I, _______________________________ hereby request and authorize:

HAZEM BARMADA, M.D., FRCSEd., FRCS (CTh)

Mississippi Stem Cell Treatment Center, An Affiliate of Cell Surgical Network, Inc.

And,

Dr. _______________________________,

To perform the following procedure:

AUTOLOGOUS ADIPOSE DERIVED STEM CELL (STROMAL VASCULAR FRACTION) DEPLOYMENT (includes stem cells and growth factors).

PURPOSE OF THIS RESEARCH STUDY

I understand the purpose of this procedure is to:

________________________________________________________________________

________________________________________________________________________

Many subjects may benefit from autologous cell therapy for various medical problems. Recent medical studies have shown that some subjects can be helped by cell therapy. Stromal vascular fraction contains adult mesenchymal stem cells. Our practice offers the stromal vascular fraction deployment research program to candidates who meet the other medical screening criteria we have established and who have agreed to comply.
with all requirements of the research program. This research program is designed to study the safety, tolerability, and effects of autologous adipose derived stromal vascular fraction deployed into subjects during a single outpatient visit and allow subjects to be followed for several years to evaluate for short term or long term adverse effects.

You are being asked to be included in this study since you have been diagnosed with a degenerative or inflammatory condition. It is appropriate for subjects to ask any questions about this form and you may even take this form home for consideration before signing. To determine whether you are an appropriate candidate for stromal vascular fraction deployment research, we will ask you to disclose all of your medical history and conditions, possibly obtain blood and other testing, and comply with the treatment and monitoring programs. If you do not completely disclose your medical history and conditions, obtain testing that we recommend and comply strictly with the protocol, you could be exposed to serious medical risks including cancer, disability and death. You are not a candidate for stromal vascular fraction deployment research if you have actively growing cancer.

POSSIBLE BENEFITS

The potential benefits of stromal vascular fraction deployment for eligible patients may include improvement in certain chronic degenerative diseases. Although some benefits often occur, some patients will experience all of them, some will experience some of them and some patients will not experience any of them. Also, the degree of benefit varies. We do not know the long term effects of stromal vascular fraction deployments. We do not know if a stromal vascular fraction administration will be effective 5-10 years after it is administered, and we know of no large study that has conclusively reviewed patients for cancer, or any long term side effect 5-10 years after a stromal vascular fraction deployment.

POSSIBLE RISKS OR DISCOMFORT
The potential risks of stromal vascular fraction deployment include, but are not limited to complications of liposuction (bleeding, bruising, discomfort, infection, scar, unwelcome cosmetic effects, reaction to local anesthesia, damage to internal organs), local reactions to intravenous infusion of stromal vascular fraction (you may experience pain, bruising, vein thrombosis, swelling, hematoma, or bleeding at the puncture site), side effects of intra-arterial injection of stromal vascular fraction, (such as embolization, "clots", damage to arteries and organs, immediate or delayed uncontrolled bleeding from the puncture site are conceivable possibilities), side effects of intra-venous injections of stromal vascular fraction (such as joint pain, swelling, bleeding, infection), and side effects of stromal vascular fraction injection into soft tissue (such as swelling, pain, bleeding, or damage to nerves or internal organs). There are also unknown long term effects of autologous stromal vascular fraction therapy.

Other possible risks could include potentially harmful reactions to resuscitative medications or measures (chest compressions, electrical shock, CPR in general, and/or call 911) in the event that a life threatening reaction is encountered and requires treatment.

If you have an active tumor or cancerous tumor that is present but you are not aware of its existence, we do not know how it would be affected - it could conceivably be made more aggressive.

**AVAILABLE TREATMENT ALTERNATIVES**

Many diseases being treated by stromal vascular fraction deployment may be relieved by other means and your study doctor can discuss these with you. Some symptoms may resolve naturally without medical intervention. Even if you are a candidate for stromal vascular fraction deployment research, you may experience no improvement and therefore would not be harmed by not receiving the deployment.

