

**Memorial Health University Medical Center
Institutional Review Board**

SUBMISSION FOR RENEWAL OF SPONSORED STUDY

Study Title:

MHUMC Study Number:

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

RESEARCH TEAM

Principal Investigator Information:

Name:

Phone:

Address:

Email:

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

Study Coordinator:

PROFILE OF ENROLLMENT STATUS

Open Temporarily closed Permanently closed Study completed except for data analysis

expected accruals: # accruals to date: → # in active treatment:
completed with no further f/u:
completed, in long-term f/u:
withdrawn:

Reason for withdrawal(s):

SUMMARY OF SAFETY ISSUES

Any change in risk since last review? No Yes → Increase OR Decrease

Explain (if yes):

Serious adverse events (since last review): # Local: # Non-Local:

Any protocol deviations or other safety issues since last review? No Yes → Explain:

OTHER INFORMATION

Please use this space to provide any other additional information or miscellaneous comments pertinent to the study:

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 continuing review 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

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

The following items have been received for this submission:

- Current version of protocol
- Study synopsis (incl. risks, benefits)
- Study history
- Summary of recent literature or findings (*if available*)
- Informed Consent Form & HIPAA Authorization (*if applicable*)
- Any study changes not yet approved by IRB

IRB REVIEW STATUS

Approved by Full Board Review

Approved by Expedited Review →

45CFR46.110.8a

45CFR46.110.8b

45CFR46.110.8c

45CFR46.110.9

Other: _____

Primary Reviewer: _____

Approval Date: _____

Duration of Approval: _____

Expiration Date: _____

Approval Date: _____

Duration of Approval: _____

Expiration Date: _____

Not approved for following reason(s):

Additional notes:

IRB Chair

Date

CPA #: _____

IRB Agenda: _____