

IMPROVEMENT ACTIVITIES: ETHICAL REVIEW AND APPROVAL PROCEDURE [®]

DOCUMENT SUMMARY/KEY POINTS

This document outlines the following:

- The Ethical Review Panel procedure for reviewing and approving improvement activities in CHARLI
- Guidelines for ethical review of improvement activities

CHANGE SUMMARY

- Document due for mandatory review. Minor grammatical changes made.
- CHARLI resources available at <https://intranet.schn.health.nsw.gov.au/clinical-governance-unit/quality-improvement-charli>

READ ACKNOWLEDGEMENT

- QI Ethical Review Panel members conducting QI ethical reviews and supporting CGU staff should read and acknowledge the document.

Approved by:	SCHN Policy Procedure and Guideline Committee	
Date Effective:	1 st June 2024	Review Period: 3 years
Team Leader:	SCHN Quality Manager	Area/Dept: Clinical Governance Unit

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Introduction

The ethical review and support of improvement activities is one of the Clinical Governance Unit's (CGU) most important roles. As per the agreement with the SCHN Human Research Ethics Committee (HREC), CGU are responsible for overseeing the Ethical Review Panel (ERP) that ensures improvement activities undertaken at SCHN undergo ethical review prior to starting, in accordance with the SCHN policy [Quality Improvement Activities: Initiation and Approval](#). This review ensures that improvement activities undertaken in the Network are ethically appropriate. Any improvement activities that are allocated a QI Ethics number are then sent on behalf of the ERP to the Executive of the HREC for ratification.

It is essential that ERP members and CGU support teams in understanding the process and make sure that it happens in a timely manner.

The aim is to:

- make initial contact with the team within 3 working days of the activity being allocated to a reviewer in CHARLI
- review and make an approval decision within 5 working days of the activity being submitted in CHARLI for activities **not requiring** ethical approval
- review and make an approval decision within 10 working days of the activity being submitted in CHARLI for activities **requiring** ethical approval.

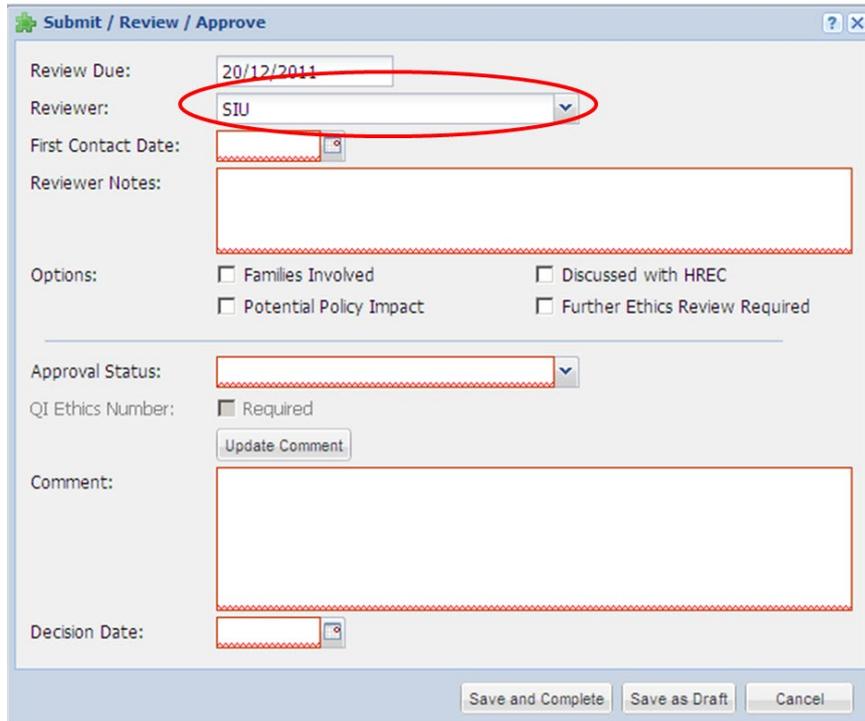
Procedure

Step 1: Initial Assignment of Improvement Activities

1. At a CHARLI triage meeting, held at least twice a week, new submissions are initially reviewed and then allocated accordingly based on availability and expertise of the reviewer. *Note: The Network Manager Quality (Chair of ERP), has final decision rights if allocation is disputed.*

