Research Study Summary for Potential Subjects

The research study is being conducted to learn how patients who undergo **routine standard of care dental implant surgery** respond to the approved over-the-counter pain-relieving drugs naproxen sodium (Aleve®) and acetaminophen (Extra Strength Tylenol®). Both of these drugs are currently recommended by dental implant surgeons to control pain after implant surgery and are therefore available to patients who do not participate in this study. In addition to studying how well each drug works, we are also looking for substances in blood, urine and the fluid between your teeth and gums, called gingival crevicular fluid (GCF), that may correlate to how well the drug works for you.

If you agree to join the study, you will be asked to complete the following research procedures:

- On the day of your surgery, you will need to arrive at the Dental School at least 45 minutes before surgery to answer some questions regarding your health and any medications you are taking and the collection of blood, urine and GCF samples for research purposes. You will need to remain at the Dental School for at least 6 hours after surgery for collecting these samples and for frequent pain ratings. So your total time at spent at the Dental School between the surgery and research procedures will be 7 to 8 hours.
- You will take naproxen sodium, 440 mg (2 Aleve's®), or acetaminophen, 1000 mg (2 Extra Strength Tylenol®), right after surgery. Your chances of getting one or the other are equal. We won't know and you won't know what you get. **You could be recommended and buy either of these pain relievers without participating in the study.**
- During the 6 hours after surgery, you will be asked to give frequent pain-ratings (on a scale of 0-10) and we will collect urine, blood and GCF samples
- At home you will continue to take naproxen sodium, 220 mg (one Aleve®), or acetaminophen 1000 mg, as instructed. We won't know and you won't know what you are taking.
- At home you will record pain ratings on the day of surgery and for two days afterwards
- If your pain is not sufficiently relieved you will be allowed to take tramadol, 50 mg, a prescription opioid that we will give you (6 pills). **You could be prescribed this pain reliever without participating in this study. Only take the tramadol if you need it!**
- You will return to the dental school at 24 hours and 72 hours after your surgery for one urine sample, one blood sample and one GCF sample.

Your participation will last for approximately 3 to 5 days. The most common risks of participation are side effects of the pain-reliever drugs. The following are possible side effects of each drug.

- Naproxen sodium: nausea, stomach pain, heartburn, dizziness, rash.
- Acetaminophen: headache, stomach ache, gas. People who take too much acetaminophen (overdose) can injure their liver.
- Tramadol: lightheadedness, dizziness, feeling sleepy, nausea, vomiting, constipation. You cannot drive when on tramadol. Misuse of tramadol can result in addiction and in some cases overdose and death.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Demonstration of OTC Naproxen Sodium's (Aleve's) Anti-inflammatory Action in Dental Implant Surgery Patients
Principal Investigators:	Elliot V. Hersh DMD, MS, PhD Department Oral Surgery/Pharmacology University of Pennsylvania School of Dental Medicine 240 South 40th Street Philadelphia PA 19104-6030 Office Phone: 215-898-9686 Katherine N. Theken PharmD, PhD Department Systems Pharmacology and Translational Therapeutics University of Pennsylvania Perelman School of Medicine Smilow Center for Translational Research 10th Floor 3400 Civic Center Boulevard Philadelphia, PA 19104 Office Phone: 215-573-9592

Coinvestigators:	Jonathan Korostoff, DMD, PhD Department of Periodontics Evans Building, 1st Floor Phone: 215-573-3965 Joseph P. Fiorellini, DMD, DMSc Department of Periodontics Evans Building, 3rd Floor Phone: 215-898-3268 Yu-Cheng Chang, DDS, MS, DMD Department of Periodontics Evans Building, 3rd Floor, East #13 Phone: 215-573-6112 Thomas Yoo DMD Departments of Periodontics and Prosthodontics Evans Building, 1st Floor Phone: 646-532-1500
Emergency Contact:	Stacey Secreto CCRC – Research Coordinator Office Phone: 215-746-8891 Cell Phone: 484-354-4442 **After Hours:** 215-868-7984. Ask for Periodontist on call

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you are an adult who requires the surgical placement of one or two dental implant screws and teeth to replace a tooth or teeth that you lost in either your bottom or top jaw, and we expect you will need some pain relievers after surgery. The surgery is the standard of care that you would be receiving whether you participated in the study or not, and the risks and benefits of the surgery will be explained by your periodontist. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to

do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor and dentist. You may find some of the medical language difficult to understand. Please ask one of the study doctors and/or the research coordinator about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

