

Memorial Health University Medical Center  
Institutional Review Board

**INITIAL SUBMISSION FOR NEW SPONSORED STUDY**

**Study Title:**

**MHUMC Study Number (assigned by IRB):**

**Study Sponsor:**

**This study involves a drug or biologic. IND # (if applicable):**

This study is:  Phase I  Phase II  Phase III  Phase IV  Treatment

**This study involves a device. IDE or HDE # (if applicable):**

This device is:  Investigational **OR**  Marketed

This device is:  Significant Risk **OR**  Non-Significant Risk (include justification of NSR determination)

**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 a drug, a device, nor pre-existing tissue/data (e.g., is a questionnaire/survey).**

**Will this study be federally-funded?**  No  Yes -> Office of Sponsored Research must have copy of grant.

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

**RESEARCH TEAM**

**Principal Investigator Information:**

Name:

Phone:

Address:

Email:

**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 (other than payment)?

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
- Outpatients
- Mentally Impaired
- General population
- Private practice
- Prisoners
- Adults
- Minors (< 18 yrs old)
- Pregnant females
- Males
- Females
- May be unable to give consent

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

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

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

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

The following items have been received for this submission:

- |   |   |
|---|---|
| <input type="checkbox"/> Complete protocol                              | <input type="checkbox"/> Informed Consent Form(s)   |
| <input type="checkbox"/> Study synopsis (incl. risks, benefits)         | <input type="checkbox"/> HIPAA Authorization Form ( <i>if not part of ICF</i> )                                   |
| <input type="checkbox"/> FDA Form 1572 ( <i>if applicable</i> )         | <input type="checkbox"/> Assent Form ( <i>if applicable</i> )   |
| <input type="checkbox"/> Investigator Brochure ( <i>if applicable</i> ) | <input type="checkbox"/> C.V. for all research team members -> <input type="checkbox"/> Already on file           |
| <input type="checkbox"/> Advertising/Educational materials              | <input type="checkbox"/> COI Statement for all research team members -> <input type="checkbox"/> Already on file  |
|   | <input type="checkbox"/> Proof of human subject protections education -> <input type="checkbox"/> already on file |

**MRAC/ORAC approval date:** \_\_\_\_\_

**IRB REVIEW STATUS**

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> Approved by Full Board Review | <input type="checkbox"/> Approved by Expedited Review | <input type="checkbox"/> Qualifies for Exempt Status |
|--|---|--|

Primary Reviewer: \_\_\_\_\_  
Secondary Reviewer: \_\_\_\_\_

Expedited Category: \_\_\_\_\_

Exempt Category: \_\_\_\_\_

Approval Date: \_\_\_\_\_  
Duration of Approval: \_\_\_\_\_  
Expiration Date: \_\_\_\_\_

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Duration of Approval: \_\_\_\_\_  
Expiration Date: \_\_\_\_\_

Not approved for following reason(s):

Additional notes:

\_\_\_\_\_  
IRB Chair

\_\_\_\_\_  
Date