

IMPROVEMENT ACTIVITIES: PREPARATION OF PAPERS IN CGU FOR HREC ENDORSEMENT

PROCEDURE [®]

DOCUMENT SUMMARY/KEY POINTS

- This document outlines the process to be undertaken by the Clinical Governance Unit (CGU) when preparing the documentation required to have ethically approved Quality Improvement activities endorsed by the Human Research Ethics Committee (HREC).

CHANGE SUMMARY

- Document due for mandatory review. No changes made.

READ ACKNOWLEDGEMENT

- Training Required – Network Manager Quality, Quality Officers
- Clinical Governance Unit (CGU) Staff should read and acknowledge they understand the contents of this document.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st September 2023	Review Period: 3 years
Team Leader:	Network Manager Quality	Area/Dept: Clinical Governance Unit

Purpose/Scope

This document outlines the process to be undertaken by CGU when preparing the documentation required to have ethically approved Quality Improvement activities endorsed by the Human Research Ethics Committee (HREC).

The procedure will be undertaken as required according to the HREC Executive meeting schedule and will be done on the day the meeting papers are due. The papers must be emailed to the Research Ethics Office 1 week prior to the agreed HREC Executive meeting each month. To obtain the HREC Executive meeting schedule contact the Research Ethics Office.

Expected results

Produce a report listing all Quality Improvement activities granted QI Ethics approval by CGU since the previous meeting, plus a report with the details of each activity, and email these to the Research Ethics Office by the due date.

Responsibilities

This procedure is undertaken by either the Network Manager Quality or Quality Officers.

Abbreviations and definitions

HREC: Human Research Ethics Committee

CGU: Clinical Governance Unit

CHARLI: Children's Hospital Achievements Research Links and Improvements (database)

Assumed Knowledge

CHARLI search and reporting functionality

Equipment and supplies

- A computer with software to generate a PDF document from a HTML page, e.g. Adobe Pro.

Procedure

1. From the CHARLI Welcome screen select the QI Ethics HREC Report button (only available to CGU Reviewers), then enter the following parameters:

- i. Start Date = day after last report was run
- ii. End Date = today's date

Note: the report uses this date range to find which activities had a CGU Submit / Review / Approve row completed, with the QI Ethics flag ticked, within the period.

2. Review the report on screen to make sure that the Initiation Details, Ethical Review section and approval comments match. If any changes are required to an activity in CHARLI the project should be resubmitted for QI ethics review. If no changes are required go to step 3.
3. Click 'Print Report' to open the print setup window:
 - i. Click the Preferences button, select Page Orientation = Landscape and click OK (font size is larger and therefore easier to read when this report is printed in Landscape orientation)
 - ii. Under Select Printer, select the PDF software.
 - iii. Click Print
 - iv. Save the file under: 'G:\Continuous Improvement\Ethics\QIE HREC Reports from CHARLI\[Year]' with a file name of 'QI Project report for [date of meeting] HREC Exec meeting'.
4. In CHARLI, search by Ethics Application Number for all activities with the QI number for the month of the upcoming meeting*, e.g. QIE-2009-04 would find all activities that are to go to an April 2009 HREC Executive meeting.

*Some activities may have a QIE for the following month. In this case, repeat the search strategy as per Step 4 for both months.

5. Run a List Export report, then:
 - i. Sort the data by QI Ethics Number and delete columns M, N and P.
 - ii. Delete any rows that have already been reported at a previous HREC Executive meeting (check previous meeting's report).
 - iii. Copy the data from the report into the Excel template located at 'G:\Continuous Improvement\Ethics\QIE project lists from CHARLI
 - iv. Save the file under: 'G:\Continuous Improvement\Ethics\QIE project lists from CHARLI\[Year]' with a file name of 'QI Project list for [date of meeting] HREC Exec meeting'
6. Compare the Excel list with the activities identified in the QI Ethics HREC Report. Any additional activities in the QI Ethics HREC Report are those that have had amendments since the last HREC report was run. If there are activities with amendments go to step 7, otherwise go straight to step 8.

7. For each amended activity perform a Search in CHARLI, select List Export, delete columns M, N and P, then copy the row and add it to list created in step 5, ensuring that the list reflects the order of the PDF report. Flag the amendments with a ** symbol in front of the activity number then save the file.
8. Email the Excel report and PDF report to the Research Ethics Office email address: SCHN-ethics@health.nsw.gov.au by the due date.

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