

ERC Form 4F: Site Visit Report

UNIVERSITY OF THE EAST RAMON MAGSAYSAY MEMORIAL MEDICAL CENTER, INC.

Aurora Boulevard, Quezon City



Research Institute for Health Sciences



ETHICS REVIEW COMMITTEE

SITE VISIT REPORT

INSTRUCTIONS TO THE RIHS ERC PANEL MEMBER/ REPRESENTATIVES: A Site Visit is conducted as result of full board action for purposes of monitoring study protocol compliance in the study site. The visit is limited to the review of study protocol related documents and procedures that have been approved by the RIHS ERC Panel that issued the ethical clearance or approval of the study. The visit should not in any way compromise the obligation to protect the privacy and confidentiality of research-related information of study participants/subjects. The Panel Chair should ensure that the Site Visit Team is well-prepared to conduct the visit through a complete review of the study protocol folder prior to the visit. This form should reflect the consensus opinion of the Site Visit Team; the results of which are reported in the next RIHS ERC Panel meeting.

RIHS ERC CODE:		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
Email:	Telephone:	Mobile:
STUDY SITE:		
STUDY SITE ADDRESS:		
SITE VISIT DATE:		
1. Total participants expected:		
2. Total participants enrolled:		
3. Are site facilities appropriate?		
3.1. <input type="checkbox"/> YES		
3.2. <input type="checkbox"/> NO		
3.3. COMMENTS:		
4. Are informed consent documents updated to the version approved by the RIHS ERC Panel?		
4.1. <input type="checkbox"/> YES		
4.2. <input type="checkbox"/> NO		
4.3. COMMENTS:		
5. Are there any SAE/SUSAR reports not previously reported to the RIHS ERC?		

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5.1. <input type="checkbox"/> YES 5.2. <input type="checkbox"/> NO 5.3. COMMENTS:												
6. Are there any events of protocol noncompliance not previously reported to the RIHS ERC? 6.1. <input type="checkbox"/> YES 6.2. <input type="checkbox"/> NO 6.3. COMMENTS:												
7. Are investigation products and study documents secured adequately? 7.1. <input type="checkbox"/> YES 7.2. <input type="checkbox"/> NO 7.3. COMMENTS:												
8. Are all other RIHS ERC-Panel-approved documents (e.g. advertisements) used in accordance with the approved study protocol? 8.1. <input type="checkbox"/> YES 8.2. <input type="checkbox"/> NO 8.3. COMMENTS:												
9. Are there any significant findings in this visit that could affect participant's/subject's rights, safety or welfare 9.1. <input type="checkbox"/> YES 9.2. <input type="checkbox"/> NO 9.3. COMMENTS:												
10. Overall, does the study site provide adequate protection for the rights, safety or welfare of study participants/subjects? 10.1. <input type="checkbox"/> YES 10.2. <input type="checkbox"/> NO 10.3. COMMENTS:												
11. How well are study participants/subjects protected? 11.1. <input type="checkbox"/> GOOD 11.2. <input type="checkbox"/> FAIR 11.3. <input type="checkbox"/> NOT GOOD 11.4. COMMENTS:												
12. Are there further actions or queries resulting from this site visit? 12.1. <input type="checkbox"/> YES 12.2. <input type="checkbox"/> NO 12.3. COMMENTS:												
13. Additional remarks												
14. Duration of visit: <hours >/ From <hh:mm> to <hh:mm>												
COMPLETED BY THE FOLLOWING RIHS ERC PANEL MEMBER/ REPRESENTATIVES:												
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">NAME</th> <th style="width: 30%;">SIGNATURE</th> <th style="width: 20%;">DATE</th> </tr> </thead> <tbody> <tr> <td>Name 1</td> <td></td> <td></td> </tr> <tr> <td>Name 2</td> <td></td> <td></td> </tr> <tr> <td>Name 3</td> <td></td> <td></td> </tr> </tbody> </table>	NAME	SIGNATURE	DATE	Name 1			Name 2			Name 3		
NAME	SIGNATURE	DATE										
Name 1												
Name 2												
Name 3												

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RECOMMENDED ACTION: *(For RIHS ERC use only)*

- ☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION
- ☐ REQUEST INFORMATION: (specify)
- ☐ RECOMMEND FURTHER ACTION: (specify)

PRIMARY REVIEWER

Signature _____

Date:

Name _____

RIHS ERC SECRETARY

Signature _____

Date:

Name _____

RIHS ERC CHAIR

Signature _____

Date:

Name _____