UnitingCare Health

Human Research Ethics Committee

Annual Report

Date: _____

1.   Please state the number of patients who were enrolled and withdrawn during the past year.

2.   Provide the total number of patients enrolled in the study locally.
        Note: Questions 1 and 2 provide information to the Committee as to the recruitment status of the research study.

4   Provide the expected date of study closure for Question 4.

5-7   As part of the ongoing study safety analysis, the HREC would like to receive all Data Safety Monitoring Board safety reports. If there is a DSMB and no report is provided, please explain why.

8-10   If you have answered "Yes", please provide the current version number and date, and the HREC approval date for the various documents.

Note: The Chief/Qualified Investigator responsible for the research study must sign and date this annual report.

HREC Project No.	Study Title:

Chief/Qualified Investigator:	

Research Coordinator name, email and Tel No:	

Address for correspondence:	

Date of initial full approval:	

The following report is provided with a request for continued approval for the period _____ to _____

1 During the past year the following number of patients were: a) Enrolled ☐ b) Withdrawn ☐	
2 Total number of patients presently enrolled in the study:	
3 Is recruitment ongoing? Yes ☐ No ☐	
4 What is the expected closure date for this study?	
5 Have there been any serious adverse events in the past year? Yes ☐ No ☐	
6 Have they been reported to the HREC? Yes ☐ No ☐	

7 If there is a Data Safety Monitoring Board, please attach the most recent report.	

	Yes	No
8 Has there been any change to the protocol in the past year?	☐	☐
If yes, current version No: Date of HREC approval:		

	Yes	No
9 In the past year has there been any change to the consent form?	☐	☐
If yes, current version: Date of HREC approval:		

	Yes	No
10 In the past year has there been any change to the Investigator Brochure?	☐	☐
If yes, current version: Date of HREC approval:		

_____   _____

Chief/Qualified Investigator Name   Signature

Date: _____