

Protocol Title: Structural Fat Grafting for Craniofacial Trauma using manual technique for processing fat graft material (BTI++)

NCT02267187

Informed Consent

Approved 04/04/2017





CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

Title: Structural Fat Grafting for Craniofacial Trauma using manual technique for processing fat graft material

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Source of Support: Department of Defense

Conflict of Interest Statement: One or more of the investigators conducting this research has a financial interest in or a patent for the development of this Coleman Cannula system. This means that it is possible that the results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully by the Principal Investigator, Dr. J. Peter Rubin, MD (412-641-3960), who has no financial conflict of interest with this research, or by the Human Subject Protection Advocate of the University of Pittsburgh (866-212-2668).

Why is this research being done?

One’s own fat may be used to improve the appearance of his/her body. This is done by taking the fat from an area where it is less needed and moving it to a more desirable area utilizing a clinical procedure called fat grafting. Fat grafting is a common cosmetic and reconstructive procedure. Plastic surgeons performed this minimally invasive procedure approximately 65,000 times throughout the United States last year alone. The



procedure involves taking fat from areas throughout the body, usually from the thighs or abdomen, with a small liposuction tube. The fat is then transferred into another area that has lost volume or fullness due to aging, trauma, surgery, birth defects, or other causes. Typically, the transferred fat results in an increase of volume in the body site being managed. The fat grafting procedure being performed in this trial is considered to be research, but not an experimental procedure. The purpose of this research is to evaluate the result of the transferred fat filling over time as well as comparing different techniques of fat processing.

Is your participation voluntary?

Before you learn about the study it is important that you know the following:

- Your participation is voluntary;
- You may decide not to take part or to withdraw from the study at any time without losing the benefits of your routine medical care.

This informed consent gives you information about the participation in this study. Please read this information carefully, you will be given an opportunity to ask questions. Please do not sign this form until you have had a chance to discuss the research study with a person on our medical staff. Your signature verifies that you have been given an opportunity to read all of the information in the consent. A copy of the consent form will be given to you.

Who is being asked to take part in this research study?

Ten (10) male and female participants, 18 years of age and older are being asked to participate in this study. We are asking subjects who have suffered head and /or face injury resulting in a deformity to participate. You may have already successfully completed a telephone screening interview and now are being seen for an on site screening visit. We are going to evaluate you to be sure that you have no conditions or illnesses that would make you unable to participate in this study. You should not participate if you have active infection anywhere within your body, have a diagnosis of cancer within the last 12 months and/or are presently receiving chemotherapy or radiation treatment, a known history of blood clotting disorders or are unable to receive a CT scan. If you are a female, of child bearing potential you will be asked to perform a urine dip pregnancy test. If you are pregnant, you will not be eligible to participate in this study

As a study subject you will be identified by a unique assigned subject ID number. Your subject number will be assigned by the research coordinator and will be specific to this research study. In order to meet the study objectives, a total of twenty (20) participants will be screened to allow for ten (10) study subjects to be enrolled, accounting for those participants who do not meet the inclusion criteria and/or drop out of the study. The total duration of your participation in this study will be approximately 12-13 months.

What procedures will be performed for research purposes?

If you decide to take part in this research study, all procedures that are being performed will be done specifically for the purpose of this research study. If you decide to take part in this research study, you will undergo the following research related procedures:

Screening Procedures: These are procedures to determine if you are eligible to take part in this research study. These are called “screening” procedures.

Screening Visit:



This screening visit will take place in the UPMC Aesthetic Plastic Surgery Center located at 3380 Boulevard of the Allies, Suite 158 Pittsburgh, Pa 15213, which will include a review of the study and the consent document.

The study investigator or co-investigator will discuss with you the nature of the research study, visit frequency, the risks and benefits, cost and payments and your rights as a research subject. You will review the informed consent document allowing ample time to review all information and ask questions. Should you wish to take the consent and review it outside of the office setting or discuss with other family, medical personnel you will be able to leave the office and return at a later date. The study investigator will provide you a private area to conduct this study document review prior to signing the informed consent.