1.1 Allocating an Ethical Review Panel member Reviewer for a NEW activity

1. Select the Activity, select the Submit/Review/Approve Tab, double click on the Ethical Review / Approval row, select the appropriate Reviewer and then click on Save as Draft.



2. An automated email will be sent from CHARLI to the ERP Reviewer, who can then go into CHARLI to read the activity details either via the link from the email or by clicking on the “My Approval Review Required” folder in CHARLI.

1.2 Allocating a ERP Reviewer for an APPROVED activity

An already approved activity needs to be reviewed by at least two ERP members if the activity methodology is changed (i.e. an amendment is made) or if new documents are developed (e.g. a survey/audit tool that was part of the activity’s original plan but not ready at the time of activity approval). There are two methods the ERP may find out that an approved activity needs to be reviewed:

i) Email notification from CHARLI

This may occur if a new Ethical Review row is added or a survey / audit task or attachment is added to the activity. CHARLI will send a notification email to previous ERP reviewer.

ii) Direct contact from the team to the ERP Reviewer

The ERP Reviewer should confirm whether changes to CHARLI are required (e.g. to initiation details / ethical review section / attachments).

- If changes are required, these amendments should be made by the team, or where the team leader cannot access CHARLI, by the ERP reviewer. Submitting an updated ethical review section will create a new Approval/Review row in CHARLI.
- If the Ethical Review section does not require updating, the ERP Reviewer will need to manually create an Approval/Review row to record details of the ethical review (see below).

To manually create an Approval/Review row:

1. Select the required activity and go to the Submit/Review/Approve Tab, select the Submit Activity button; the Submit/Review/Approve 'pop-up' will display.
2. Select the appropriate reviewer and save. A new Approval/Review row is created.

Step 2: Initial Review of the activity in CHARLI

1. The ERP Reviewer is to read the activity details and determine if the activity requires further information, edits and/or is ethically sound.
2. If the activity is complex or the ERP is unsure, they can consult with fellow ERP members prior to approaching team.

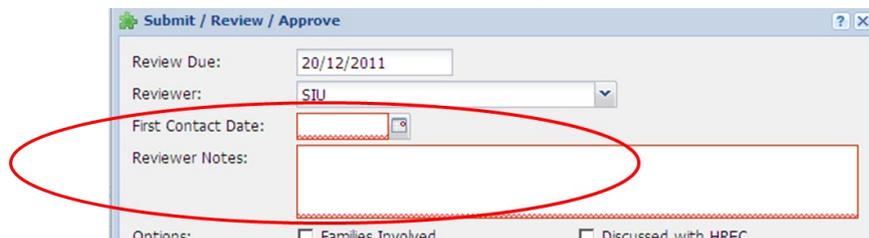
Step 3: Making First Contact with the team

The ERP Reviewer will aim to make first contact with the team (generally the Team Leader) within 3 days of submission being allocated to them. First contact can include a phone call, email or page. The date of first contact and details of all the contacts made are to be recorded in CHARLI using the Submit/Review/Approve row. Double click on the Submit/Review/Approve row and complete the details as follows:

- First Contact Date: enter date first contact is made
- Reviewer Notes: record here the details of contact made and progress notes about the review process until the review is completed, e.g.:
5/1/20 Left voice message to call back and arrange meeting.
6/1/20 Met and agreed to changes to survey. Now waiting for team leader to make changes

Note: The project team can see what has been entered here, so make sure that all comments entered are appropriate.

