Date Received: _____
IRB Agenda: _____

Memorial Health University Medical Center
Institutional Review Board

INITIAL SUBMISSION FOR NEW ORIGINAL STUDY

Study Title:

MHUMC Study Number *(assigned by IRB):*

☐ **This study involves clinical treatment.**

☐ **This study involves pre-existing tissue and/or data.**

Is the tissue or data de-identified? ☐ No ☐ Yes

Is there a link enabling identification of subjects by third party? ☐ No ☐ Yes
If "yes," will the study team have access to the link? ☐ No ☐ Yes

☐ **This study involves neither clinical treatment nor pre-existing tissue or data (e.g., is a questionnaire/survey).**

What is the estimated duration of this study? ☐ < 1 year ☐ 1-2 years ☐ > 2 years

RESEARCH TEAM

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

Program Director:

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

Study Coordinator:

Have all members of the Research Team submitted a CV and Conflict of Interest Form? ☐ No ☐ Yes

Have all members of the Research Team completed the required NCI educational module (or an approved equivalent) on human subject protections? ☐ No ☐ Yes

Do any members of the Research Team have a specific financial interest in this study?
☐ No ☐ Yes -> Explain:

SUBJECT INFORMATION

How many subjects do you anticipate enrolling at this site?

Which of the following types of subjects will be recruited for this study? *(Check all that apply)*

☐ Inpatients ☐ General population ☐ Adults ☐ Males
☐ Outpatients ☐ Private practice ☐ Minors (< 18 yrs old) ☐ Females

☐ Mentally Impaired ☐ Prisoners ☐ Pregnant females ☐ May be unable to give consent

How will subjects be recruited for this study? *(Check all that apply)*

☐ Practice patient population ☐ Referrals ☐ Chart review ☐ Database/registry
☐ Public Advertisement ☐ Other:

Will subjects be paid or receive any type of reimbursement/incentives for participation?
☐ No ☐ Yes -> Explain:

CONFIDENTIALITY

Will the subject's name, social security number, medical record number, or any other personal identifier (other than coded information) be sent off site? ☐ No ☐ Yes

Explain security measures in place to protect confidentiality:

INFORMED CONSENT PROCESS

Will this study require an informed consent process? ☐ Yes ☐ No → If "no", provide explanation:

(If "yes"): Do you agree that all potential subjects will be given ample time to read the Informed Consent Form prior to conducting any study-related procedures, and to spend as much time as needed to thoroughly explain the study, including its risks, the subject's right to decide not to participate or to withdraw at any time, and respond to any subject questions about the study, and allow them as much time as needed to consider their decision and discuss it with their family members if they so desire prior to enrolling them as subjects? ☐ Yes ☐ No

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 initial and 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:

- ☐ Complete protocol
- ☐ Study synopsis (incl. risks, benefits)
- ☐ Advertising/Educational materials
- ☐ Informed Consent Form(s)
- ☐ HIPAA Authorization Form (*if not part of ICF*)
- ☐ Assent Form (*if applicable*)
- ☐ C.V. for all research team members -> ☐ Already on file
- ☐ COI Statement for all research team members -> ☐ Already on file
- ☐ Proof of human subject protections education -> ☐ already on file

IRB REVIEW STATUS

☐ Approved by Full Board Review

Primary Reviewer: _____
Secondary Reviewer: _____

Approval Date: _____
Duration of Approval: _____
Expiration Date: _____

☐ Approved by Expedited Review

Expedited Category: _____

Approval Date: _____
Duration of Approval: _____
Expiration Date: _____

☐ Qualifies for Exempt Status

Exempt Category: _____

☐ Not approved for following reason(s):

Additional notes:

_____ _____
IRB Chair Date