Date Received: _____

Memorial Health University Medical Center
Institutional Review Board

SUBMISSION FOR CHANGE OF PROCEDURE TO ORIGINAL STUDY

Study Title:

MHUMC Study Number *(assigned by IRB):*

This study involves: ☐ Clinical treatment ☐ Pre-existing data/tissue ☐ Questionnaire/survey

Initial approval date: **Estimated duration of study?** ☐ < 1 year ☐ 1-2 years ☐ > 2 years

Type of review requested for this submission: ☐ Expedited ☐ Full Board

RESEARCH TEAM

Principal Investigator Information:
Name: Phone:
Address: Email:

Program Director:

Sub-investigator(s) *(list all)*:

Study Coordinator:

TYPE OF CHANGE TO STUDY: *(check all that apply)*

☐ Study Update	☐ Permanent closure to accrual	☐ Change in Investigators
☐ Revised Protocol	☐ Temporary closure to accrual	☐ Revised 1572
☐ Amendment	☐ Reactivation of Enrollment	☐ Promotional Materials
☐ Addendum	☐ Consent Modification	☐ Administrative Letter
☐ Investigator Brochure	☐ Assent Modification	☐Other
☐ DSMB Report	☐ HIPAA Modification	

Current Subject Status:
accruals to date: → # in active treatment: # completed with no further f/u:
completed, in long-term f/u: # withdrawn:
Reason for withdrawal(s):

Details: *(Include brief summary of changes, including amendment/revision numbers, version dates, etc., and any anticipated impact on existing accruals):*

Change in Risk:
Any change in risk due to procedure change? ☐ No ☐ Yes → ☐ Increase OR ☐ Decrease

Explain (if yes):

INVESTIGATOR STATEMENT

I certify that the information provided on this submission form is accurate. I acknowledge the MHUMC Institutional Review Board (IRB) has the authority to oversee this study and to suspend the study if necessary to protect the rights and welfare of the study subjects. I agree to provide the MHUMC IRB with the information it requires to conduct oversight of this study on a timely basis, and if the information is not provided, the MHUMC IRB may suspend the study. I agree to protect the privacy of research subjects' protected health information (PHI) as required by federal HIPAA regulations. I agree to conduct the study in accordance with the conditions of approval required by the MHUMC IRB and in accordance with all applicable federal and state regulations, and institutional policies. On an ongoing basis, I agree to disclose to the MHUMC Institutional Review Board any potential Conflicts of Interest that may arise in the course of my official duties on behalf of Memorial Health.

_____ _____
Principal Investigator (signature) Date

_____ _____
Program Director (signature) Date

**** * * Section below for IRB administrative use only * * ****

☐ Approved by Full Board Review
Approval Date: _____

☐ Approved by Expedited Review
Approval Date: _____

☐ Not approved
Reason: _____

Additional notes:

_____ _____
IRB Chair Date

CPA #: _____

IRB Agenda: _____