

**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.
2. **Aim and Hypothesis**Clearly state the aim/hypothesis of the study. If there are several, list and number them.
3. **Significance**State the significance of the study. For example, might the results of this study effect what a dental practitioner what treatment they will use in his/her practice? State how your survey results will be significant to the appropriate population (e.g., clinicians, patients, etc.).
4. **Materials and Methods**Explain in detail how your research will be conducted.
State if there will be a query in axiUm by IT or who will supply the data. Include what ADA codes will be included in the query.
State the sample size and be sure to include inclusion/exclusion criteria.

State the number of records that will be reviewed in order to find your sample size.
Include a date for how far back you will look at records (e.g., 1/1/10) and an end date (e.g., 6/30/13) for the records that will be reviewed. The end date must be in the past, you cannot put a future date.
Be specific as to what data you will collect from the charts (e.g., for patients - age, gender, etc.; e.g., for student info – what grades, what course, etc.).

#### ConfidentialityState how data will be kept confidential.

#### For example, “All study data will remain confidential to the fullest extent of the law. All subject records will be maintained under lock and key by the PI and will be available only to the investigators and research staff. All electronic data will be kept on Tufts BOX, which will only be accessible by study team members, and is HIPAA compliant. Electronic data will be password protected and only accessible to study investigators (e.g. Tufts Box). Data will be queried by IT based on the inclusion criteria. According to Dental IT policies, this will be done after the study has received approval from the IRB and the study team has submitted a request for the records with the IRB approval. The study team will then be granted research access to these records for review. A password protected excel spreadsheet including the axiUm record numbers and no other identifiable information will be given to the investigators. Upon the completion of data analysis, the generic account will be disabled and the password will be changed so that study team members will no longer have access.”

#### If you are not collecting any identifying data you may state, ‘No identifying information will be collected.”

#### If you are recording identifying information, include information about how you will code the data and keep it confidential. For example, “Upon review of each record, the record number will be checked off on the spreadsheet and each subject will be assigned a unique numerical identifier in a second electronic spreadsheet with the extracted data, which will allow coding of data for analysis. There will be no link between identifiable information (axiUm record number) and the collected data in the second study data spreadsheet. Upon completion of the study, the electronic spreadsheet with axiUm records numbers will be deleted.”

#### If you have identifying information, will the data that links the study participant to their identifying information be deleted at the end of the study? State if so.

#### If you have paperwork you will be collecting, state what room it will be stored in. “Data will be kept in a locked cabinet, in a locked room (PI’s Office).”

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

#### Vulnerable Populations

If you are specifically 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.*

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

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.