During this consenting process we will ask for your permission to obtain digital records (i.e. photography or video) at any and all portions of your pre-operative (before your operation, operative (during your operation), and post-operative (after your operation) study participation. These may include, but not be limited to, videos of personal interviews, functional assessment testing and study physical exams or photos of your follow up course, biopsies, etc. These videos and photos will be stored without any additional identifiable information such as your name or date of birth, for an indefinite amount of time in a secure (password protected), encrypted, location on the UPMC server.

We will also be asking your permission to allow Dr. J. Peter Rubin and research team to use any and all these digital recordings for medical education and training, publication, and media reports – and, in any mode of transmission, including and not limited to: print, email, television, internet, etc. If you agree to this use of your photography or video recordings you will be asked to sign in a separate section of this consent document.

After this detailed discussion of the study and conclusion of any and all questions, the study investigator, who is a physician, will obtain informed consent. The research coordinator will document the consenting process and prior to beginning any research activities; provide a copy of the fully executed informed consent document to you for your records. No research related procedures, including but not limited to the screening procedures or the review of medical records will be performed before the informed consent has been obtained. All screening procedures will be performed at the UPMC Aesthetic Plastic Surgery Center in a private room and will take approximately 2-3 hours of your time.

- Once informed consent has been obtained
- If you are female of child bearing potential, you will receive a urine pregnancy dip test. If the test result is positive, inclusion criteria will not have been met and you will not be able to participate in the study.
- Medical and surgical history review: The PI and/ or co-investigator will perform a medical and surgical history review with you this may include past medical and surgical procedures pertaining to the craniofacial trauma, laboratory tests, radiological tests, and consults pertaining to trauma event. If you do not bring medical records to the visit or if they are not available at the time of this screening evaluation, the investigator will accept direct report from your referring physician, the referral source and /or your self-report. This information will be documented to your research chart. This report will consist of past medical /surgical history pertaining to the craniofacial defect and trauma. The Principal Investigator will base determination of your study eligibility on a combination of evaluation criteria to include physical examination, referral physician direct report, and /or subject self-report and



psychological (SCID) assessment all pertaining to past injury and current status of the area of interest.

- A medical history and physical exam inclusive of a craniofacial examination will be performed by the study investigator.
- Collection of your vital signs (Temperature, heart rate (HR), respiratory rate, blood pressure (BP), height, weight and BMI calculation, medication profile to include prescription and vitamins / supplements, and allergies.
- Collection of demographic information to include date of birth, gender, race and ethnicity, smoking history, relationship status, educational level, dominant handedness, and allergies. .

You will receive a baseline Structured Clinical Interview (SCID) to ensure that the presence or absence of a psychiatric disorder has been evaluated and documented. The study investigator will use a standard psychiatric diagnostic interview form. This interview form enables the study investigator to ultimately make a determination of presence of a psychiatric diagnosis. As part of the clinical interview, the study investigator will obtain a demographic history which consists of questions specifically about your household status.

Standard-of-care 2D Photographs: Pictures will be taken of the entire face (only) with a professional-grade camera creating images with high resolution and excellent detail. The pictures that will be taken may include following views:

1. Front view
2. AP three-quarter Right
3. AP three-quarter Left
4. Lateral Right
5. Lateral Left

Dependent on investigator evaluation we may opt to obtain the following views:

1. Inferior view
2. Superior view

The pictures will be taken at the UPMC Aesthetic Plastic Surgery Center in a private room and will take approximately 10 minutes. 2D photographs will be taken by the PI, Co-Investigator or the study or a research coordinator.

All screening procedures will be performed at the UPMC Aesthetic Plastic Surgery Center in a private room and will take approximately 2-3 hours of your time. Upon discovery of a clinically significant and/or unexpected disease or condition during the conduct of the screening procedures, the study investigator will notify you of any event that could be of clinical significance needing further evaluation, or of a diagnosis of any



unexpected disease or condition that occurred during the conduct of the study's research procedures. The study investigator will at the time of discovering the event contact your referring physician or primary care physician for further evaluation of the event. Should the event be of a critical nature needing immediate intervention, the study investigator will proceed with immediate clinical intervention, and all study related procedures will stop.

