SITE RESOURCES CHECKLIST

Clinical Trials outside UERMMMCI by UERMMMCI Personnel

SELF-ASSESSMENT TOOL

DATE: _____

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: Complete this form if you are a UERMMMCI principal investigator applying for ethical clearance from the RIHS ERC for a clinical trial or clinical research that will be conducted outside the UERMMMCI premises. This form is mandatory for the aforementioned investigator-site category. All fields should be completely filled out. If necessary, supporting documentation may be required.

Kindly fill out this form accordingly

RIHS ERC Code	
Principal Investigator	
Contact Number	
External Site	
External Site Address	
Medical Director (External Site)	
Contact Number	
Study Sponsor	
Study Protocol Title	

A. Safety Requirements for Research Participants

Does your Institution provide a **24-hr emergency room** service?

_____ YES, proceed to A-1 and do not fill out A-2

_____ NO, proceed to A-2

A-1	Yes	No	Remarks
1. Does your emergency room have a fully loaded			

e-cart?			
2. Does your emergency room have a functioning defibrillator?			

A-2	
1. If you do not have a 24-hr emergency room service, where do you intend to refer your research participants in case of adverse events especially after office hours?	<Name of emergency facility>
2. Describe nature of your appointment in the hospital where patients will be referred for emergency care in case of an adverse event? (NOTE: Final RIHS ERC approval also depends on the feasibility of logistics in cases of adverse events to ensure safety of participants)	<description>

B. Administrative Questions

	YES	No	Remarks
1. Do you have an office space in the clinic that is conducive to the conduct of the clinical trial?			
2. Do you have a telephone line?			
3. Do you have a fax machine on 24 hrs?			
4. Will the sponsor be willing to shoulder expenses for monitoring of the study by the RIHS ERC (1 visit per one year duration of study by two RIHS ERC members and 1 Staff doing the site visit)?			
5. Are you and your clinic/hospital administrator willing to have a Memorandum of Agreement (MOA) with UERM regarding the review of the study protocol and monitoring of the conduct of study by the RIHS ERC?			
6. Where do you plan to recruit your research participants?	<name of site>		
7. How many patients with the condition of interest do you see per month in your clinic or hospital?	<quantity>		

PRINCIPAL INVESTIGATOR	Name	
Date:	Signature	
ADMINISTRATOR[1]	Name	
Date:	Signature	

[1] Signatory official for clinic or hospital