- Click Save as Draft to save the changes.



Note: It is important that the date of first contact is entered on the actual day contact is made as the date cannot be backdated and this date will be used when calculating CGU KPIs.

Step 4: Printing out activity information from CHARLI (optional)

To view a hard copy of the information entered in CHARLI, 3 reports are available:

1. From Activity Menu Tab click on Reports, select Status Report, select Print Report.
2. From the Ethical Review Tab, select the required row, select Run Report, select Print Report.
3. From the Submit/Review/Approve tab, select the required row, select Reports, select CGU Review Report, select Print Report.

Step 5: Reviewing the activity with the project team

- When reviewing the activity, consider the potential ethical implications of the project; Resources to assist teams and ERP Reviewers are available at <https://intranet.schn.health.nsw.gov.au/clinical-governance-unit/quality-improvement-charli>
- Discuss the activity with the team and determine whether the details in CHARLI reflect the discussions, or if changes to the details in CHARLI are required.

Note: The project team can view the details in CHARLI but are not able to edit the activity whilst it is under review.

- If the updates required are minor, the ERP Reviewer can make the changes directly in CHARLI on the team's behalf.
- If the changes are more significant, there are a number of ways to facilitate the process of agreeing updates to CHARLI:
 - Sit with the team to amend CHARLI together (ERP Reviewer will need to log in); or
 - Create a Word document of the details in CHARLI by copying and pasting the Status Report and Ethical Review Report to facilitate correspondence about proposed changes.
- If major changes are required, the activity can be set to Modifications Required to enable the team to make the changes themselves.
- Attach any final versions of documents to the activity, e.g. if a survey or audit tool has been amended ensure that the revised version is attached and flagged as Final.

Step 6: Making the Approval Decision

Please refer to [Appendix A](#) for information to consider when activities are reviewed. The ERP Chair will have final decision for any activities that a clear consensus has not been reached.

For out of session approvals, a minimum of two ERP members must be involved in the review. The ERP Chair must be made aware (via email or verbally) of this out of session prior to occurring, but does not have to attend.

Step 7: Recording the Approval Decision in CHARLI

1. Go to the Submit/Review/Approve tab, select the Approval/Review row and double click.
2. Finalise the Reviewer Notes to reflect the latest discussion with the Project Team as this cannot be updated once the review is completed.
3. In the Options section tick any of the boxes that apply.

Note: Tick as follows:

Families involved: families are part of the project team or are being consulted e.g. survey/focus group

Family information review: families have been asked to review a publication

Potential policy impact: activity may result in the development of or amendment to an existing policy/procedure/guideline

Discussed with HREC: activity has been discussed with Research Office, prior to approval

Further ethics review required: team to submit survey/audit etc. for review by CGU after activity has been approved.

Note: Do not tick Families involved or Family information review if the activity is receiving an Approval Status of "Review Only" or "Modifications Required".

4. Select the Approval Status.
5. Tick the QI Ethics Number required box.
6. Click on the **Update Comment** button; this will populate the Comment box with an appropriate comment based on the Approval Status and whether or not a QI Ethics Number is required.
7. Complete the Comment by adding specific details in relation to the review/approval such as, "Thank you for taking on board the recommended changes to the survey" or "Thank you for agreeing to report only collated and de-identified data." or "As agreed please send your draft audit tool to the ERP for review and approval."

Note: For more information on Approval Comments see [Appendix A](#).

8. Select '**Save and complete**', the activity, review is now complete for ERP.

Step 8: Further Ethics Review – recording approval decisions

There are two situations which need approval recorded by ERP after the initial review and approval of an activity. In both situations this will result in the activity being sent back to the Executive of the HREC for ratification.

8.1 Draft document/tool sent to ERP for review

When “Further ethics review required” has been identified in [Step 7](#), this means that whilst the activity methodology has been approved the team is still required to send something back to ERP for review e.g. survey, audit tool, information sheet, focus group questions prior to use.

