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| **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.

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| HREC Project No. | Study Title: |
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| Chief/Qualified Investigator: |  |

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| Research CoordinatorTelephone No: |  |

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| Address for correspondence: |  |

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| **1 Did the study begin?** Yes [ ]  No [ ]  |
| 2 **If NO**, explain why not: |
| **3 Was the study terminated early**? (If NO go to Question 4) Yes [ ]  No [ ]  |
| (a) Date of Termination:  |
| (b) Why was the study terminated early?  |
| (c) Describe how all subjects have been informed of the termination:  |
| (d) Have all subjects been informed of any potential risks due to early closure? Yes [ ]  No [ ]  |

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| 4 **Study Closure** |
| (a) Date of study closure |
| (b) How many patients were expected to be recruited at this site?  |
| (c) What was the final number of patients recruited at this site?  |
| 1. If there is a major discrepancy between (b) and (c) please comment on possible reasons:
 |
| (e) How many study subjects chose to withdraw from the study at this site?  |
| (f) Have study subjects been informed of the type of medication they received in the study? N/A [ ]  Yes [ ]  No [ ]  |
| (g) If NO, when will this occur? If they will not be informed of the type of medication please explain why not |
| **5 Study Outcomes** |
| (a) Have the study findings been presented at any scientific meeting? Yes [ ]  No [ ]  If YES, provide meeting title and date:  |
| (b) Do the investigators or the sponsor plan to publish the results? Yes [ ]  No [ ]  If NO, why not?  |
| (c) If study results are already published please provide a copy of the abstract/publication or reference. |
| **6 Data Storage** |
| (a) Where are the data being stored and for how long?  |
| 1. Who has responsibility for the maintenance of records?
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