The effects and nature of adipose derived stromal vascular fraction deployment, the risks involved, the possible complications, and the possible consequences as well as alternatives have been fully explained
to me. I have been given an opportunity to ask any questions concerning the type of procedure and fully understand the responses. I have been given information and instruction sheets pertaining to the proposed procedure. It is my responsibility to read these and abide by the recommendations.

FINANCIAL CONSIDERATIONS

I have been informed that my stromal vascular fraction deployment is part of a patient funded research protocol and therefore, I am responsible for the cost of the procedure.

By participating in this study, I will not be entitled to any remuneration from any patents or later company profits.

I authorize the doctors of MISSISSIPPI STEM CELL TREATMENT CENTER (MSCTC) to employ assistants, nurses, physicians, radiologists, and/or anesthesiologists, or technologists necessary for the procedure and approve their participation. I also authorize the operating surgeon to perform any other procedures, which he may deem necessary or desirable in attempting to improve the conditions encountered during the procedure.

My participation in this research protocol is voluntary and may be withdrawn at any time without penalty. My participation in this may also be withdrawn at any time by MSCTC for any reason without my consent.

I authorize MSCTC and assistants, photographers and technicians to take photographs or video recordings necessary before, during and after. ***Please initial appropriate line: I Permit __ I do NOT Permit ____ such photographs or video recordings and any information relating to my case to be published in professional journals and medical books or to be used for any other purpose that MSCTC or CSCTC may deem appropriate without any further consent, authorization or release by me.
I am willing to discuss my experience with other patients of MSCTC. 

***Please initial: YES _____ NO _____

You must be advised that in case of emergency we will provide resuscitative procedures. I agree _____ I do NOT agree _____

For women: stromal vascular fraction deployment represents potential unknown risks to women who are pregnant or who may become pregnant after deployment. There are also unknown risks to an embryo or fetus. Anesthesia that accompanies this procedure may be harmful to an unborn baby. If you have had a hysterectomy or are post-menopausal you are excluded from having to take a pregnancy test. MSCTC will provide you with a pregnancy test prior to the procedure. All that is required is a small amount of urine. I have been advised by MSCTC to undergo a pregnancy test prior to my operation. I am declining to submit to such test and am certain I am not pregnant. Therefore, I waive any claim I may have against MSCTC should unexpectedly find myself to be/have been pregnant during my operation. I also understand that I have the right to request a pregnancy test after signing this informed consent. *** Please initial ____

I know the practice of medicine and surgery is not an exact science and, therefore, reputable practitioners cannot properly guarantee outcomes. I acknowledge that no guarantee or assurance (expressed or implied) has been made by anyone regarding the Stromal Vascular Fraction deployment procedure that I have herein requested and authorized.

By signing this consent, I acknowledge that I:

(1) read this form (or it was read to me) carefully;
(2) asked any question that I wished;
(3) received satisfactory answers to my questions and requests for additional information;
(4) will disclose my medical history and conditions truthfully and completely to the practice;
(5) will inform the practice promptly of any change in my health or symptoms or any complication of treatment; and
(6) voluntarily agree to participate in the research protocol.
I will receive a copy of this signed and dated consent.

Dated: ____________________

________________________________________
Signature of Patient or Legal Guardian

________________________________________
Printed Name of Patient or Legal Guardian

________________________________________
Witness' Signature

________________________________________
Signature of person giving informed consent

For any questions about the following:

• Questions about the research
• Questions about research-related injury or illness
• Questions about one's rights as research subjects

Contact Dr. Barmada at (228) 875-0885 or (866) 885-4823.
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Sponsor: MISSISSIPPI STEM CELL TREATMENT CENTER

Investigator- Hazem Barmada, M.D., FRCSEd., FRCS (CTh)

STUDY TITLE AND NUMBER: AUTOLOGOUS ADIPOSE DERIVED STROMAL VASCULAR FRACTION DEPLOYMENT #CSN111

Research, Privacy, and the new Health Insurance Portability and Accountability Act (HIPAA)

1. What is the purpose of this form?

We would like to use your health information for research. This information includes data that identifies you during the process of data collection. The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996 require your approval to use health information about you that identifies individuals. This approval is called an Authorization.