Once the tool is finalised, the ERP Reviewer records the review and approval of the document by:

- Ensuring the final version of the document is attached to the activity in CHARLI
- Recording an approval decision:
 - Go to the Submit/Review/Approve tab, and click on Submit Activity, this will create a new Ethical approval/review row.
 - Complete the pop up similar to [Step 7](#), with the following exceptions:
 - If a QI Ethics number is already allocated to the activity, **do not** tick the QI Ethics Number box for this review.
 - **do not** select Add Comment as the standard comment does not apply for post-approval reviews. Just add a comment that describes what new information/documents have been provided and what has been agreed.

Note: This approval can be completed outside of the Ethical Review Panel meeting; check the approval decision and comment with at least another member of the ERP.

8.2 Amendment to agreed methodology

Sometimes the project team may decide to change the approved methodology for the activity they are working on; where this is the case the changes (amendment) must be documented and approved in CHARLI.

Recording of the Amendment (team/reviewer to complete this step):

- Enter date in the Initiation Details Tab and describe change to methodology.

Initiation Details - Step 3 of 4

Describe Planned Investigations And / Or Changes

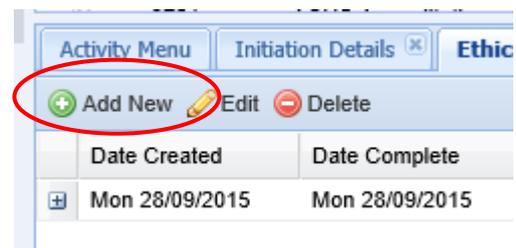
A staff survey will be conducted to determine to if staff felt they were informed and prepared for the Accreditation Survey. It will also help CGU to determine what resources, tools and cc
This survey will be made available online via survey monkey and printed hard copies made available.

3/12/15

The team will also be running a focus group with staff to further explore the survey results

Describe Plans For Evaluation

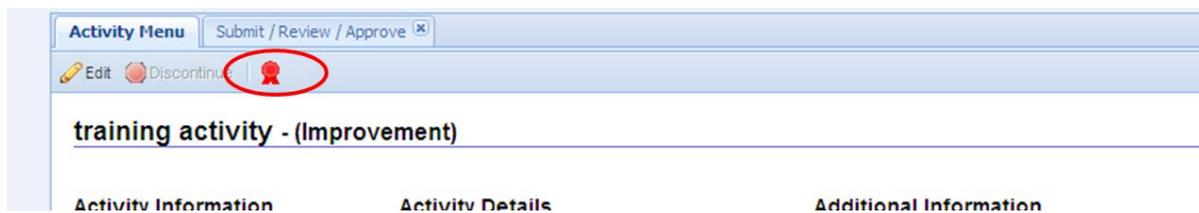
- In the Ethical Review Tab, select Add New, this will display a new Ethical Review Pop Up.