Research Interventions/Interactions: Upon completion of your screening procedures, the study investigator will determine your study eligibility and if you meet the study criteria, you will be asked to complete research interventions. These procedures will be performed at the UPMC Aesthetic Plastic Surgery Center in a private room. The research procedures for this clinical trial are as follows:

Pre-Graft Study Visit (PGSV):

- If you are female of child bearing potential, you will receive a urine pregnancy dip test. If the test result is positive you will not be permitted to continue participation in this research study.
- Body Mass Index (BMI) Measurement: We will measure your weight via a standard medical scale.
- Collection of subject's vital signs (Temperature, heart rate (HR), respiratory rate, blood pressure (BP), medication profile to include prescription and vitamins / supplements, allergies, and Adverse Event Assessment.
- 3-Dimensional image: the investigator or study staff will take photographs of your entire face (only) with the Canfield 3D camera system. The camera takes 2 simultaneous photographs of the face from different angles and makes a 3-dimensional image. The 3D camera system is not a medical device and is not regulated by the FDA. The pictures will be taken at the UPMC Aesthetic Plastic Surgery Center in a private room and will take approximately 10 minutes.
- A limited medical history and physical exam with a craniofacial exam by the investigator
- The investigator will rate the appearance/volume of the graft site using a craniofacial volume and appearance grading scale
- Standard 2D Photographs
- CT Scan with 3D rendering: We will perform a CT scan of your head. A CT scan (sometimes called CAT scan) combines special x-ray equipment with sophisticated computers to produce multiple images or pictures of the inside of the body. CT scans of soft tissue and blood vessels provide greater clarity and reveal more details than regular x-ray exams. The CT scanner is typically a large, box like machine with a short tunnel, in the center. You will lie on a narrow examination table that slides into and out of this tunnel. Rotating around you, the x-ray tube and electronic x-ray detectors are located opposite each other in a ring. The CT scan will take place at Presbyterian Hospital and will take approximately 60 minutes.
- Quality of Life Assessment: We will ask you to complete various questionnaires, some by yourself and some given by our research staff. The questionnaires are about your quality of life, including but not limited to your satisfaction with health services, life and how those things that affect you. Completion of the questionnaires will take place at the UPMC Aesthetic Plastic Surgery Center in a private room and will take approximately 1 hour.
- Pre-op Laboratory Test: Approximately 12-15mls (3 teaspoons) will be obtained from a vein in your arm performed by laboratory personnel located on the 5th floor of the UPMC Montefiore Hospital building for clinical lab analysis. These tests include the following: Complete Blood Count with Differential and Platelets (CBC with Diff and Platelets) (a test that checks how well your blood is able to fight infection), Comprehensive Chemistry panel which include electrolytes, phosphorous, calcium,



BUN, creatinine glucose, albumin, total bilirubin, alkaline phosphatase, AST, ALT, GGT, LDH and Lipids (tests to check how well your kidneys and liver are working) and a PT/ PTT/ INR (tests to check how well your blood is able to clot).

- Electrocardiogram (EKG): You will receive an electrocardiogram (EKG—a tracing of the electrical activity of your heart that involves the use of sticky patches on your arms, legs and chest) to examine your heart
- Chest X-ray- done only if indicated by age and medical history

The total time commitment from you for this visit is estimated to be approximately 3-4 hours in length.

Fat Graft Surgical Procedure: For the purpose of this study the fat grafting procedure is a research procedure. The fat grafting procedure will occur at UPMC Magee or Montefiore Hospital Surgical Suites. On the day of the surgical procedure, prior to entering the operating room, the Investigator physician will mark your facial area(s) intended for fat grafting procedure. It is very important to remember that this research procedure is not an experimental procedure. Fat grafting is a minimally invasive clinical procedure that has been widely used by plastic surgeons within reconstructive surgery for many years. Fat grafting is known as a filler providing an accurate means to restoring facial soft tissue structure.

On the day of the surgical procedure, prior to entering the operating room, the Investigator physician will mark the facial areas intended for fat grafting. Standard 2D pictures may also be obtained at this time at the discretion of the investigator.

