

Memorial Health University Medical Center
Institutional Review Board

Date Received: _____

SUBMISSION FOR CHANGE OF PROCEDURE TO SPONSORED 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:

Sub-investigator(s) (list all):

Study Coordinator:

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

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

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completed, in long-term f/u: # withdrawn: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.

Principal Investigator (signature)

Date

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

<input type="checkbox"/> Approved by Full Board Review Approval Date: _____	<input type="checkbox"/> Approved by Expedited Review Approval Date: _____	<input type="checkbox"/> Not approved Reason: _____
Additional notes:		
_____ IRB Chair	_____ Date	CPA #: _____ IRB Agenda: _____