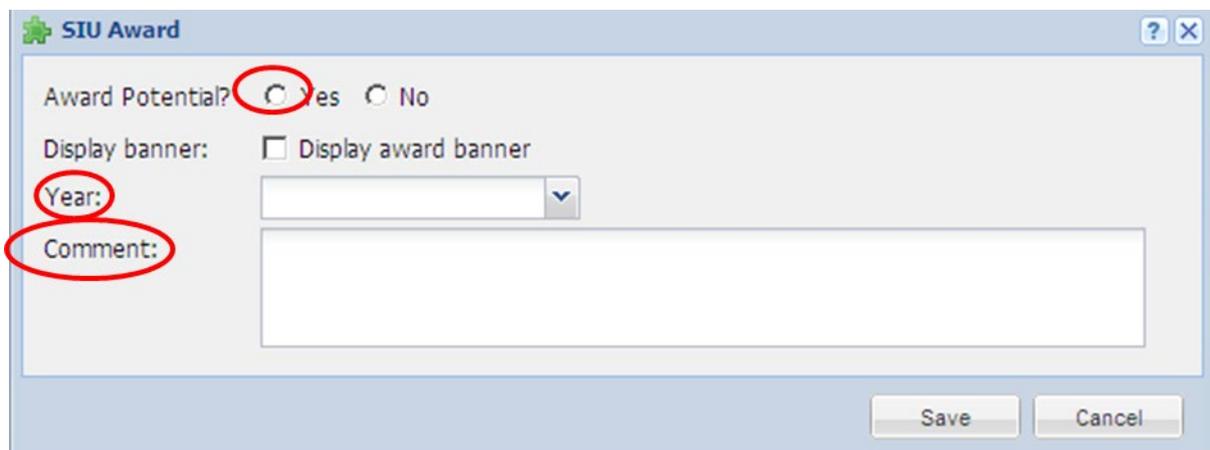
- Update the pop up as required. If other responses to questions remain unchanged – do not edit these.
- Submitting/completing the new Ethical Review row automatically generates a new Ethical Review row on the submit/review/approve tab.
- The ERP Reviewer to complete the review as described in [step 8.1](#) above.

Identifying Potential Quality Award Entries

Where a project has the potential to be entered into the SCHN Quality and Innovation Awards this can be identified at this point (as well as down the track) by clicking on the Award button available on the Activity Menu tab.



1. On the Award pop-up select Award Potential = Yes
2. Select the Award Year, e.g. if the SCHN Quality and Innovation Awards for the year are already over then enter next year.
3. Enter a comment if required and save.



The screenshot shows a 'SIU Award' dialog box. It contains the following fields and controls:

- 'Award Potential?' with radio buttons for 'Yes' (selected) and 'No'.
- 'Display banner:' with a checkbox for 'Display award banner'.
- 'Year:' with a dropdown menu.
- 'Comment:' with a large text input area.
- 'Save' and 'Cancel' buttons at the bottom right.

The 'Year' dropdown and the 'Comment' text box are circled in red.

Problems Encountered

Unable to make contact/obtain additional information

Where an activity has been submitted in CHARLI and attempts to arrange a meeting/obtain additional information about the activity have been unsuccessful (this includes email, phoning, paging several times) within 7 days of initiating contact, the ERP reviewer will send an email to the Team Leader to let them know that if a response is not received within 3 days of this email the activity will be sent back to them (i.e. set to 'Modifications Required') in CHARLI.

Sample Email – multiple attempts to contact

(sent to Team Leader)

As we have been unable to meet to discuss the potential ethical implications of your activity, we have not been able to finalise this ethical review. Since a considerable amount of time has passed from when the activity was first submitted, we will send this activity back to you in CHARLI (i.e. set it to Modifications Required) unless we hear from you otherwise within the next 3 days.

If the activity is set to Modifications Required, please contact me when you are ready to work on this activity again and we will be happy to continue with the ethical review process.

Action when no response received

If no response is received to the above email by the due date, the ERP reviewer will set the approval status to Modifications Required.

Sample Modifications Required Comments

“This activity is being set to Modifications Required as the ethical review cannot be progressed due to the Ethical Review Panel being unable to contact/obtain additional information from the Team Leader. Please contact CGU Quality Stream when you are ready to work on this activity again and we will be happy to continue with the ethical review process.”

“This activity is being set to Modifications Required because the ethical review cannot be progressed as the Team Leader is on leave. Please contact CGU Quality Stream when your Department is ready to work on this activity again and we will be happy to continue with the ethical review process.”