Patients who have dental implant surgery usually experience some pain that may last for 2 or 3 days after the procedure, and over-the-counter (OTC) pain relievers such as naproxen sodium (Aleve®), acetaminophen (Tylenol® ES) or ibuprofen (Advil®) are usually recommended by their periodontal surgeons. A few people may experience pain that is severe enough to require a prescription opioid such as hydrocodone in Vicodin® or tramadol in Ultram® as well as OTC pain relievers.

The purpose of this study is to compare the effects of OTC naproxen sodium, 440 mg (2 Aleve®), followed by 220 mg once every 8 hours for 3 days to the effects of acetaminophen, 1000 mg (2 Tylenol® Extra Strength), taken three times per day for 3 days. We will evaluate how well the two drugs relieve pain and whether they reduce the amount of substances in your blood, urine and gums (gingiva) near the implants that are known to cause pain. **The drug that you receive will be determined solely by chance and you or your periodontist will not choose what medication you receive.**

How long will I be in the study? How many other people will be in the study?

Your participation in this study will last approximately 3 days. The entire study should be completed in about 18 months. A total of 35 subjects will participate in this study, all being enrolled at the University of Pennsylvania.

What am I being asked to do?

The study is divided into three visits, all at the University of Pennsylvania School of Dental Medicine located at 240 South 40th Street in Philadelphia. You will be invited to participate in the study only if your treating periodontist is a member of the research team who has scheduled you for implant surgery, believes you can safely participate in the study, and has given the research team permission to talk to you either in person during one of your routine periodontal clinic visits or by phone. If you express interest in participating we tell you what the study is about and what is expected of you as a study participant. We will ask you several questions about your overall health, any medication or substance intake (including medically approved or recreational use of marijuana, for example) and your experience (good and bad) with pain relievers. Patients who are smokers or have recently taken marijuana or other recreational drugs will be excluded from the study.

Before you are enrolled in the study, you will be asked to read and sign this informed consent. You will have time to discuss it with family, friends, or other doctors before

signing it, and no research procedures will be done until then.

On the **Day of Surgery (Visit #1)** the following procedures will be performed:

1. **All** females of child-bearing potential will have a urine pregnancy test performed. **The results of this test must be negative for continued study participation. This is done solely for research purposes.**

   In addition, all potential subjects will undergo a urine drug screen for potential drugs of abuse or drugs that can interfere with study results such as codeine (in Tylenol #3), oxycodone (in Percocet), marijuana, benzodiazepines (like Valium), cocaine, other stimulants (amphetamines) or nicotine. **You must test negative for these drugs for continued study participation. This is done solely for research purposes.**
2. We will then stick a needle connected to a catheter (small plastic tube) into a vein in your arm that will be used to collect blood samples immediately before surgery and at multiple points after surgery. These samples are **only for research purposes, and the total amount of blood drawn on this day will be 4 tablespoons (60 ml).** Samples will be taken immediately before surgery, after the surgery is done but before you take the study pain medication, and at one hour, two hours, 4 hours and 6 hours after you **take the study pain medication**. We will keep the catheter in your vein, so we don't have to stick you with the needle again (although being stuck again with a needle again is possible if the tube becomes clogged and we can't get any blood from it). These blood samples will be analyzed for the amount of certain chemicals in your blood that may change with how much pain you experience.
3. At the same time a blood sample is drawn, we will also ask you to provide a urine sample **for research purposes**, so we can look at certain chemicals in your urine that may correlate with your pain level and with how well the pain reliever is working.
4. Right after the blood sample is drawn, we will also place thin cardboard strips between your teeth and gums near the implants, a painless procedure to collect GCF **for research purposes**. **The results of these blood, urine and GCF tests won't be available until several months after the study is completed and will have no impact on your treatment and care.**
5. Your implant surgery will be performed by one of the attending periodontal surgeons using accepted standards of care **(not for research purposes but for your routine care as if you were not on the study)**, including the use of injected numbing medications (2% lidocaine with epinephrine and/or 3% mepivacaine) so you don't feel pain during surgery, and additionally the use of nitrous oxide plus oxygen (laughing gas) if you need it to relax. **You and/or your insurance company are responsible for the costs of the surgery, the numbing medication and the laughing gas.**
6. Once the surgery is complete and you are feeling comfortable, we will move you to the Clinical Research Center on the third floor of the Dental School in the adjoining building called the Schattner Center. You will receive a dose of naproxen sodium,440 mg (2 Aleve®), or acetaminophen 1000 mg (2 Tylenol® Extra Strength), by mouth with 8 ounces of water **for research purposes**. You will probably still be numb and pain free when you take the study pain medication. Your chances of getting either drug is one in two, or fifty-fifty. The study medication that you will receive will be determined solely by