With the fat graft procedure the subject will be given general anesthesia, a medicine that will relax and assist to in keeping the subject unconscious (in a sleep like state) during the entire procedure. Once unconscious, the plastic surgeon, using small narrow tube-like instruments called cannulas, will remove fat from various places throughout the body (commonly the abdomen and thighs). The amount of fat removed for the abdomen and/or thigh and re-added the desired area will vary between subjects according to the size of the area that needs to be filled. The processing of the fat graft material is done using a Teflon non-adherent gauze pad in a rolling technique that separates the aqueous and oil layers from the injected component. The plastic surgeon will then use the Coleman cannulas (specialized smaller cannulas with varied shapes and tip sizes specifically made to deliver smaller amounts of fat) to fill the desired area. The facial areas which are known to have tight spaces with varying angles and can have scarring bands (scar tissue) makes the Coleman cannula appropriate for this type of fat delivery. The Coleman Cannula System is also associated with less graft re-absorption than other techniques. The Coleman Cannula System is not experimental and is commercially available in the United States and in compliance with Federal regulations.

During the Fat grafting reconstructive surgery procedure, the study investigator will obtain an additional sample portion of your fat (Lipoaspirate) consisting of up to 80mls (5.5 tablespoons) to be used for research purposes. The research sample is a requirement of your participation in the study; if you wish not to give this sample, you will not be able to participate in this clinical trial. The research sample collected will remain under the oversight of Kacey Marra, PhD, Co-Investigator, and examined for cellular information within the Plastic surgery lab located on the 16th floor of the Biomedical Science Tower, University of Pittsburgh. This research sample will be de-identified and labeled with a unique study ID number. This research sample will be kept indefinitely and may be provided to a secondary investigators (investigators not listed on the front of this informed consent document) not associated with this research study. Your specimens will be made anonymous



so no identifiers can be linked back to you. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Once the surgical procedure has been completed you will need to go to an area called the recovery room where you will be monitored for several hours until you are stable enough to be released to home. There might be a possibility that you will be admitted to the hospital overnight for observation as deemed necessary by the plastic surgeon.

Follow up procedures /Post graft study visits:

Post Op study visit (Day 3-6): This study visit will occur with the study investigator or research team and will take place approximately in 3-6 days post surgical procedure for the purpose of incision assessment and suture removal. The entire visit will take approximately 30-45 minutes and will be scheduled with the subject prior to hospital discharge post fat graft procedure.

- Limited medical history and physical with craniofacial exam
- Collection of any adverse events (Should an adverse medical event occurred prior to the visit, the research team will do due diligence to collect information pertaining to the event through your direct report and /or medical record review and /or referring physician report)
- Collection of current medications, allergies and vital signs since you were last seen.

Study visit (V1-V3): This study visit will occur with the study investigator or research team and will take place 7-21 days after the fat grafting surgical procedure. This visit will be scheduled by the research coordinator and discussed with the subject prior to the fat graft procedure. These research procedures will be repeated at both 3 months after the fat grafting procedure [Visit 2 (V2)] and at 9 months after the fat grafting procedure [Visit 3 (V3)], your time commitment for these visits will take approximately 2-3 hours for each visit. The following will be performed:

- If you are female of child bearing potential, you will receive a urine pregnancy dip test. If the test result is positive you will not have be permitted to continue participation in this research study.
- Limited medical history and physical with craniofacial exam performed by the study investigator.
- Body Mass Index (BMI) Measurement: We will measure your weight via a standard medical scale.
- 3Dimensional photographs
- The investigator will rate the appearance/volume of the graft site using a craniofacial volume and appearance grading scale
- 2D Photographs
- Quality of Life Psychosocial assessments
- CT Scan with 3D renderings
- Collection of subject's vital signs (Temperature, heart rate (HR), respiratory rate, blood pressure (BP), medication profile to include prescription and vitamins / supplements, and allergies.
- Collection of any adverse events (Should an adverse medical event occurred prior to the visit, the research team will do due diligence to collect information pertaining to the event through your direct report and /or medical record review and /or referring physician report)
- Structured Clinical Interview (SCID) (Visit 3 V# ONLY)



Due to traveling distances for participants who are enrolled into this trial, we have included a (+/-) of 14 days (2 weeks) for the completion of Visit 2 and Visit 3 as a convenience for the coordination of schedules.

What are the possible risks, side effects and discomforts of this research study?

As with any research procedure, there may be adverse events or side effects that are currently unknown, and certain of these unknown risks could be permanent, severe or life threatening. Every attempt will be taken to minimize these risks. An example of how we minimize these risks is the use of qualified personnel with the knowledge and appropriate skill needed to perform the procedures for this research study.

