**STUDY PROTOCOL AMENDMENT SUBMISSION FORM**

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *A study protocol amendment is a written description of a change/s to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the CLHRDC-ERC that issued the ethical clearance or approval prior to the implementation of an amendment. Obtain an electronic copy of this form and encode all information required in the space provided. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form. Print the report in A4 size paper; then date and sign this form before submission.*

|  |
| --- |
| CLHRDC-ERC Code: |
| Study Protocol Title: |
| Approval Date: |
| Principal Investigator: |
| E-mail: | Telephone: | Mobile: |
| Amendment Submission Date: (to be filled out by CLHRDC-ERC) <mm/dd/yyyy> |
| 1. No. of Amendment/s:
 |
| 1. State Nature of Study Protocol Amendment (cite study protocol section and page where amendment is found)
 |
| 1. Type of Review:
	1.  **EXPEDITED** REVIEW FOR AMENDMENTS THAT:
* Do not involve significant change in the study populations
* Do not involve the collection of stigmatizing information
* Do not change approved use of anonymized or archived samples
* Do not involve further recruitment of participants
* Involve study protocols previously classified under expedited review
* Are administrative in nature (such as contact details of study personnel)
* Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants
	1.  **FULL BOARD REVIEW** for any amendments not cited under EXPEDITED REVIEW
 |
| Signature of Principal Investigator: |

RECOMMENDATIONS (for CLHRDC-ERC use only)

|  |
| --- |
| Comments of Primary Reviewer |
| 1. Effect of amendment on feasibility of the study
 |
| 1. Effect of amendment on safety and well-being of subjects
 |
| 1. Effect of amendment on overall risk-benefit ratio
 |
| RECOMMENDED ACTION:* APPROVE
* MINOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE PANEL CHAIR
* MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL PANEL REVIEW
* DISAPPROVE
* PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE
 |
| PRIMARY REVIEWER Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: <mm/dd/yyyy> Name <Title, Name, Surname> |