TITLE: Adipose Derived Stromal Cell Transplantation as an Adjunct to Arthroscopy in Treatment of Effusion Synovitis of the Early Degenerative Knee

NCT NUMBER: NCT03922490

DATE OF DOCUMENT: December 11, 2018

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Study Title:	Adipose Derived Stromal Cell Transplantation as an Adjunct to Arthroscopy in Treatment of Effusion Synovitis of the Early Degenerative Knee		
Protocol No:	2018-1534	**Sponsor:**	HSS
Principal Investigator:	Riley Williams III, MD	**Phone Number:**	(212)606-1855
Research Coordinator:	Arjun Khorana	**Coordinator Contact:**	(212)606-1693
IRB #	2018-1534		

Participating Site(s)	Location	Participating Investigator	Site Phone Number
HSS Main Campus	West Side, NY	Riley Williams III, MD	(212)606-1693
HSS Main Campus	East Side, NY	Andrew Pearle, MD	(212) 774 2878

1. OVERVIEW OF KEY INFORMATION REGARDING THIS RESEARCH STUDY.

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you have been identified as a patient with mild to moderate osteoarthritis, and are planning to undergo arthroscopic knee surgery as treatment for your condition. The information in this form is meant to help you decide whether or not to participate in this research study.

- Your **participation is voluntary.**
- You may decide not to participate in this research study.
- If you do participate, you may withdraw from the research study at any time.
- You do not have to participate in this study to receive treatment for your condition.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take home a copy of this document to consider or discuss with family and friends before making your decision.

A. WHY IS THIS STUDY BEING DONE?

Lipogems is the name of the FDA approved technology used to obtain stromal cells from fat that will be aspirated/removed by suction from the abdomen and then injected into the knee after your doctor completes your knee arthroscopy. The purpose of this study is to study the clinical outcomes and effects of the injection of fat-derived stromal cells (the scientific name being "adipose derived autologous stromal cell transplantation (ADSC)") as an addition to knee arthroscopy in the treatment of knee swelling and pain associated with mild to moderate knee osteoarthritis with or without meniscus tears. The study that we are asking you to enroll in may provide more information to the medical community about how this procedure affects your pain, the

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daily function of your knee and if there is any change that can be observed on MRI imaging after the procedure for the management of your condition. Currently, without this study, we do not have enough information to answer this question well.

If you are enrolled, you will be one of 50 subjects who will be enrolled in this study at HSS.

B. YOUR INVOLVMENT:

- As part of your surgery, you will undergo a diagnostic knee arthroscopy. This procedure would have been performed regardless of enrollment in the study. During the diagnostic knee arthroscopy, your surgeon will determine whether you are eligible to participate in the study.
- If you have a torn meniscus, inflamed joint lining or loose fragments in the knee, this will be removed and treated and you will still be eligible for the study.
- If, however, your doctor determines that you need more invasive treatments (such as cartilage transplantation, meniscal repair, removal of a substantial amount of your meniscus), then you will be excluded from the study and will not have fat tissue suctioned from your abdomen. The standard of care treatment will then proceed based on what your doctors feels is the best care for your condition.
- After your surgeon completes the arthroscopic procedure, the recommended amount of fat-derived stromal cells (about 2 teaspoons) will be injected into your knee. There will be approximately 1 tsp of excess fat derived stromal cells, which will be transported to our research facility so that the contents can be stored for later examination.
- After surgery, 4 visits are required by you over the next 6 months: at 2 weeks after surgery to monitor your incision, at 6 weeks, 12 weeks, and 6 months. You will also be contacted by phone after 12 months to complete your final questionnaire.
- Visits will occur at HSS west side campus.
- Each of these visits may take up to 1-2 hour(s).
- Procedures will include: repeat MRI at 6 months after the procedure and completion of 5 questionnaires.
- Please see the chart listed in Section 2 below for additional information.

C. MOST COMMON POSSIBLE RISKS AND DISCOMFORTS ASSOCIATED WITH YOUR PARTICIPATION IN THE RESEARCH STUDY:

- **Aspiration of Fat Cells**
  - The known risks for aspiration/transfer of fat cells include a risk for soreness, redness, swelling, and or pain. This procedure requires needle access and this may result in discomfort, pain, bruising, tenderness, bleeding, swelling and or infiltration at the injection site. These symptoms are temporary. There is a slight risk of infection at the injection site as with any other injection procedure.

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- **Knee Arthroscopy**
  - Risks of knee arthroscopy are uncommon, occurring in less than 5% of patients. These risks include swelling, infection of the skin or within the knee joint; abnormal wound healing, damage to structures within or around the knee which is very rare, but may cause further injury and symptoms and numbness to the skin around the knee and shin which us usually temporary.
- **MRI**
  - MRI is generally a well-tolerated procedure, and all patients will be screened for MRI safety prior to imaging. In addition, the Hospital for Special Surgery operates the MRI units within the safety guidelines established by General Electric Health Care, Milwaukee, Wisconsin. There is no ionizing radiation involved with MR imaging The potential risks are minimal and include claustrophobia, coil element heating and peripheral nerve stimulation, although the latter two are considered highly unlikely, given that the patients will be imaged within preset safety guidelines to eliminate peripheral nerve stimulation. Coil element heating ranges from a mild sensation of heat to a potential burn. This is considered highly unlikely, as the coils have all undergone extensive testing and clinical use, and special pads are placed surrounding all contact points.
  - For more information on possible risks and discomfort see Section 4 of this consent form

D. BENEFITS OF PARTICIPATING IN THE RESEARCH STUDY:

This study includes experimental/investigational procedures which may or may not give you immediate benefit or any benefit. The knowledge gained may benefit others in the future.

E. ALTERNATIVES TO BEING IN THE STUDY:

ALTERNATIVES: WHAT OTHER TREATMENT IS AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition. You may choose to not have surgery. You may choose to undergo knee arthroscopy without the Lipogems procedure or you may choose to undergo the knee arthroscopy with the Lipogems procedure but choose not to be enrolled in the study.

The following medications and/or procedures are available as common alternative treatments for your condition:

- Oral and topical anti-inflammatory medications
- Physical therapy
- Cortisone steroid injection
- Hyaluronic acid injection (Synvisc, Orthovisc, etc.)

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You should ask the study doctor about other alternative treatments that may be available for your condition. The option exists to undergo the knee arthroscopy procedure without the Lipogems procedure. If you do undergo the knee arthroscopy without Lipogems procedure, you may still volunteer to be followed by your surgeon during the same time intervals as subjects who elected to have the knee arthroscopy with the Lipogems procedure. This may also help us understand how patients with your condition react to knee arthroscopy when compared to knee arthroscopy and the Lipogems procedure. If you prefer to participate in the observation arm of the study (for patients who do not want to undergo Lipogems but are already planning to undergo knee arthroscopy for management of their condition), then you will be asked to sign a separate study consent. Then you will be asked to undergo the scheduled follow-ups, imaging and questionnaires that the research group is receiving at the intervals noted below but you will not undergo any additional procedures or the Lipogems procedure.

2. WHAT WILL YOUR PARTICIPATION REQUIRE?

If you decide to be in this study, the following procedures will be performed:

RES= Research procedures
SOC= Standard of care (care you would receive if you were not participating in this study)

Study Visit #	Lipo-aspiration and Injection	Surveys / Questionnaires	Surgery	X-Rays	MRIs	Physical Exam	Phone Contacts
#1 - Baseline		RES		SOC	SOC	SOC	SOC
#2 - Surgery (HSS Main or West Side ASC)	SOC		SOC				
#3 - Week 2 post-op		RES				SOC	SOC
#4 - Week 6 post-op		RES				SOC	SOC
#5 - Week 12 post-op		RES				RES	RES
#6 - Week 24 post-op		RES			SOC	SOC	SOC
#7 - 1 year post-op		RES					RES