chance (like a flip of a coin). All study medications will look exactly alike so neither you, nor the study doctors or the research coordinator will know what you are receiving. However, this information can be obtained in the case of an emergency.

7. After administering the study medication, we will ask you to report the amount of pain you are having every 20 minutes for 6 hours. During this 6-hour in-house evaluation period we will also ask you about any bad effects (side effects) you think the medication has given you. **The responses you provide us are solely for research purposes.**
8. You will be encouraged to allow at least 60 minutes for the study pain medication to work before taking any additional pain relievers, but if you start experiencing pain which is too uncomfortable, you will receive a dose of tramadol, 50 mg. Tramadol is an opioid (narcotic) and **if misused is potentially addicting**. We will supply it in a dispenser containing six 50 mg tablets so we can easily count how many you need during the entire course of the study. If you take one while in the research unit, five will be left for you to take home.
9. At 6 hours (while you are still at the Dental School), you will take your second dose of study medication. If you are in the acetaminophen group, you will receive acetaminophen, 1000 mg (two Tylenol® Extra Strength). If you are in the naproxen group, your medication will be two placebo look-alike pills which contain no pain medication. We are doing this because your second dose of naproxen sodium (Aleve®) should not be taken for another 6 hours and you and the study team should not know what you are taking. **This again is being done for research purposes.**
10. After you take this dose of study medication, we will give you a specialized cardboard and plastic dispenser, a blister pack, containing your study medication and instructions how and when to take it. Some pills in your blister pack may be placebos, **so that all study medication looks alike** and you and the study team remain unaware of what you are taking. **All this is being done for research purposes.**
11. Once you understand how to use the blister pack, you will then be scheduled for your **24- hour postsurgical visit** (**Visit #2)** back in the dental school and will be permitted to go home. The total amount of time you will be at Penn on the day of your surgery will be approximately 7 to 8 hours. The research coordinator or other research personnel will contact you by phone or text message the night after surgery to see how you are doing and ask you a few questions about how much pain you are experiencing. **It is important to realize that while there are placebo pills in this study, everyone in the study will be taking either 660 mg of naproxen sodium (3 Aleve®) a day or 3000 mg of acetaminophen (6 Tylenol® Extra Strength) per day for the three days of the study. This is the maximum approved recommended dose for each drug. In other words, everyone will be getting what is considered a good dose of pain medication and nobody will just be taking placebos that don't contain any pain medication.**

When taking the study medication at home:

1. You will follow the instructions on the blister pack. Basically, on the day of surgery you will take a dose (two capsules of study medication) 6 hours after you leave the

Dental School.

2. On the first day and second day after surgery, you will take two capsules of study medication upon awakening and 6, 8, 12 and 16 hours later. You will take the study medication whether or not you are experiencing pain because one of the study goals is to try to prevent pain.
3. In case you have pain that becomes very uncomfortable, you will be allowed to take one of the tramadol pills, but no more than one every 6 hours. **Do not take any tramadol if you don't need it.** You will be given a study medication log to use in recording the time you take each dose of study medication in the blister pack and how much pain you were experiencing before dosing. You will also record if and when you took any tramadol. You should bring the blister pack, the tramadol dispenser and the medication log sheets back with you to the 24-hour and 72-hour study visits. **While all the drugs you are taking at home are FDA approved, the drug you are assigned to and when you are taking it is solely for research purposes.**

Visit #2, the 24-hour Postsurgical Visit, will take place in the Clinical Research Unit located on the third floor of the Dental School's Schattner Building (where you were the day before)**.**

1. We will check the blister pack to see if you took the study medication as directed and also count how many tramadol tablets are left. We will ask you at this time how much pain you experienced at home and how well you think the study medication worked for you.
2. We will then collect a urine sample, a blood sample (2 teaspoons) from a needle placed in a vein in your arm and a GCF sample using the cardboard strips placed between your gums and teeth. We will again be analyzing chemicals in the three fluids to see if they can help us predict how much pain patients will experience and how well the pain relievers work. **The total amount of time for this visit will be approximately 30 minutes.** You will then be scheduled for **Visit #3, the Final Study Visit.** This will take place two days later (or 72 hours after your surgery).

