Reviewer: _____

MEMORIAL HEALTH UNIVERSITY MEDICAL CENTER
Savannah, Georgia

IRB REVIEWER'S ASSESSMENT FOR NEW STUDY SUBMISSIONS

Study: _____ □ Primary review
□ Secondary review

Reviewer's report to full board at meeting should include the following general information about the study:

- Sponsor
- Study purpose/objectives
- Basic study design
- Summary of potential benefits and risks
- Targeted population & expected local enrollment
- Local recruitment plan

Does the ICF include the following elements required by federal regulations 21CFR50.25 and 45CFR46.116?	***Yes***	***No***	***N/A***
(1) Statement that the study involves research			
(2) Explanation of purpose of research			
(3) Expected duration of subject's participation			
(4) Description of procedures to be followed			
(5) Identification of any procedures which are experimental			
(6) Description of any foreseeable risks or discomforts			
(7) Description of any benefits to subject or to others that may be reasonably expected from the research			
(8) Disclosure of alternative procedures or course of treatment, if any			
(9) Description of measures to protect confidentiality (refer to HIPAA section below)			
(10) Explanation about compensation, if any			
(11) In case of injury or accident, explanation of what medical treatments are available, who will pay for this treatment, and availability of any additional compensation			
(12) Explanation of whom to contact for answers about the research (PI's name and phone #)			
(13) Explanation of whom to contact for answers about subject's rights (IRB Chair's name and phone #)			
(14) Explanation of whom to contact in the event of a research-related emergency (name and 24-hour phone #)			
(15) Statement that participation is voluntary, and subject's refusal to participate will not involve penalty or loss of benefits			
(16) Statement that the subject may discontinue participation at any time without penalty or loss of benefits			
(17) Under 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."			
(18) Under new 45CFR46.116(a)(2), for studies that evaluate two or more standards of care, reasonably foreseeable risks or discomforts have been adequately identified			

Does the ICF include the following additional elements, as appropriate?	***Yes***	***No***	***N/A***
(1) Number of subjects to be involved in the study, both overall and MHUMC			
(2) Description of consequences if subject decides to withdraw from research, and procedure for orderly termination of subject's participation			
(3) Statement that study may involve risks that are currently unforeseeable (e.g., to fetus or embryo)			
(4) Anticipated circumstances under which investigator may terminate subject's participation without regard to subject's consent			
(5) Description of any additional costs subject may incur due to participation in research			
(6) Statement that new significant study findings will be provided to subject			

In accordance with the HIPAA Privacy Rule (45CFR164), are the following elements included in either the ICF or a separate form to authorize use/disclosure of subjects' protected health information (PHI)?	***Yes***	***No***
(1) Description of information intended for use in the study		
(2) People/organizations who may use/disclose the information (e.g., investigator, research coordinator)		
(3) People/organizations who will receive the information (e.g., sponsor, FDA, OHRP, IRB, etc.)		
(4) Purpose of the use/disclosure		
(5) Statement about subject's right to refuse to sign authorization		
(6) Statement about subject's right to revoke authorization, which must be submitted in writing to the investigator		
(7) Statement informing subject of potential re-disclosure of information by recipient		
(8) Statement that subject will receive a signed copy of authorization		

In accordance with the HIPAA Privacy Rule (45CFR164), if the study qualifies for a waiver of authorization (i.e., there is no ICF), is the following information provided by the investigator to justify the waiver?	***Yes***	***No***
(1) The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on: (a) an adequate plan to protect the identifiers from improper use and disclosure; (b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and (c) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart		
(2) The research could not practicably be conducted without the waiver or alteration		
(3) The research could not practicably be conducted without access to and use of the PHI		

In accordance with federal regulations 21CFR56.111 and 45CFR46.111, are the following criteria satisfied?	***Yes***	***No***
(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.		
(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research.		
(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.		
(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 21CFR50 and 45CFR46.116.		
(5) Informed consent will be appropriately documented, in accordance with and to the extent required by 21CFR50.27 and 45CFR46.117.		
(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.		
(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.		

REVIEWER'S RECOMMENDATIONS

Recommendation for approval: ☐ yes ☐ no If yes, recommended duration of approval? ☐ 1 year ☐ 6 mos ☐ 3 mos

Comments: _____

_____ _____

Signature of Reviewer Date