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Surgical Procedure

- As part of your surgery, you will undergo a diagnostic knee arthroscopy. This procedure would have been performed regardless of enrollment in the study.
- An arthroscopy means “looking into a joint” with a camera. It allows the surgeon to examine the knee joint and perform some operations without having to open the knee completely. Through the first incision, we pass a telescope with a camera. This shows pictures on a nearby television screen. The second or third incision may allow tools or drains to be passed into the joint. The tools include probes, shavers, scissors and punches. The surgeon might not be able to say exactly what needs to be done until they are looking inside the knee.
- To begin the procedure, the surgeon will make a few small incisions, called "portals," in your knee. A sterile solution will be used to fill the knee joint and rinse away any cloudy fluid. This helps your orthopaedic surgeon see the structures inside your knee clearly and in great detail. Your surgeon's first task is to properly diagnose your problem. Your surgeon will insert the arthroscope and use the image projected on the screen to guide it. If surgical treatment is needed, your surgeon will insert tiny instruments through other small incisions.
- During the diagnostic knee arthroscopy, your surgeon will determine whether you are eligible to participate in the study. At the time of the knee arthroscopy, your doctor will be able to visualize any common injuries in the knee such as torn meniscus (the cartilage between the bones in the knee), pieces of torn cartilage that are loose in the joint and can cause irritation, swollen or inflamed lining of the joint, torn ligaments in the knee or cartilage damage that requires a repair procedure or significant removal of your meniscus. If it is determined during the diagnostic arthroscopy by your surgeon that you are not eligible for the study then you will not be enrolled in the study and you may not undergo the fat harvesting procedure.
- If you are determined to be eligible for the procedure, then the surgeon will proceed with the fat harvest procedure.
- Your surgeon will make a tiny puncture through your skin in your abdomen around your belly button to injection saline fluid in the layer of fat that is just below your skin. This will have free up fat tissue to allow for suction into a syringe. After 10 minutes allowing the saline to separate the fatty tissue, a small portion of fat [60 ml or approximately 4 tbsp] mixed with 60 mL of saline water will be removed from your abdomen and processed using the Lipogems device. This occurs through a very gentle process called micro-fragmentation, during which your fat is washed, rinsed, and resized into smaller clusters while maintaining the natural properties of your fat. The system removes blood, inflammatory cells, and fatty oils, leaving only the desirable concentrated fat.
- This tissue (2 tsp.) will then be injected into the knee. The procedure will occur while you are sedated. Additionally, 1 tsp. of fat will be stored for further laboratory examination.

Questionnaires/Surveys
By taking part in this research study, you will be asked to complete 5 questionnaires to let us know how your knee feels. You will be required to complete the questionnaires before your surgery and at the following time points after your surgery: 6 weeks, 12 weeks, 6 months and 12 months.

You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care, that is, care that you would receive even if you were not in this study.

3. COST TO YOU

Those research procedures listed in Section 2 (marked as "RES") will be covered by the study and will not be your financial responsibility.

As indicated in Section 2, those costs which are considered Standard of Care for your treatment here at Hospital for Special Surgery will be your/or your insurance's responsibility. You will be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this study. You will also be financially responsible for any medical care costs not covered by your health insurance.

HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis in accordance with HSS's financial assistance policy. You will be responsible for any costs not covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS does not cover all of the costs). For more information about the Financial Assistance Program or to request a Financial Assistance Application call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: https://www.hss.edu/financial-assistance-notice.asp.

4. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY?

The known effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study are:

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- **Aspiration of Fat Cells**
  - Subjects will undergo the injection of fat cells if your doctor finds you eligible after the diagnostic knee arthroscopy. The known risks for aspiration/transfer of fat cells include a risk for soreness, redness, swelling, and or pain. This procedure requires needle access and this may result in discomfort, pain, bruising, tenderness, bleeding, swelling and or infiltration at the injection site. These symptoms are temporary. There is a slight risk of infection at the injection site as with any other injection procedure. There are rare but possible risks and complications due to fat transfer including an allergic reaction to the local anesthetic (numbing medication), hematoma or seroma (an accumulation of blood or fluid under the skin that may require removal), changes in sensation, unsatisfactory results that may necessitate additional procedures, permanent discoloration caused by a ruptured blood vessel at the treatment site, a divet or dimpling in the area of the tissue harvest, a blood clot in the treatment leg or donor site.
- **Knee Arthroscopy**
  - Risks of knee arthroscopy are uncommon, occurring in less than 5% of patients. These risks include:
    - Swelling: The knee may fill with fluid or rarer, blood. This usually resolves on its own however may occasionally require a second operation or draining of the fluid.
    - Persistence of pain: In patients who have arthritis, the results of arthroscopic surgery are more variable. Some patients significantly benefit from surgery, others do not. In the patient who has arthritis it is difficult to predict preoperatively to what extent the patient will benefit and your symptoms of pain may carry on despite the procedure. A repeat arthroscopy or other knee operation may be required to treat your pain.
    - Infection: the wound sites may become red, painful and hot. There may also be a discharge of fluid. These are signs of infection and can usually be treated by antibiotics. Very rarely, the infection may spread to the knee joint itself (requiring a washout) and/or the blood (sepsis) requiring intravenous antibiotics.
    - Damage to structures within or around the knee: this is rare, but may cause further injury and symptoms. This may need further treatment including operation.
    - Damaged instruments: these may break within the knee and require an opening of the joint to remove them.
    - Abnormal wound healing: the scar may become thick, red and painful (keloid scar). There may also be some oozing of clear fluid which should resolve on its own.
    - Numbness: the skin around the knee and shin may be temporarily or more permanently numb due to damage of small superficial nerves.
- **MRI:**

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MRI is generally a well-tolerated procedure, and all patients will be screened for MRI safety prior to imaging. In addition, the Hospital for Special Surgery operates the MRI units within the safety guidelines established by General Electric Health Care, Milwaukee, Wisconsin. There is no ionizing radiation involved with MR imaging The potential risks are minimal and include claustrophobia, coil element heating and peripheral nerve stimulation, although the latter two are considered highly unlikely, given that the patients will be imaged within preset safety guidelines to eliminate peripheral nerve stimulation. Coil element heating ranges from a mild sensation of heat to a potential burn. This is considered highly unlikely, as the coils have all undergone extensive testing and clinical use, and special pads are placed surrounding all contact points. If you are pregnant or suspect that you may be pregnant, you should notify your physician. Due to the potential for a harmful increase in the temperature of the amniotic fluid, MRI is not advised for pregnant patients. MRI generally is not advised for patients with epilepsy. There may be other risks depending upon your specific medical condition. Be sure to discuss any concerns with your physician prior to the procedure.

There may be risks or side effects that are unknown at this time. If we learn about new risks that may affect your willingness to continue your participation, we will make you aware of them and you will be asked to re-consent to continue your participate in the study.

Your condition may not get better from being in this study.

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information [(i.e., names, social security numbers, medical record numbers)]; (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

5. PREGNANCY

Due to the risks associated with knee arthroscopy and aspiration of fat, women who are pregnant or nursing a child may not receive the type of surgery or procedure needed to participate in this research study. If you are currently pregnant or nursing a child, you may not participate in this study. But if you become pregnant or begin nursing a child after you have enrolled in this study and after the surgery or procedure has occurred, you may continue to participate in this study. If you are pregnant at the time of any post-operative imaging required for this study, please inform the investigation staff. You may defer your post-operative MRI and still be enrolled in this study.

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6. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at HSS and your medical care at HSS, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

7. PAYMENT FOR PARTICIPATION

You will not be paid for your participation in this study.

8. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (such as blood or tissue) collected from you during the study, or other permitted activities under this consent, even if they are used to develop or make a commercial product (such as a drug, device, biologic substance, or test).

9. RESEARCH STUDY LISTED ON THE INTERNET.

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.

10. WHO WILL BE ABLE TO SEE YOUR RECORDS AND PERSONAL INFORMATION AND KNOW THAT YOU ARE IN THE STUDY?

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. Except in certain instances, including use of your information to provide clinical services, receive payment for those services, or perform health care operation activities such as quality improvement or quality assurance functions, the study doctor must obtain your authorization (permission) to use or give out any health information that might identify you.

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What information may be used or given to others?