Visit #3, the Final Study Visit, will take place approximately three days after your surgery at the Clinical Research Unit on the third floor of the Schattner Building.

1. All the same things that were done at Visit #2 (counting how many pills you used, asking you about your pain, and collecting urine, blood and GCF samples) will be performed at this visit. We will also take back any unused medication from you. This visit will last approximately 30 minutes. This will complete your study participation.
2. The total amount of blood taken in this study will be approximately 5.5 tablespoons (80 ml).

What are the possible risks or discomforts?

Naproxen sodium (Aleve®) is an over-the-counter and prescription pain reliever approved by the FDA. It is generally well tolerated in the short amount of time you would be receiving it during this study. Naproxen sodium can cause stomach bleeding and allergic reactions. **Allergic reactions can occur with even the low doses of naproxen sodium that we**

are studying so if you have a history of allergies to naproxen sodium (Aleve®, Anaprox®) ibuprofen (Advil®, Motrin®), ketorolac (Toradol®, SPRIX®), aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs), or if you have had an asthmatic attack while taking any of these drugs, you should not be in this study. In addition, administering drugs like naproxen sodium shortly before or after heart surgery can cause unwanted complications, so if you are scheduled to have heart surgery or have had heart surgery within 6 months of this study, you will not be allowed to participate.

Acetaminophen is also an FDA-approved over-the-counter pain reliever. The most common side effects of acetaminophen include headache, stomach ache and gas. People who take too much acetaminophen (overdose) can injure their liver. Therefore, it is important to follow the instructions that we give you for taking study medication. The daily amount of acetaminophen you would be taking in this study is six 500 mg tablets, or a total of 3000 mg, which is below the FDA's maximum recommended daily dose of eight 500 mg tablets (4000 mg). Acetaminophen can also cause serious allergic reactions, so **if you are allergic to any Tylenol® product or any product that contains acetaminophen, you should not be in this study.**

Tramadol is an FDA-approved prescription opioid pain reliever. The most frequently reported adverse reactions to tramadol are lightheadedness, dizziness, feeling sleepy, nausea, vomiting and constipation. Other effects reported with tramadol include difficulty passing urine, mood changes (both bad and good), and skin rash. If you need to take tramadol during this study, you should not drive a car or operate heavy machinery because your ability to do these tasks may be impaired. Tramadol may cause serious side effects in people on antidepressant medicines. Therefore, if you are on one of these drugs, you will not be allowed to participate in the study. **Drugs that contain tramadol have abuse potential, such as people using the drugs to get high or trying to sell them on the street. People who misuse drugs like tramadol can become addicted and in some cases overdose and stop breathing or have seizures. Therefore, it is imperative that you use the tramadol exactly as you are instructed in this study, and that you keep all your study medication in a secure place where other people will not have access to it. Any unused tramadol must be brought back to us during your final visit.**

The risks associated with drawing blood samples from your vein include pain and bruising at the needle insertion site, feeling faint and, rarely, nerve damage or infection. The research coordinator who performs this is highly trained at taking blood from veins.

Your blood or other specimens will not be sold to any person, institution, or company for financial gain or commercial profit. Neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide. Your blood will not be used for whole genome sequencing. All measurements done with your blood and other specimens are for research purposes only, and you will not be informed of the results of the research performed on your samples. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your health records; however, the results of this research may be used in reports and research publications. The investigators do not wish to identify you in connection with this research

and will use procedures designed to prevent the results of this research from being linked to you. For example, a study ID number will be used to identify the tubes that contain your samples, and the label will not include your name or other health information. If your samples or other health information are used in reports and research publications, you will not be identified by name, address, or phone number.

