QUALITY IMPROVEMENT ACTIVITIES: INITIATION AND APPROVAL

POLICY & PROCEDURE©

DOCUMENT SUMMARY/KEY POINTS

- This document describes the process to follow when:
  - Initiating a Quality Improvement Activity
  - Approving a Quality Improvement Activity
  - Completing and reporting on Quality Improvement Activities
- The key contact for the SCHN for initiating and approving *Quality Improvement Activities* is the Clinical Governance Unit (CGU) (9845 3442).
- **CHARLI**, the database used to document Quality Improvement Activities, is available via the Applications screen at CHW and SCHN Networked computers or via SCHN Citrix portal for SCH users accessing a SESIAHS computer. Look for the CHARLI icon.

- You can only access CHARLI if you are an SCHN employee. If you are employed via a shared service, contact CGU for further advice.
- The Clinical Governance Unit has been delegated by the Human Research Ethics Committee to grant *Quality Improvement (QI) Ethics* approval for activities whose project methodology is ethically appropriate.
- This policy does not directly discuss the process for initiating a Research Activity. Contact the Research Ethics Office (9845 1253) for more information or visit the Human Research Ethics Intranet site.

CHANGE SUMMARY

- The following changes have been made:
  - Links to CGU email, Human Research Ethics Internet site and NSW intranet sites updated.
  - Removal of links to word templates to initiate and complete a Quality Improvement activity and staff unable to access CHARLI directed to contact CGU.

READ ACKNOWLEDGEMENT

- All managers should read and acknowledge this document.
- Any staff member intending to undertake a quality improvement activity should read this document.
- All other staff should be aware of this document.

TABLE OF CONTENTS

Introduction

The Sydney Children's Hospital Network (SCHN) places great importance on continually improving care and service for patients, families and staff. The benefits of documenting these improvements are that it:

- Enables Quality Improvement activities to undergo ethical review prior to starting, in accordance with NSW Health Guideline Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW.
- Avoids duplication of Quality Improvement activities as the Clinical Governance Unit (CGU) can direct staff to similar activities already taking place.
- Enables support/assistance in Quality Improvement activities for staff who require it.
- Ensures all Quality Improvement activities are properly documented as they occur. This facilitates a number of reporting processes including for Accreditation requirements.
- Supports the NSW Health CORE Values of Collaboration, Openness, Respect and Empowerment across the Network.

Definitions

Quality Improvement Activity

An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation) is a Quality Improvement activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably.

Improvement activities follow various methodologies but the basic principles are the same; making decisions based on data and evaluating changes to ensure they are successful and sustainable. A Quality Improvement activity has a defined start and a planned finish date.

Quality Improvement activities can include:

- Using feedback from patients and/or staff, e.g. survey or focus group, to improve services
- Using data, e.g. audit results or incident data, to identify and implement process improvements
- Developing and evaluating education material/fact sheets for staff or families
- Identifying and implementing best practice
- Implementing checklists and procedures to ensure consistency in practice.

Note: Some Quality Improvement Activities can be considered as having research elements and have ethical implications that are more appropriately reviewed by a Human Research Ethics Committee; and, some research studies can also result in quality improvement as a secondary outcome. Please see the flowchart diagram on page 10 to help you determine whether your activity is Quality Improvement or Research. If you are unsure about which of these categories your project may fall into, please contact the Clinical Governance Unit or the Research Ethics Office.

Ongoing Quality Improvement Activity

An ongoing Quality Improvement activity is an activity that is conducted on a regular basis such as monthly data collection, running and evaluating an annual workshop or tri-annual policy mandatory review. It does not have a planned end date. The ongoing activity is conducted to ensure that a process is working as required. The establishment of *the Ongoing Quality Improvement Activity* is usually the outcome of a *Quality Improvement Activity*.

Example

A Quality Improvement Activity is conducted to ensure that discharge summaries are completed on time and are of the required quality. A team is formed and a plan is developed, data is collected and improvements are made and evaluated. When no further changes are required this activity is considered complete.

To ensure that the improvements are maintained regular reviews of the completion rates of discharge summaries will be undertaken. The team will also conduct an audit every 3 months to review the quality of the discharge summaries. These reports and audits would be considered as Ongoing Improvement Activities.

Note: Both Improvement and Ongoing activity types must be initiated, approved and reported on using CHARLI.

CHARLI

CHARLI is the database used to initiate, approve and report on Quality Improvement activities taking place within the SCHN. It also has capacity to record information about special achievements, publications, presentations and visits by/to external organisations.

CHARLI is available via the Applications screen at CHW and SCHN Networked computers or via SCHN Citrix portal for SCH users accessing a SESIAHS computer. Look for the CHARLI icon.

Area Head

Area Head refers to Departmental Heads, Clinical Program Directors / Divisional Heads or Network Directors.