By signing this Authorization form, you are giving permission for the use of your protected health information for research purposes. This information may include data that identifies you. Please carefully review the information below. If you agree that we can use your protected health information, you must sign and date this form to give your approval.

2. What protected health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that will be needed for their research. If you participate in this research study, information that will be used and/or released may include the following:

We will use your information from your medical records, results of laboratory tests and case report forms and both clinical and research observations made while you take part in the research. Clinical information collected will include any new diagnoses, reported symptoms, changes in body appearance, how well you feel physically and emotionally, what medications you are prescribed and how many times you have missed taking your prescribed study medication, and any problems you may be
having that are related to taking your study medication. Blood may be collected at each study visit and the results of those tests will also be recorded.

3. Why do the researchers want my protected health information?

In enacting HIPAA, Congress mandated the establishment of Federal standards for the privacy of individually identifiable health information. The Privacy Rule establishes safeguards to protect the confidentiality of medical information and provides guidelines for research organizations such as Kessler Foundation Research Center to use or disclose protected health information for purposes preparatory to research such as to aid study recruitment. We believe that the protection of identified medical information will facilitate medical research because research participants know that their information is protected in accordance with the Privacy Rule.

4. Who may see your protected health information for this research study?

Your health information may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research. We may share this information with others who are in charge of the research and/or who pay for or work with us on the research or those who make sure that we do this research properly. This authorization form will explain how your protected medical information will be used and shared (disclosed) in this research study.

To meet regulations or for reasons related to this study, the study team may share a copy of this approval form and records that identify you with the following people:

- The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
5. **What happens if I sign this Authorization?**

If you agree to give approval to use and share your protected information as described in this form, your authorization will not expire unless you cancel it. The information collected during your participation for this study will be kept indefinitely. By signing this approval form, you give us permission to use and share your protected health information.

6. **What happens if I do not sign this approval form?**

If you do not sign this approval form, you will not be able to take part in the research study for which you are being considered.

7. **If I sign this form, will I automatically be entered into the research study?**

No, you cannot be entered into any research study without further discussion and a separate consent form. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research approval (Informed Consent) form.

8. **What happens if I want to remove my approval?**

You can change your mind at any time and remove your approval to allow your protected health information to be used in the research. If this happens, you must remove your approval in writing. Beginning on the date you remove your approval, no new protected health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your approval.

If after signing this form, you want to remove your approval, please contact the person(s) below. He/she will make sure your written request to remove your approval is processed correctly.

Hazem Barmada, M.D.
Tel. (228) 875-0885 and Fax (228) 875-8819

- Members of the study team, including MSCTC, Dr. Berman, Dr. Lander, Dr. See.
FDA (United States Food and Drug Administration) - the government agency that reviews all research information for approval of new drugs and treatments for the public.

You have the right to look at your study information at the study doctor's office and to ask (in writing) for corrections of any of your information that is wrong.

We will make every effort to keep information we learn about you private. However, research involves gathering, recording, and transferring information that needs to be verified and other people may need to see the information (these others are listed on this form). Some of these people may share your health information with someone else. If they do, the same laws that the hospital, clinic or institution must obey to protect your health information may not apply to these other people or institutions.

9. *How long will these approvals last?*

If you agree by signing this form that researchers can use your protected health information, this approval has no expiration date. However, as stated above, you can change your mind and remove your approval at any time.

Questions should be directed to the research staff person who is reviewing this form with you. You can also call the Mississippi Stem Cell Treatment Center privacy officer at (228) 875-0885 ext. 1.
SIGNATURE PAGE

This form does not replace the Informed Consent to participate in research. It provides additional information related to the use and disclosure of your protected health information. Your signature means that you are giving approval (authorization) for the use and disclosure of your protected health information for research purposes, as described in this form. You will be given a copy of this form to keep.

______________________________    _________________________
Signature of Research Participant          Date

Printed Name of Research Participant

______________________________    _________________________
Signature of Investigator Obtaining Approval          Date

Printed Name of Investigator