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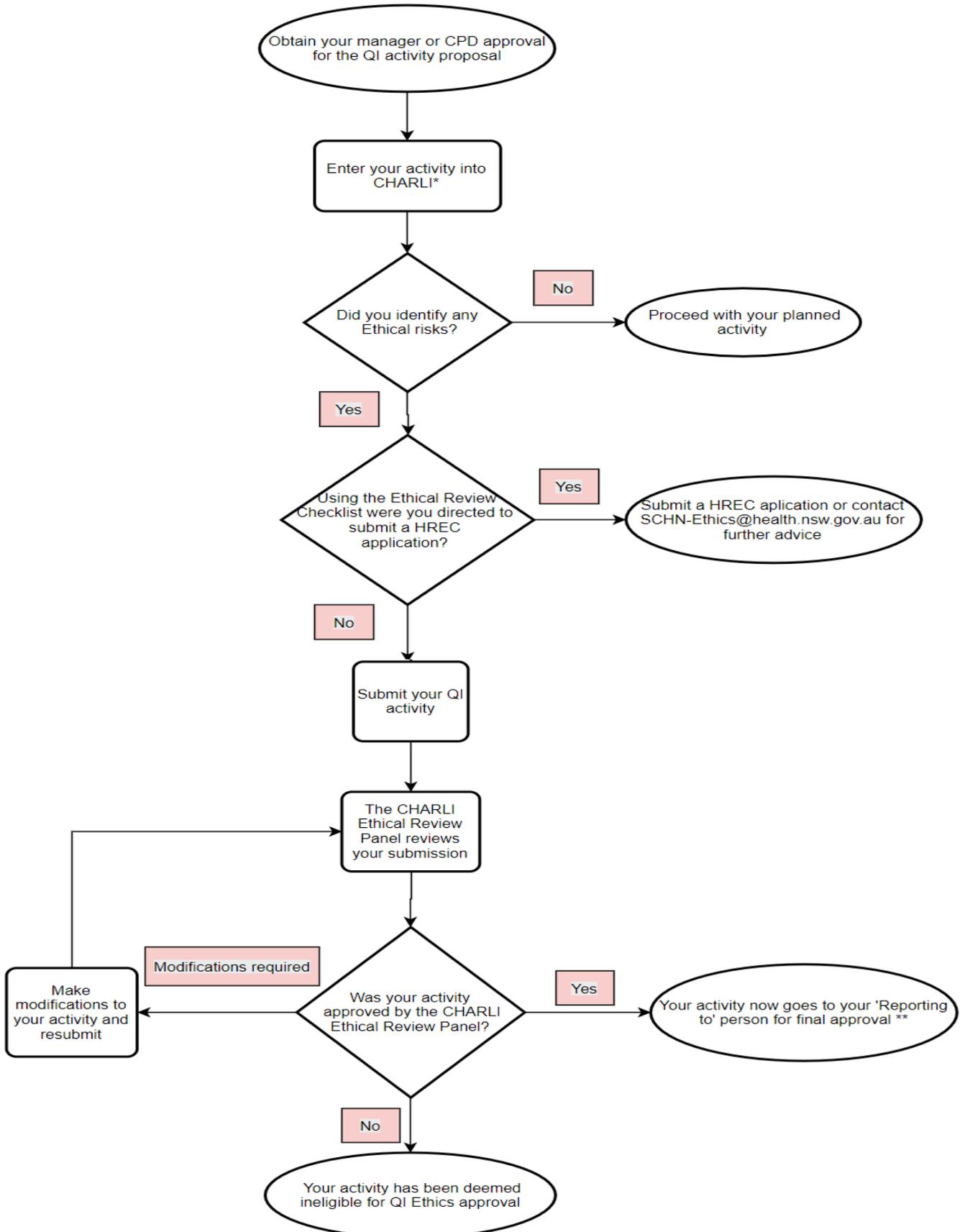
Appendix A: Guidelines for Ethical Review / Approval Decisions

This appendix contains flowcharts which will help determine the appropriate Approval Status for an activity. Once the Approval Status is determined this needs to be entered in CHARLI. CHARLI contains standard comments that apply to each of the approval statuses. The table below provides some extra points about what should be included in the approval/review comment in addition to the standard comment.