Risks of Breach of Confidentiality: Participation in this research study does involve the potential risks of a breach of confidentiality of the medical record information and associated privacy of the participants. The study investigators will take steps to reduce these risks by: 1) removing direct participant identifiers (i.e., names, social security numbers, medical record numbers) from information stored in the study records; 2) securing, in a separate location, and limiting access to information linking codes assigned to the study record information with direct participant identifiers; and 3) limiting access to information contained within the study records to study investigators only.

Risks of Clinical Interview: There is a risk of psychological discomfort some people experience when they share sensitive information about themselves. In this study, such disclosures occur during this interview and to reduce this risk we have highly trained staff to perform this interview.

Risks of Quality of Life Assessment: There is a risk of psychological discomfort some people experience when they share sensitive information about themselves. In this study, such disclosures occur on the questionnaires. To reduce this risk, we have highly trained staff give the questionnaire.

Risk of Electrocardiogram (EKG): It is common (Occurs in 10-25% of people (10 to 25 out of 100 people) that you may experience irritation or redness at the sites where small adhesive disks are placed on the chest skin to hold the wires that are hooked to the computer that measures heart rhythm.

Risks of CT Scan and Chest X-Ray : Participation in this research study involves exposure to radiation from the CT scan. The amount of radiation exposure that you will receive from this CT scan is about 1.3 rem (rem is a unit of radiation exposure) to your head, with minimum exposure of other areas of your body. You will receive a total of 5.2 rems for the entire study. (If needed, a chest x-ray adds 0.01rem.) For comparison, radiation workers are permitted, by federal regulation, a maximum radiation exposure of 50 rems per year to any single body organ. There is no minimum amount of radiation exposure that is recognized as being totally free of the risk of causing genetic mutations (abnormal cells) or cancer. However, the risk associated with the amount of radiation exposure that you will receive from taking part in this study is felt to be low and comparable to everyday risks.

Risks of Photographs: You may feel uncomfortable while photographs of your face are being taken. We will do everything to minimize this risk including taking the pictures as quickly and efficiently as possible. There is also a risk of loss of confidentiality. Your photographs will be labeled with an ID code and will be kept in a password protected computer and a locked office. Again, you may decide at any time that you do not want to participate in this study.



Risks of Venipuncture (blood withdraw): Infrequent (Occurs in 1% to 10% or 1 to 10 out of 100 people): mild pain and discomfort at the injection or needle insertion site as well as possible infection, bleeding, bruising and soreness. Rare (Occurs in less than 1% or less than 1 out of 100 people): severe pain; swelling; possibly an infection from the actual injection; fainting.

Risks of Surgical Fat Graft Procedure:

Common Risks:

Change in appearance: Typically the transferred Fat loses some of it's volume over time and then becomes stable. It is possible that more treatments maybe needed to maintain the desired volume of the transferred fat and resulting appearance. Less commonly, if you experience significant weight gain, the transferred fat may increase in volume and cause an undesirable appearance.

Skin Contour: While most transferred fat results in a natural feel, it is possible that some or all of the fat may become firm, hard or lumpy. If some of the fat does not survive the transfer it may result in fat necrosis (fat tissue death) causing firmness and discomfort and pain. Cysts may also form at the site of the transferred fat.

Asymmetry: symmetrical body appearance may not result from a fat graft procedure. Factors such as skin tone, fatting deposits, boney prominences, and muscle tone may contribute to normal asymmetry in body features.

Pain: Chronic pain may occur rarely after fat removal or graft.

Infrequent Risks:

Bleeding: It is possible, though unusual, to experience a bleeding episode during or after this procedure. Should bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma).

Seroma: Although unlikely, a collection of fluid may appear at the site where the fat was removed. This is usually treated by draining the fluid with a needle.

Infection: Infection is unusual after this procedure, but should infection occur, additional treatment including antibiotics or surgery may be necessary.

Tissue Loss: In rare cases, the grafted fat may cause the skin over the transferred area to be injured resulting in loss of the skin and surrounding tissue. This may leave scars and disfigurement.

Damage to deeper structures: Deeper structures such as nerves, blood vessels and muscles may be damaged during the course of this procedure. The potential for this to occur varies according to where on the body the procedure is being performed. The injury to deeper structures may be temporary or permanent.

