentiality**

If you are not collecting identifying information, you may state, “There will be no link between the surveys (answers) and the individual respondents. No identifying information will be collected.”

If you are collecting identifying information (e.g., student ID number in order to link pre- and post-surveys), you must state what data you will collect, how you will store it, and how it will be kept confidential.

*Some of this language will be specific to your study; Dental Research Administration will assist with this.*

1. **Data Storage**

If you have paper documents list where they will be kept. You may use the following language,  *“*Paperwork will be kept in a locked cabinet, in a locked room (DHS-*List room number*).”
If you will have electronic data, it must be kept password protected. You may use the following language, “Electronic data will be kept on a password protected computer.”

1. **Data Analysis**

Put the sample size justification and the statistical analysis that you agreed upon with the statistician in this section.

1. **Vulnerable Populations**

If you are recruiting students or faculty, list that here. If you are including students or faculty, state the following, *“*A letter of support from the Dean of TUSDM is included with this submission.”

*If you are recruiting students or faculty, a Dean’s letter is necessary from the Dean of TUSDM. Dental Research Administration will assist with this.*

1. **References**

References should be in an appropriate style (ex. MLA, APA) and should be placed in the order they occur in the document. All references should be numbered in the document and in this section.

***NOTE:*** If necessary, you may also add sections to your protocol. If you are a UG student, PG student, or MS student, you cannot be the Principal Investigator.