AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Sponsor: GULF COAST STEM CELL & REGENERATIVE MEDICINE CENTER

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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.

DR. Hazem Baramda M.D.
Tel. 228-875-2840 and Fax 228-875-8819

- Members of the study team, including Dr. Barmada, 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 GULF COAST STEM CELL & REGENERATIVE MEDICINE CENTER privacy officer at 228-875-2840.

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.

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Signature of Research Participant **Date**

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Printed Name of Research Participant

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Signature of Investigator Obtaining Approval **Date**

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Printed Name of Investigator