Serious complications may include blood clots, partial collapse of lungs, pulmonary embolism, fat embolism, stroke, infection, blindness loss of vision, and/or death.

Other Risks to the surgical fat graft procedure:

Scarring: All invasive procedures produce scars, some more visible than others. Although good wound healing after a procedure is expected, abnormal scars may occur both within the skin and within the deeper tissues.

Scars may be unattractive and of different color other than the surrounding skin color. There is the possibility of visible marks from sutures used to close the wound. Scars may also limit motion and function. Additional treatment including surgery may be needed to treat scarring.



Long term effect: subsequent changes in the shape or appearance of the area where the fat was removed or placed may occur as a result of aging, weight loss or gain, or other circumstances not related to the Fat grafting procedure.

Unsatisfactory result: There is a possibility of unsatisfactory result from the procedure resulting in unacceptable visible deformities, loss of function, wound disruption, skin death and loss of sensation.

Allergic reaction: In rare cases local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may result from drugs used during the procedure.

Risks of General Anesthesia:

Although all types of **anesthesia** involve some **risk**, major side effects and complications from anesthesia are uncommon. Your specific risks depend on your health, the type of anesthesia used, and your response to anesthesia.

Serious side effects of general anesthesia are uncommon in people who are otherwise healthy. But because general anesthesia affects the whole body, it is more likely to cause side effects than local or regional anesthesia. Most side effects of general anesthesia are minor and can be easily managed.

Infrequent Risks: General anesthesia suppresses the normal throat reflexes that prevent aspiration, such as swallowing, coughing, or gagging. To help prevent aspiration, an **endotracheal (ET) tube** may be inserted during general anesthesia. When an ET tube is in place, the lungs are protected so stomach contents cannot enter the lungs. Aspiration during anesthesia and surgery is very uncommon. To reduce this risk, people are usually instructed not to eat or drink anything for a specific number of hours before anesthesia so that the stomach is empty. Anesthesia specialists use many safety measures to minimize the risk of aspiration.

Insertion or removal of airways may cause respiratory problems such as coughing; gagging; or muscle spasms in the voice box, or **larynx** (laryngospasm), or in the bronchial tubes in the lungs (bronchospasm). Insertion of airways also may cause an increase in blood pressure (hypertension) and heart rate (tachycardia). Other complications may include damage to teeth and lips, swelling in the larynx, sore throat, and hoarseness caused by injury or irritation of the larynx.

Other serious risks of General anesthesia:

These include changes in blood pressure or heart rate or rhythm, heart attack, or **stroke**. Death or serious illness or injury due solely to anesthesia is rare and is usually also related to complications from the surgery. Death occurs in about 1 in 250,000 people receiving general anesthesia, although risks are greater for those people with serious medical conditions.

Some people who are going to have general anesthesia express concern that they will not be completely unconscious but will "wake up" and have some awareness during the surgical procedure. Awareness during general anesthesia is very rare because anesthesia specialists devote careful attention and use many methods to prevent this.

Risks from reactions to anesthetic medicines:

Some anesthetic medicines may cause **allergic** (redness, swelling, hives, rash, tongue or throat swelling, difficulty breathing) or other abnormal reactions in some people, but these are rare. If you suspect you may have such a problem, you should tell both your surgeon and anesthesia specialist well before your surgery. Testing will then be arranged as necessary. A rare, potentially fatal condition called **malignant hyperthermia (MH)** may



be triggered by some anesthetics. The anesthetics most commonly associated with malignant hyperthermia include the [inhalation anesthetics](#) and the muscle relaxant medicines.

What are the possible benefits from taking part of this research study?

Historically fat grafting procedures performed for clinical purposes have supported positive cosmetic and surgical results in patients. Although we can not guarantee a positive outcome from this research fat grafting procedure, there may be a direct benefit to you from your participation in this research study. In addition, this research may provide a greater understanding of the effects of fat grafting over time.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study?

Neither you nor your insurance company will be charged for any testing procedures, such as the research CT scans, physical exams, lab tests and processing, fat graft procedure, questionnaires, or the photographs that are done during your participation in this research study.

