

ERC Form 6B: Protocol Approval Template



<mm/dd/yyyy>

<NAME OF PI>

Principal Investigator

<Institution/Affiliation>

Re: <Study Protocol Title><RIHS ERC Code>

Dear <TITLE OF PI><SURNAME>:

We wish to inform you that the study protocol titled “_title of research protocol_” underwent expedited review and is hereby granted approval for implementation by the **RIHS ERC**. The study has been assigned <RIHS ERC code>, which should be used for all communication to the RIHS ERC related to this study. This ethical clearance is valid for one year until <expiration date>.

The following documents have been approved for use in the study.

1. Study Protocol <version #><date of document>
2. Study Protocol file 1 <version #><date of document>
3. Study Protocol file 2 <version #><date of document>

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Study Protocol file 3 <version #><date of document>
2. Study Protocol file 4 <version #><date of document>

While the study is in progress, the Principal Investigator is requested to submit the following documents WHEN APPLICABLE:

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1. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using the **RIHS ERC FORM 4(A): Study Protocol Amendment Submission Form**.
2. Revisions in the informed consent form using the **RIHS ERC FORM 4(A): Study Protocol Amendment Submission Form**.
3. Reports of adverse events including from other study sites (national, international) using the **RIHS ERC FORM 4(G): Adverse Events Report**.
4. Notice of early termination of the study and reasons for such using **RIHS ERC FORM 4(E): Early Study Termination Application Form**.
5. Any event which may have ethical significance.
6. Any information which is needed by the RIHS ERC to do ongoing review.
7. Notice of time of completion of the study using **RIHS ERC FORM 4(C): Final Report Form**.
8. Application for renewal of ethical clearance at **least 30 days before the expiration date of this approval** through submission of **RIHS ERC FORM 4(B): Continuing Review Application Form**.

Thank you.

Very truly yours,

<NAME OF CHAIR>

Chair, RIHS ERC