If you choose to be in the study, the study doctor will get personal information about you. The information might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about phone calls
- Records about your study visits
- Records of physical exams
- Laboratory, x-ray, and other test results
- Questionnaires
- Records about any study device you received

Who may use, disclose, or receive my information?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

- The Principal Investigator and other Investigators for this study, including your study doctor.
- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, Weill Cornell Medical Center and Memorial Sloan-Kettering Cancer Center
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS main campus or HSS satellite site(s) responsible for administering clinical trials and other research activities, as well as other administrative or management activities of HSS.
- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The sponsor of this study. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.
- Any Contract Research Organization (CRO) the sponsor may use. (A CRO is an independent entity with which a research sponsor contracts to oversee and facilitate various aspects of the clinical research process on the research sponsor's behalf.)
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.
- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, Weill Cornell Medical Center and Memorial Sloan-Kettering Cancer Center. An IRB is a

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committee of health care providers, community representatives, and others that initially approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.

- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

Why will this information be used and/or given to others?

Your health information may be given to others to carry out this study. The sponsor will analyze and evaluate the results of this study. People working for the sponsor also visit HSS and other research sites to make sure this study is being done correctly.

Your health information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can get approval to market new products resulting from this study. Your information may also be used to meet the reporting requirements of governmental agencies.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

Your health information may also be used for certain health care operations activities, such as quality improvement and quality assurance activities of HSS and of the medical practices of physicians and other health care providers who provide clinical and related services at HSS.

In some cases, the doctors involved in this study may use your personal health information for another research study, or share the information with another investigator for a future research study. If done, all identifying information will be removed from your personal health information and you will not be required to provide additional consent to do so.

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

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is "blinded" so that during the study you will not know what treatment or other intervention you are receiving).

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May I revoke (take back) my permission to use and give out my health information?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the Principal Investigator at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

11. SOURCE OF FUNDING

Funding for this study will be internally funded.

12. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

☐ The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

☒ The Conflict of Interest Committee for Research has determined that there is a potential conflict of interest associated with this study. Please read the information below carefully.

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In this study, Dr. Riley Williams, the Principal Investigator, has reported to HSS that he may receive payments from Lipogems USA, the company sponsoring the study whose product is the subject of this study, as a member of their medical advisory board. Because of these interests, Dr. Williams may benefit financially from the outcome or success of this study. HSS's Conflict of Interest Committee has reviewed the potential conflict related to the doctors' financial interest in Lipogems USA.

As part of the effort to reduce the potential for this financial interest to influence the conduct of this study or the analysis of the results of this study, HSS will require that in any publication of the study results, Dr. Williams will disclose the fact that he had a financial interest in Lipogems USA during the time of this study.

If you have questions about the financial interest of Dr. Williams in Lipogems USA , you may ask Dr. Williams to explain it to you. HSS requires its physicians to answer your questions about significant financial interests they hold which are related to studies done at HSS. However, if you are not comfortable discussing this matter with Dr. Williams, you may contact the Vice President of Research at (212) 774-2394 to discuss the financial interest or any other information about the HSS's conflict of interest process that you may want to know about before deciding to participate in this study. You may also contact HSS's Office of Legal Affairs at (212) 606-1592, if you have any questions regarding the disclosure process described above. If, because of the potential for conflict of interest, you choose not to participate in this study, you can withdraw, and you can choose to continue with other treatments at HSS.

13. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

14. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. Riley Williams can be reached at (212)606-1855 during office hours and at 212-606-1000 after business hours. Dr. Andrew Pearle can be reached at (212) 774 2878 during office hours and at 212-606-1000 after business hours.

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If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the HSS Institutional Review Board at (212) 774-7123.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

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Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this "Informed Consent to Participate in Research" form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

☐ I AM NOT in another research study at this time.

☐ I AM in another research study at this time.

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If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

_____

Print Name of Participant | Signature of Participant | Date

_____ _____

Print Name of Parent/Legal Guardian (if applicable)[1] | Signature of Parent/Legal Guardian | Date

_____ _____

Print Name of Person Obtaining Consent | Signature of Person Obtaining Consent | Date

_____

As an HSS representative, and the person obtaining consent, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

NOTE TO INVESTIGATORS:

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S ELECTRONIC MEDICAL RECORD**.

[1] The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»