If you receive a bill or believe that your health insurance has been billed for something that is part of this research study, immediately notify a member of the research team or UPMC Patient Billing Services. All the procedures associated with this study are being covered under a grant funded by the Department of Defense.

Will I be paid if I take part in this research study?

You will be remunerated for your participation in this research study at a per diem total rate of \$104.00/day. You will receive the remuneration upon completion of each study visit. Your reasonable travel expenses will be reimbursed at 50 cents per mile round trip. Proper supporting documentation for mileage reimbursement is demonstrated by trip tickets or a Mapquest inquiry from the subject's place of residence to the study site displaying round trip mileage. Travel may include air fare coverage round trip booked through the University of Pittsburgh travel agency "People's Travel". You will be reimbursed using the UPMC "WE PAY" system at the time of each visit.

Your participation may lead, in the future, to new inventions or products. If the investigators are able to develop new products from the research use of your tissue or biological sample, there are currently no plans to share with you any money or other rewards that may result from the development of these new products.

Who will pay if I am injured as a result of taking part in this research study?

University of Pittsburgh researchers and their associates who provide services at the University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator or one of the Investigators listed on the first page of this form.



Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?

Any information obtained from or for this research study will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet in the Plastic Surgery Offices. Your identity on these records will be de-identified (identified by a case number rather than by your name), and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Any information obtained from or for this research study will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet in the Department of Plastic Surgery Offices. Your specimens will be stored in Department of Plastic Surgery lab. Your identity on these records, including specimens, will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. The information gathered from your participation in this research will be de-identified and may be provided to a secondary investigators not associated with this research study.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will involve the recording of past, current and/or future identifiable medical information from your hospital and/or other (e.g. physician office) records. The information that will be recorded will be limited to the tests inclusive of past medical and surgical procedures pertaining to the craniofacial trauma, laboratory tests, photographs and videos, radiological tests, consults pertaining to trauma event and associated results that are processed by personnel within the UPMC. This research study will result in identifiable information that will be placed into your medical records held at UPMC. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record will be derived from the medical/surgical (fat grafting procedure). Psychiatric interview information will be entered into the medical record only if it is important to ensure your medical/physical safety.

Who will have access to the identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

Department of Defense and their contracted entities will review and/or obtain identifiable information; which may include the subject's identifiable medical information related to participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for preparing required scientific



analyses of the research data. While the study funding source, Department of Defense (DOD), understands the importance of maintaining the confidentiality of the identifiable research and medical information, the UPMC and the University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the Department of Defense.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by investigators, for hospital and health care services (e.g. laboratory tests) associated with this research study participation, (2) addressing correct payment for tests and procedures ordered by the investigators, and/or (3) for internal hospital operations (i.e. quality assurance).

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use or disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study indefinitely. The University of Pittsburgh guidelines on the retention of research records is 7 years from the final reporting or publication of the research.

May I have access to my medical information that results from my participation in this research study?

In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to your UPMC medical record information (including information in your medical record that is a result from your participation in this research study) at your request.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on you current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your doctor is involved as an investigator in this research study. As both your doctor and a research investigator, he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with



another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purpose described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if, you do not complete the study procedures or if you have complications resulting from your fat graft procedure.

Media / Photography /Interviews/Video recordings:

By opting to sign below in this section of the Informed Consent Document, I give the Principal Investigator, Dr. J. Peter Rubin, and/or his team permission to digitally record (i.e. photography or video) any and all portions of my pre-operative, operative, and post-operative course of treatment. These may include but not limited to videos of personal interviews, functional assessment testing and clinical exams or photos of follow up clinical course, biopsies, etc. All videos and photos will be number coded to ensure that there is not additional identifiable information collected and stored (such as name, date of birth, etc.) The images will be stored indefinitely in a secure (password protected), encrypted, and backed up hard drive location on the UPMC server. In addition, I give my consent for Dr. J. Peter Rubin and/or his team to use any and all these digital recordings for medical education and training, publication, and media reports – and, in any mode of transmission, including and not limited to: print, email, television, internet, etc.

I may choose not to sign this section of the consent and still continue to participate in the main portion of this clinical trial.

Printed name of Subject



Participant's Signature

Date

Time

VOLUNTARY CONSENT:

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Printed Name of Participant

Participant's Signature

Date

Time

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Time

