UnitingCare Health

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:

Chief/Qualified Investigator:	
Research Coordinator	
Telephone No:	

Address for correspondence:	

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 al	l subjects	have been	informed	of the	termination:
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(d) Have all subjects been informed of any potential risks due to early closure?

Yes

No

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?
(d)	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	
5	Study Outcomes
	Study Outcomes Have the study findings been presented at any scientific meeting? Yes If YES, provide meeting title and date:
(a)	Have the study findings been presented at any scientific meeting? Yes No
(a)	Have the study findings been presented at any scientific meeting? Yes No If YES, provide meeting title and date: Do the investigators or the sponsor plan to publish the results? Yes No
(a) (b)	Have the study findings been presented at any scientific meeting? Yes No If YES, provide meeting title and date: Do the investigators or the sponsor plan to publish the results? Yes No If NO, why not? Yes No If
(a) (b) (c)	Have the study findings been presented at any scientific meeting? Yes No If YES, provide meeting title and date: Do the investigators or the sponsor plan to publish the results? Yes No Do the investigators or the sponsor plan to publish the results? Yes No If If NO, why not? If study results are already published please provide a copy of the abstract/publication or reference. If
(a) (b) (c) 6	Have the study findings been presented at any scientific meeting? Yes No If YES, provide meeting title and date: Do the investigators or the sponsor plan to publish the results? Yes No Do the investigators or the sponsor plan to publish the results? Yes No If If NO, why not? If study results are already published please provide a copy of the abstract/publication or reference. Data Storage

Chief/Qualified Investigator Name

Signature

Date: