Date of Issuance:

NOTICE OF MEETING

TO:

<NAME OF RIHS ERC REVIEW PANEL> Members:

Name 1
Name 2
Name 3
Name 4
Name 5
Name 6
Name 7
Name 8

DATE OF MEETING:
TIME OF MEETING:
VENUE OF MEETING:

AGENDA:

1. **Call to order:**
2. **Determination of quorum:**
3. **Disclosure of Conflict of interest:**
4. **Reading and approval of the agenda:**
5. **Reading and Approval of the Minutes of the last meeting:**

6. **Business arising from the Minutes of the last meeting:**
7. **Protocol review**
   - **7.1. FULL REVIEW**
     - **7.1.1. Study Protocols for Initial Review:**

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of scientific soundness	1. Objectives/Expected output: 2. Literature review: 3. Research design: 4. Sampling design: 5. Sample size: 6. Statistical analysis plan (SAP): 7. Data analysis plan: 8. Inclusion criteria: 9. Exclusion criteria: 10. Withdrawal criteria: 11. Specimen handling: 12. PI qualifications: 13. Suitability of the site: 14. Duration: 15. Conflict of Interest: 16. Privacy and Confidentiality: 17. Informed consent process: 18. Vulnerability: 19. Recruitment: 20. Assent: 21. Risks: 22. Benefits: 23. Incentives or Compensation: 24. Community Considerations: 25. Collaborative study terms of reference: 26. Methodology:	Summary of Recommended Actions:
Assessment of Ethical Issues	1. Statement that the study involves research: 2. Statement describing the purpose of: 3. Study-related treatments and probability for random assignment: 4. Study procedures including all invasive procedures: 5. Reason for inclusion of subject: 6. Responsibilities of the participant: 7. Expected duration of participation in the study: 8. Approximate number of participants in the study: 9. Study aspects that are experimental:	

	10. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner: 11. Risks from allowable use of placebo (as applicable): 12. Reasonably expected benefits; or absence of direct benefit to participants, as applicable: 13. Expected benefits to the community or to society, or contributions to scientific knowledge: 14. Description of post-study access to the study product or intervention that have been proven safe and effective: 15. Alternative procedures or treatment available to participant: 16. Compensation or insurance or treatment entitlements of the participant in case of study-related injury: 17. Anticipated prorated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount: 18. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries: 19. Anticipated expenses, if any, to the participant in the course of the study: 20. Appropriateness of language used: accurate, simple and concise content 21. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled: 22. Statement that the study monitor(s), auditor(s), the RIHS ERC Ethics Review Panel, and regulatory authorities will be granted direct access to participant's medical records for purposes **ONLY** of verification of clinical trial procedures and data: 23. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published;	

	including limitations to the investigator's ability to guarantee confidentiality: 24. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant: 25. Possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study: 26. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed: 27. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development: 28. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation: 29. Statement describing access of participant to the result of the study: 30. Statement describing extent of participant's right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure): 31. Foreseeable circumstances and reasons under which participation in the study may be terminated: 32. Sponsor, institutional affiliation of the investigators, and nature and sources of funds: 33. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider: 34. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury: 35. Statement that the RIHS ERC has approved the study, and may be reached through the	

	following contact for information regarding rights of study participants, including grievances and complaints: **Maria Milagros U. Magat, MD, MEM** **Chair, RIHS ERC** **Address:** 2/F JMC Bldg Aurora Blvd. Quezon City **Email: e**thicsreviewcommittee@uerm.edu.ph **Tel:** +63 2 7161843 local 358	
Recommended Action		

7.1.2. Resubmissions or Study Protocols for Modification:

RIHS ERC Code		
Study Protocol Resubmission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of scientific soundness	1. Objectives/Expected output: 2. Literature review: 3. Research design: 4. Sampling design: 5. Sample size: 6. Statistical analysis plan (SAP): 7. Data analysis plan: 8. Inclusion criteria: 9. Exclusion criteria: 10. Withdrawal criteria: 11. Specimen handling: 12. PI qualifications: 13. Suitability of the site: 14. Duration: 15. Conflict of Interest: 16. Privacy and Confidentiality: 17. Informed consent process: 18. Vulnerability: 19. Recruitment: 20. Assent: 21. Risks: 22. Benefits: 23. Incentives or Compensation: 24. Community Considerations: 25. Collaborative study terms of reference: 26. Methodology:	Summary of Recommended Actions:
Assessment of Ethical Issues	1. Statement that the study involves research: 2. Statement describing the purpose of: 3. Study-related treatments and probability for random assignment: 4. Study procedures including all invasive	