Approval Review Status	Points to consider in approval/review comment
<p>Approved - with QI Ethics Number</p>	<p>Summarise the key points that were discussed highlighting the ethical issue(s) addressed. Include any points the team has agreed to, e.g. Thank you for agreeing to:</p> <ul style="list-style-type: none"> - only report and publish deidentified data. - send your draft survey for families to CGU for review and approval prior to use. - only contact families that have consented to participate in the focus group. - work with CGU to develop the evaluations for consumers and external clinicians. <p><i>If the Human Research Ethics Committee (HREC) Chair has been consulted about the activity this should also be mentioned in the comment and the "Discussed with HREC" box ticked in the Submit/Review/Approve pop-up.</i></p> <p>For an Improvement Activity which may result in the initiation of additional projects</p> <p>In the comment include the following "Please ensure that any additional projects initiated as a result of this activity receive appropriate ethics approval prior to commencement."</p> <p>For an Improvement Activity which affects staff/ patients outside the Network</p> <p>In the comment include the following "We note the project involves staff and/or patients outside of SCHN and so may require additional approval from those organisations before commencing."</p> <p>For Ongoing activity previously approved as an improvement activity</p> <p>If the activity was previously approved as an improvement activity with a QI Ethics No., a new number is not required to be allocated, so use the following comment: "CGU has reviewed your activity and since this is the ongoing monitoring of a previously ethically approved activity a new ethics number is not required. You may use ethics no. < > which was allocated to activity < > as the ethics no. for this activity. The activity must now be approved by the Reporting To Person(s) in CHARLI prior to commencing.</p>

Approval Review Status	Points to consider in approval/review comment
<p>Approved - no QI Ethics Number</p>	<p>Summarise the key points that were discussed with the team. Include any points the team has agreed to, e.g. Thank you for agreeing to:</p> <ul style="list-style-type: none"> - send your draft survey for staff to CGU for review prior to distribution - evaluate your activity by measuring how long the process takes before and after the changes are implemented.
<p>Review Only</p>	<p>Summarise any key points that were discussed with the team, e.g. Thank you for agreeing to:</p> <ul style="list-style-type: none"> - monitor the number of incidents relating to this process to ensure there is no increase in the number recorded. - submit your procedure through the ePolicy process. - submit an Ongoing activity in CHARLI as this activity is to be continued on a regular basis. <p>For an activity that has minimal ethical implications</p> <p>Include the following prior to the sentence about the activity going to the Reporting To person “However we note that the ethical implications are minimal.”.</p>
<p>Modifications Required</p>	<p>Outline in detail the changes the team is required to make to their activity, e.g. Please:</p> <ul style="list-style-type: none"> - Attach the audit tool you will be using to collect data. - Reword the aim statement to reflect the proposed outcome of the activity. - Update the Ethical Review Tab to include details about the survey you wish to conduct, including how it will be distributed. - Outline in detail the project methodology including how the project will be evaluated. <p><i>If the HREC has been consulted about the activity this should also be mentioned in the comment and the “Discussed with HREC” box ticked in the Submit/Review/Approve pop-up.</i></p>
<p>Not Approved</p>	<p>Outline in detail why the activity cannot be approved, e.g.:</p> <ul style="list-style-type: none"> - This activity cannot be approved via the QI Ethics process and must be resubmitted via the Research Ethics approval process. Please contact the Research Ethics Office for assistance. - The project methodology is not appropriate and no agreement could be reached on an alternative solution. - The following ethical issues cannot be resolved... - The team has decided to not proceed with the activity. <p><i>If the HREC has been consulted about the activity this should also be mentioned in the comment and the “Discussed with HREC” box ticked in the Submit/Review/Approve pop-up.</i></p>

Flowchart – QI Ethical Review



Flowchart – QI Ethical Review – amendment to existing activity

Ethical Review Process – amendment to existing activity

