Participant ID:_____

Protocol Title: **Comparison of two routinely used protocols to maintain bone volume after tooth extraction**
Principal Investigator: Eli Machtei
Study Population: Patients seen in the Harvard Dental Center pre-doctoral and resident clinics.
Version Date:7 /22/16

About this consent form

You are being asked to take part in a research study. Please read this form carefully. If you have any questions, ask the researchers at any time. You should not sign this form unless you understand what is written in it and have had your questions answered. You have the right to take your time in making decisions about participating in this research. You may discuss your decision with your family, your friends, your doctor, and/or your dentist. If you decide to participate in this research you will be asked to sign this form. A copy of the signed form will be given to you to keep.

Participation is voluntary

You are invited to take part in this research because you have a tooth which requires removal, you want to have an implant to replace it, and you meet the study's inclusion criteria. It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

What you should know about a research study

- Someone will explain this research study to you.
- A research study is something you volunteer for.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

What is the purpose of this research?

After tooth removal, the bone where the tooth was taken out shrinks. This can be a problem if future dental implants are planned at the removal site. In order to avoid this problem, currently, two surgical options are used. No one knows if one is better than the other so the purpose of this study is to compare these two options to see if one is better.

How many people will take part in this research?

About 30 people will take part in this research.

How long will I take part in this research?

You will be asked to make 5 appointments over approximately 5 months. Depending on the nature of the visit, each appointment can last 15 min to 3 hours.

What can I expect if I take part in this research?

Study procedures and schedule are listed below. All procedures and exams are normal practice at the Harvard School of Dental Medicine (HSDM) and you would receive them even if you weren't in the study with the following exceptions (done for our research purposes only):

- Signing the Research Informed Consent Form at visit #1 or before.
- Dental CT scan at visit #2.
- Getting measurements taken of your gums with a small ruler, a small measuring device that goes around your teeth, and a very thin needle and rubber stopper. You will be numb during this measurement at visits #2 and #5.

Receiving the tooth extraction and bone preservation surgery at visit #2. This will involve getting numb with local anesthetic (medication applied to numb your gums and teeth), having the tooth removed, getting a bone graft (material placed to help grow bone) and membrane (a covering that helps with healing) placed into the socket, and getting sutures (stitches) to close up the gums.

- Attending a six week post-surgery follow-up exam where we will look in your mouth to make sure you are healing normally at visit #4.
- Getting an additional impression taken of your mouth at visit #5.

Study Visits

Visit #1 Baseline Exam | 1-2 hours

At the first study visit, you will have a consent discussion with the researchers who will answer any questions that you have. If you would like to participate, you will be asked to sign this form. Then you will receive teeth cleaning instruction and measurements will be taken of your teeth and gums with a small ruler. Photos of your mouth, X-rays and CT scans will be taken. Impression of your teeth will also be taken.

Visit #2 Tooth Removal Surgery | 2-3 hours

You will randomly be assigned to one of the two treatment groups. Assigning groups in this way is like tossing a coin (50/50 chance) to determine who will be in which group. Both treatments are routinely used: one is not known to be better than the other. Measurements of your teeth, gums, and bone will be taken with a small ruler before and during surgery. After you are numbed more measurements will be taken with a very thin needle and a small measuring device that goes around your bone. Your tooth will be removed, the area will be grafted with bone and stiches will be placed. You will be given verbal and written instructions on how to care for your mouth after the surgery.

Please note: An implant will NOT be placed at this visit.

Visit #3 Follow Up Exam | 15-20 min

Two weeks after your tooth removal surgery, we will look at the place where your tooth was removed ask you if you have had any side effects. If there are stiches, they will be removed.

Visit #4 Follow Up Exam | 15-20 min

Six weeks after your tooth removal surgery, we will look at the place where your tooth was removed ask you if you have had any side effects.

Visit #5 Implant Placement at HSDM | 2-3 hours

Four months after your tooth removal surgery, we will take more measurements (of your teeth, gums and bones in your mouth) and impressions of your mouth. X-rays and CT scan will be done as would happen if you were not in the study. Your dentist will place the implant at this time.

What are my responsibilities?

As a participant, you are responsible for attending all visits and informing study investigators if any questions, concerns, or symptoms arise. You may stop being in the study at any time and will be referred to your usual treating dentist for any needed follow-up.

What are the risks and possible discomforts?

Risks and discomforts of the tooth removal surgery are the same as with any type of dental surgery and would be similar to what you might experience if you were to receive this surgery outside of this research project. They include:

- Swelling of your face and gums
- Bruising of your skin at the area of tooth removal
- Discomfort at the surgery site
- Minor bleeding from the tooth removal site
- During tooth extraction, infection, communication with sinuses (upper teeth) and nerve injury (lower teeth) are rare occurrences that pose a minimal risk of surgery.

Inconveniences or discomfort caused from research activities (that you would not experience if you were to have the surgery done outside of this research project) include:

- Gum pocket measurements may produce mild discomfort as a small ruler is placed into gum pockets.
- Taking dental impressions can be slightly but temporarily uncomfortable.
- The inconvenience in attending the additional six week post-operative visit.
- Due to the collection of identifiable data, a breach in confidentiality is a possible but minimal risk.
- An additional CT scan is also a foreseeable inconvenience and as with all CT scans
    - This additional scan is not commonly done in private practice but can be normal practice at HSDM depending on the specific case.
    - This scan will be required for participation in this study and will not exceed the one additional CT scan.
    - The additional x-ray exposure will be minimal. The expected radiation exposure from the additional CT scan is 0.15 millisieverts; in comparison, the annual average natural background radiation to an individual in the US is 6.2 millisieverts per year.
    - If you are pregnant, we discourage you from participating in this study.

Are there any benefits from being in this research study?

You are likely to benefit from this study regardless of which group you will be assigned to. Both treatment options are likely to yield positive and significant results. You would experience similar procedures and outcomes as you would if you had the same treatment done outside of this study.

What are my alternatives to participating in this research?

You can choose to undergo treatment for tooth removal with or without implant placement with your dentist without participating in this study.

Can I still get dental care at Harvard if I choose not to participate in this research*?*

Yes, you may still get dental care at HSDM if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your dental care will not be affected. If you would like to stop participating

in this research you should let us know. We will make sure that you stop the study safely. It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Will I be compensated for participating in this research?

You will not be compensated for participating in this research.

What will I have to pay for if I participate in this research?

There are no additional study related expenses other than what you (or your insurance) would pay for the standard of care. The cost will be charged (and possibly billed to insurance) as any other normal procedures at the dental clinic.

Costs that you may incur during the study

i) Transportation costs (i.e. parking, gas, public transportation)
ii) The tooth extraction will be charged as is usual in normal dental care.
iii) The first CT scan will be charged. The second CT scan will be done for free. The cost of at least one CT scan is generally charged in normal (non-research) care.

You will receive the following for free (which are normally charged as part of standard dental care)

i) Socket preservation surgery
ii) Bone graft material
iii) Collagen membrane
iv) Additional X-rays

Implants are not included in this study nor are they provided by this study. Their placement should be discussed and done with your dentist.

What happens if I am injured as a result of participating in this research study?

If physical injury resulting from participation in this research should occur, although Harvard's policy is not to provide compensation, medical treatment will be available including first aid, emergency treatment and follow-up care as needed, and your insurance carrier may be billed for the cost of such treatment. In making such medical treatment available, or providing it, the persons conducting this research project are not admitting that your injury was their fault.

Can my taking part in the research end early?

You may decide not to continue in the research at any time without it being held against you. The researchers can remove you from the research at any time without your approval for any reason. Should you be removed or decide to stop participation, remaining procedures and follow-up should be done with your usual dentist.

If I take part in this research, what happens to the information you collect?

Every reasonable effort will be made to keep all of your research information confidential. Your identifiable data will not be released to other parties without your consent. Any research data released or published will not identify you.

However, data collected, including your identifiable information, may be seen by the Harvard Institutional Review Board (IRB) that oversees the research and/or the Quality Improvement Program.

If I have any questions, concerns or complaints about this research study, who can I talk to?

The Principal Investigators of this study: Eli Machtei, DMD (617) 319-2283 and David Kim, DDS (617) 319-5440

- If you have questions, concerns, or complaints,
- If you would like to talk to the research team,
- If you think the research has hurt you, or
- If you wish to withdraw from the study.

This research has been reviewed by a Harvard Longwood Medical Area Institutional Review Board (Harvard Faculty of Medicine or Harvard T.H. Chan School of Public Health). If you wish to speak with someone from the IRB, please contact the Office of Human Research Administration (OHRA) at 617-432-2157 (or toll-free at 1-866-606-0573) or 90 Smith Street, Boston, Massachusetts 02120 for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Authorization to Use and/or Share Your Protected Health Information (PHI)

Federal law requires Harvard to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as "health information."

The health information that we may use or disclose for this research includes your demographics, health condition and medications, smoking status and dental record (such as missing teeth, gum condition, jaw bone condition, x-rays of the implants). Dental x-rays and CT scans will be taken before the socket preservation surgery and 4 months after the surgery.

If you decide to take part in this research study, your health information may be used within Harvard researchers and dental staff and may be shared with others outside of Harvard.

- **Health information about you that might be used or shared during this research**
- **Information from your hospital/clinic records within this institution or elsewhere, that may be reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside this institution, you will be asked to give permission for these records to be sent to researcher(s) conducting this study.**
    - New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- **Why health information about you might be used or shared with others**
  The reasons we might use or share your health information are:
  - To do the research described above
  - To make sure we do the research according to certain standards – standards set by ethics and law, and by quality groups

- For public health and safety – for example, if we learn new health information that could mean harm to you or others, we may need to report this to a public health or a public safety authority
- For treatment, payment, or health card operations

- **People and groups that may use or share your health information**

1.People or groups within this institution

- Researchers and the staff involved in this research study
- Harvard review board that oversees the research
- Staff within this institution who need the information to do their jobs (such as billing, or for overseeing quality of care or research)

2.People or groups outside the institution

- People or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers
- Federal and state agencies such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protection, and other U.S. or foreign government bodies, if required by law or involved in overseeing the research
- Organizations that made sure hospital/clinic standards are met
- The sponsor of the research study, Valeant Pharmaceuticals North America LLC, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study
- A group that oversees the data (study information) and safety of this research study

- **Time period during which your health information might be used or shared with others**
  Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your Privacy Rights

- You have the right <u>not</u> to sign this form permitting us to use and share your private information for research. If you <u>do not</u> sign this form you cannot take part in this research study. This is because we need the private information of everyone who takes part.

- You have the right to withdraw your permission for us to use or share your private information for this research study. If you would like to withdraw your permission, you must notify the person in charge of this research study in writing.

- If you withdraw your permission, we will not be able to take back any information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.

- If you withdraw your permission you cannot continue to take part in this research study.

- You have the right to see and get a copy of your private information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study.

SIGNATURE

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

Your signature below indicates your permission to take part in this research and to the use and disclosure of your protected health information:

Printed Name of participant	
Signature of participant	Date
Printed name of person obtaining consent	

Signature of person obtaining consent	Date