	procedures: 5. Reason for inclusion of subject: 6. Responsibilities of the participant: 7. Expected duration of participation in the study: 8. Approximate number of participants in the study: 9. Study aspects that are experimental: 10. Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner: 11. Risks from allowable use of placebo (as applicable): 12. Reasonably expected benefits; or absence of direct benefit to participants, as applicable: 13. Expected benefits to the community or to society, or contributions to scientific knowledge: 14. Description of post-study access to the study product or intervention that have been proven safe and effective: 15. Alternative procedures or treatment available to participant: 16. Compensation or insurance or treatment entitlements of the participant in case of study-related injury: 17. Anticipated prorated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount: 18. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries: 19. Anticipated expenses, if any, to the participant in the course of the study: 20. Appropriateness of language used: accurate, simple and concise content 21. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled: 22. Statement that the study monitor(s), auditor(s), the RIHS ERC Ethics Review Panel, and regulatory authorities will be granted direct access to participant's medical records for purposes **ONLY** of	

	verification of clinical trial procedures and data: 23. Statement that the records identifying the participant will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality: 24. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant: 25. Possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study: 26. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed: 27. Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development: 28. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation: 29. Statement describing access of participant to the result of the study: 30. Statement describing extent of participant's right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure): 31. Foreseeable circumstances and reasons under which participation in the study may be terminated: 32. Sponsor, institutional affiliation of the investigators, and nature and sources of funds:	

	33. Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider: 34. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury: 35. Statement that the RIHS ERC has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: **36. Maria Milagros U. Magat, MD, MEM** **37. Chair, RIHS ERC** 38. **Address:** 2/F JMC Bldg Aurora Blvd. 39. Quezon City 40. **Email:** **e**thicsreviewcommittee@uerm.edu.ph *41.* **Tel:** +63 2 7161843 local 358	
Recommended Action		

7.1.3. Study Protocols for Clarificatory Interview/Clarification:

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Summary of Modifications:		Summary of Recommended Actions:
Assessment of PI responses to RIHS ERC queries		
Recommended Actions		

7.1.4. Withdrawal of Study Protocol Applications:

RIHS ERC Code	
Study Protocol Submission Date	
Study Protocol Title	
Principal investigator	

Type of review		
Primary reviewer		
Assessment of reasons for Study Protocol withdrawal		Summary of Recommended Actions:
Recommended Actions		

7.1.5. Study Protocol Amendment Application:

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of amendment requested		Summary of Recommended Actions:
Recommended Actions		

7.1.6. Continuing Review Applications:

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of continuing report		Summary of Recommended Actions:
Recommended Actions		

7.1.7. Final Reports:

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of final report		Summary of Recommended Actions:
Recommended Actions		

7.1.8. SAE and SUSAR Reports:

RIHS ERC Code	
Study Protocol	

Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of SAEs reported		Summary of Recommended Actions:
SAE 1	Submission Date	
	Date of SAE	
	Date of randomization	
	Age	
	Sex	
	Country	
	Nature of AE	
	Co-morbidities	
	Status	
Recommended Actions		

7.1.9. Site Visit Reports:

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of Site Visit Report		Summary of Recommended Actions:
Recommended Actions		

7.1.10. Study Protocol Non-Compliance (Deviation or Violation) Reports:

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of Non-Compliance Report		Summary of Recommended Actions:
Recommended Actions		

7.1.11. Early Study Termination Applications:

RIHS ERC Code	
Study Protocol Submission Date	
Study Protocol Title	
Principal investigator	

Type of review		
Primary reviewer		
Assessment of risks from early termination		Summary of Recommended Actions:
Recommended Actions		

7.1.12. Queries or Complaints:

RIHS ERC Code		
Study Protocol Submission Date		
Study Protocol Title		
Principal investigator		
Type of review		
Primary reviewer		
Assessment of query or complaint		Summary of Recommended Actions:
Recommended Actions		

8. Other Matters:

9. Adjournment:

Chair, RIHS ERC

ANNEX 1

REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR

1. Study Protocols for Initial Review

RIHS ERC Code	
Study Protocol Submission Date	
Study Protocol Title	
Principal Investigator	
Type of review	
Primary reviewers	
ACTION	

2. Resubmissions or Study Protocols for Modification

RIHS ERC Code	
Study Protocol Submission Date	
Study Protocol Title	
Principal Investigator	
Type of review	
Primary reviewers	
ACTION	

3. Study Protocol Amendments Applications

RIHS ERC Code	
Study Protocol Approval Date	
Amendment Submission Date	
Study Protocol Title	
Principal Investigator	
Type of review	
Primary reviewers	
ACTION	

4. Continuing Review Applications

RIHS ERC Code	
Study Protocol Approval Date	
Application Date	
Study Protocol Title	
Principal Investigator	
Type of review	
Primary reviewers	
ACTION	

5. Final Reports

RIHS ERC Code	
Study Protocol Approval Date	
Report Date	

Study Protocol Title	
Principal Investigator	
Type of review	
Primary reviewers	
ACTION	

6. Study Protocol Non-Compliance (Deviation or Violation) Reports

RIHS ERC Code	
Study Protocol Approval Date	
Report Date	
Study Protocol Title	
Principal Investigator	
Type of review	
Primary reviewers	
ACTION	

7. Early Study Termination Applications

RIHS ERC Code	
Study Protocol Approval Date	
Application Date	
Study Protocol Title	
Principal Investigator	
Type of review	
Primary reviewers	
ACTION	