Policy

- All *Quality Improvement Activities* and *Ongoing Quality Improvement Activities* undertaken at the SCHN are to be:
  - Discussed with your manager for their support to proceed
  - Initiated using the CHARLI database
  - Reviewed and granted approval by CGU where ethical implications are minimal or suitably addressed

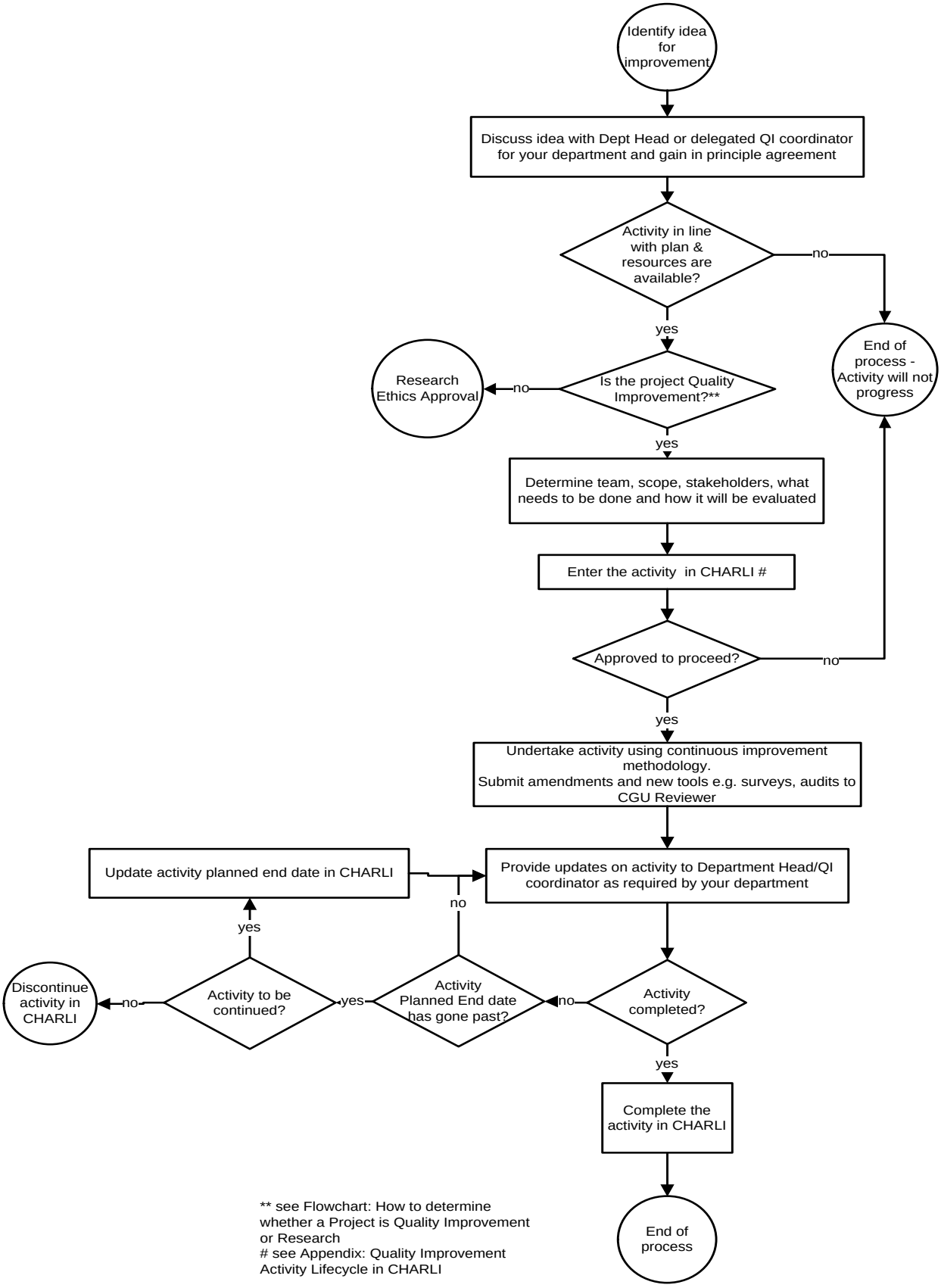
  - Reviewed for ratification of CGU approval by the Human Research Ethics Committee's (HREC) sub-committee, the Executive Committee (for those activities that receive Quality Improvement Ethics Approval)
  - Approved by an Area Head or their delegate, via CHARLI
  - Have all reporting, including progress and final reports, conducted through CHARLI
- Once a quality improvement activity is approved by CGU and the Area Head the project can commence, however the HREC Executive Committee may request further information or changes as part of their review process.

