Date Received: __________

Memorial Health University Medical Center
Institutional Review Board

SUBMISSION FOR RENEWAL OF 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

RESEARCH TEAM

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

Program Director:

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withdrawn: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):

Any serious adverse events since last review? ☐ No ☐ Yes → Explain:

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

______________________________ ______________

Program Director (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

Primary Reviewer: ___________________

Approval Date: ______________________
Duration of Approval: ________________
Expiration Date: _____________________

☐ Approved by Expedited Review →

- ☐ 45CFR46.110.8a
- ☐ 45CFR46.110.8b
- ☐ 45CFR46.110.8c
- ☐ 45CFR46.110.9
- ☐ Other: __________________________

Approval Date: ______________________
Duration of Approval: ________________
Expiration Date: _____________________

☐ Not approved for following reason(s):

Additional notes:

______________________________ ______________

IRB Chair Date

CPA #: _____________________

IRB Agenda: ________________