

 **TITLE**

Principal Investigator:
Co-Investigators:

Study Site: Tufts University School of Dental Medicine

One Kneeland Street

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.

How many focus groups will you do?

How many people will be included?

Who will be included?

 Please include list of questions that will be asked.

Please include script.

**Focus Group Overview:**

**Moderator/Assistant:**

**Length:**

**Question Format:**

**Incentives:**

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?

*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 answers and the individual respondents. No identifying information will be collected.”

If you are collecting identifying information (e.g., name), 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**
2. Proffit WR, White RP.: Who needs surgical-orthodontic treatment? Int J Adult Orthodon Orthognath Surg5:81–89, 1990.
3. Hutton, C. E.: Patients’ evaluation of surgical correction of prognathism: Survey of 32 patients, I. Oral Surg. 25:225-228. 1967.
4. Kiyak, H. A., Hohl, T., Sherrick, P., West, R. A.. McNeill, R. W., and Bucher, F.: The psychological impact of orthognathic surgery: A 9-month follow-up, J. Oral Surg. 81:404-412.
5. Eysenck, H. J.: Manual for the Eysenck Personality Inventory, San Diego, 1968, EDITS.
6. Fitts, W. H.: Manual for the Tennessee Department of Mental Health Self-Concept Scale, Nashville, 1965, Tennessee Department of Mental Health.
7. Secord, P. F.. and Jourard, S. M.: The appraisal of body cathexis: Body cathexis and the self, J. Consult. Psychol. 17:343-347, 1953.
8. Eliot & Associates.: Guidelines for Conducting a Focus Group, 2005.