Reproductive risks: Because of unknown effects of naproxen sodium, acetaminophen and tramadol, there could be serious harm to unborn children or children who are breast-feeding. These effects could also harm the mother. In addition, implant surgery is never performed on pregnant women because the risks of surgery and the surgical numbing regimens outweigh any benefit. It is also possible that harmful side effects that are not yet known could happen to both the mother and to the unborn or breast-feeding child from both the surgery and the study drugs. If you are currently pregnant, you will not be able participate in the study. If you are a woman who is able to become pregnant, you will be given a urine pregnancy test at the beginning of **Visit #1** (**Surgical Visit).** You are asked to use a medically accepted method of birth control (such as abstinence, birth control pills, birth control shot [Depo-Provera injection], progestin implant, condoms with spermicide, diaphragm, cervical cap, intrauterine device [IUD], surgical methods of birth control) while you participate in the study. You should not become pregnant while you are taking part in this study. If you do become pregnant, you must tell the investigator and consult an obstetrician or maternal- fetal specialist.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any direct benefit from being in this research study.
The results of this study may help researchers gain a better understanding of managing pain in patients undergoing dental surgery and how well patients will respond to naproxen sodium and other pain relievers.

What other choices do I have if I do not participate?

The alternative to participating in this study is not to participate. If you do not participate, you would receive your dental implant surgery and be prescribed an FDA-approved pain reliever such as an NSAID like ibuprofen (Advil®, Motrin®), naproxen sodium (Aleve®, Anaprox®), acetaminophen (Tylenol® Extra Strength) or acetaminophen/hydrocodone (Vicodin®). If you choose not to participate in the study, this decision will have no impact on the care that you would receive at the University of Pennsylvania School of Dental Medicine. If you are an employee or student at the University of Pennsylvania, participating or not participating in this study will not enhance or detract from your career or class standing.

Will I be paid for being in this study?

You will be compensated in the following manner for your time spent in the study.

- Visit #1 Surgical Visit - $150
- Visit #2, 24-hour postoperative visit - $125
- Visit #3, 72 Hour Post-Surgical Visit - $125
- Total Compensation - $400

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, the University will report this income to the Internal Revenue Service.

Will I have to pay for anything?

You or your insurance company will be billed for the costs of the dental implant surgery, including presurgical X-Rays or nitrous oxide if you need it. The cost of the study medications will be paid for by the study. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

What happens if I am injured from being in the study?

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Pennsylvania. If you wish further information or think something unusual has occurred because of your participation in the study, you should contact the Principal Investigator, **Dr. Hersh**, listed on the first page of this consent form. You may also contact the **School of Dental Medicine's Clinical Pharmacology Research Unit** at 215-746-8871 and ask for Stacey. And you may call the After Hours number listed on the first page and ask for the periodontist on call.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your study doctor, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the FDA has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will

not interfere with your future care at the University of Pennsylvania.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by a clinical research monitor (someone who reviews the accuracy of study documents), they may review your research records.

What information about me may be collected, used or shared with others?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Social Security number
- Personal and family medical history
- Current and past medications or therapies
- Any bad effects from study pain relievers
- Information from a physical examination that generally also includes blood pressure readings, and heart rate
- For females, results of a urine pregnancy test
- Results from pain questionnaires

Why is my information being used?

Your information is used by the research team to contact you during the study. Your health information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator and the Investigator's study team
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Clinical Research (the office which monitors research studies)

- Authorized members of the workforce of the University of Pennsylvania School of Dental Medicine and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the University of Pennsylvania Institutional Review Boards.

Who, outside of the Hospital of the University of Pennsylvania, might receive my information?

Oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections

Once your personal health information is disclosed to others outside the University of Pennsylvania School of Dental Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

How long may the University of Pennsylvania School of Dental Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the University of Pennsylvania may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the principal investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

By signing this document, you are permitting the Department of Periodontics to use and disclose personal health information collected about you for research purposes as described above.

What may happen to my information and samples collected on this study?

Your information and samples will be de-identified, meaning that all identifiers linking them to you have been removed. The information and samples could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania School of Dental Medicine and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by the dental school. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care at PENN Dental Medicine and are participating in a University of Pennsylvania research study that uses the dental school's service, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study.

In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.
Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team.
Information within your EMR may also be shared with others who are determined by the University of Pennsylvania School of Dental Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Please Print)	Signature	Date