

ERC Form 4A: Study Protocol Amendment



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 RIHS ERC Panel 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.*

RIHS ERC CODE:		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
Email:	Telephone:	Mobile:
STUDY SITE:		
STUDY SITE ADDRESS:		
AMENDMENT SUBMISSION DATE:		
<i>(To be filled out by the Principal Investigator):</i>		
1. NO. OF AMENDMENT/S:		
2. STATE NATURE OF STUDY PROTOCOL AMENDMENT (cite study protocol section and page where amendment is found)		

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3. LIST OF DOCUMENTS for which YOU ARE REQUESTING APPROVAL:

4. TYPE OF REVIEW: *(to be checked and classified by the ERC Chair)*

4.1. ☐ EXPEDITED REVIEW FOR AMENDMENTS THAT:

- Do not involve changes in 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

4.2. ☐ FULL BOARD REVIEW for any amendments not cited under EXPEDITED REVIEW

SIGNATURE OF PRINCIPAL INVESTIGATOR:

COMMENTS OF PRIMARY REVIEWER:

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

- ☐ APPROVAL
- ☐ MODIFICATION TO THE STUDY PROTOCOL
- ☐ DISAPPROVAL

PRIMARY REVIEWER	Signature _____
Date:	Name _____
RIHS ERC SECRETARY	Signature _____
Date:	Name _____
RIHS ERC CHAIR	Signature _____
Date:	Name _____