

Human Research Ethics Committee

Study Closure or Early Termination Report

Date: _____

General Guidelines:

It is important that the HREC file number be provided in order to link the closure to the appropriate file. If more space is needed, please create additional line spaces. If submitting a hard copy, please photocopy double-sided.

Please note that “study closure” means time of data archiving.

Questions:

The questions in the study closure form are self-explanatory. The information being requested covers three main areas:

- 1) Early termination of studies;
- 2) Closure of completed studies;
- 3) Follow-up procedures for patients, publications and data storage.

Research subjects should be made aware of changes to study protocols. It is also incumbent on the researcher to inform subjects of the medication they were taking during the study (once the study is completed) and also to publish/present the findings, whether positive or negative.

Note: The Principal/Qualified Investigator responsible for the research study must sign and date the study closure form.

| | |
|------------------|--------------|
| HREC Project No. | Study Title: |
| | |

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| Chief/Qualified Investigator: | |
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|---------------------------------------|--|
| Research Coordinator Telephone No: | |
|---------------------------------------|--|

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| Address for correspondence: | |
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|---|--|
| 1 Did the study begin? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 2 If NO , explain why not: | |
| | |
| 3 Was the study terminated early? (If NO go to Question 4) | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| (a) Date of Termination: | |
| (b) Why was the study terminated early? | |
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