Initiating a Quality Improvement Activity

The flowchart on page 7 describes the process to be followed when conducting a Quality Improvement activity, however prior to commencing a Quality Improvement activity the following must be considered:

- Has the need for the improvement been clearly identified, for example, through:
  - Patient and family feedback
  - Feedback from complaints
  - Review of incidents
  - Audit results from another project/regular auditing
  - Identified risk
  - External review
  - Initiation by an external body e.g. Clinical Excellence Commission
  - Benchmarking
  - Review of clinical indicators
  - Literature review
  - Best practice evidence
  - Staff member or consumer identifies a need for improvement
- Will the activity contribute to achieving agreed Network strategies and objectives?
- Are the resources to undertake the activity available?
- Would the activity continue to be important to complete if the staff member initiating the activity was no longer working in the same role or clinical area, i.e. is it important to the whole team?
- Will you be able to undertake measurement to know that the changes made are an improvement?
- Are the changes likely to be sustainable into the future?

Procedure –SCHN Quality Improvement Activity Process



Is an activity Research or Quality Improvement?

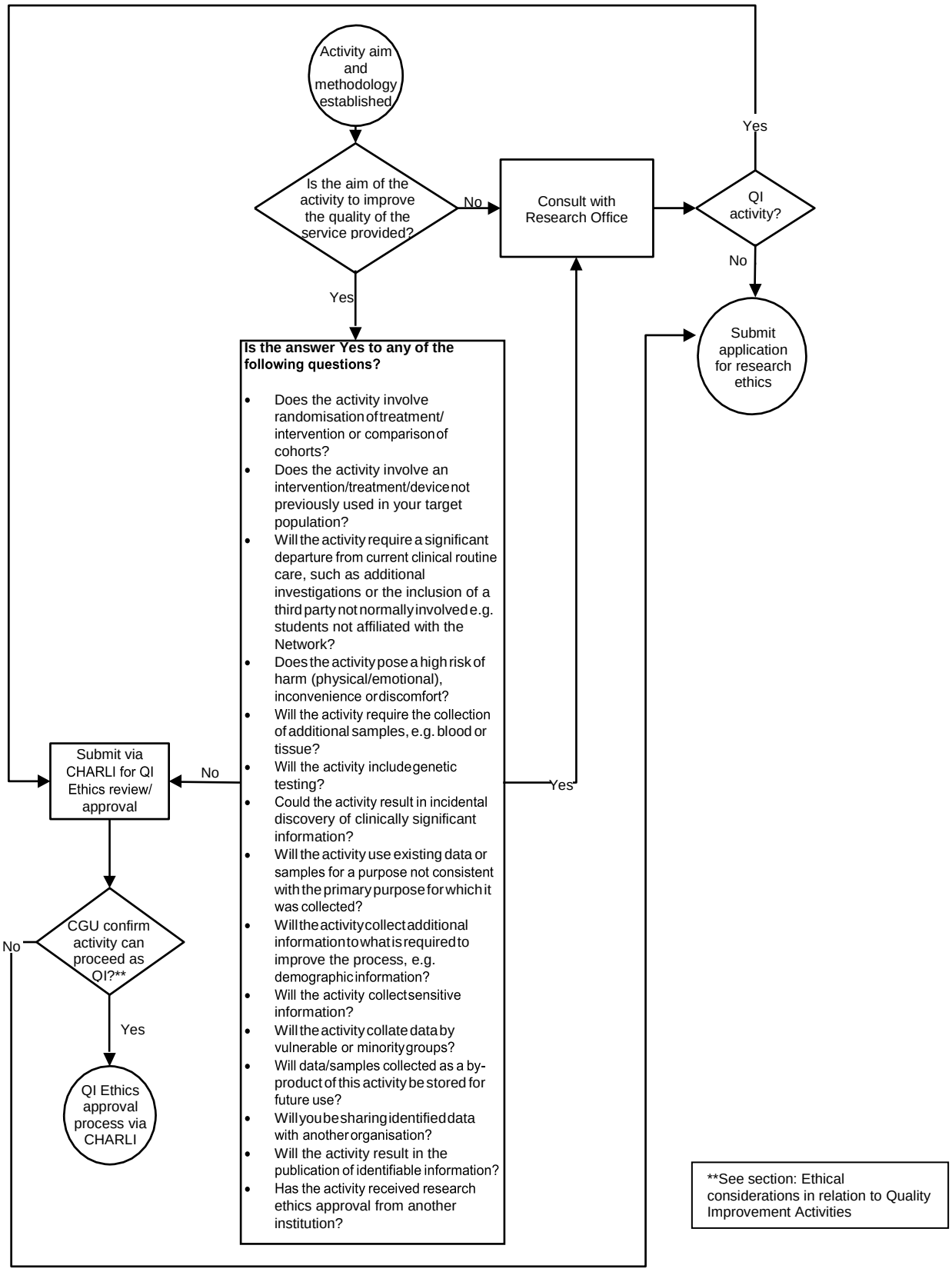
A research activity includes, at least, investigation undertaken to gain knowledge and understanding or to train researchers[1]. Quality Improvement and research are activities that are on a continuum and it can sometimes be hard to distinguish between the two. Regardless of the type of activity, the core ethical principles of the *National Statement,* merit and integrity, justice, respect and beneficence should be adhered to when designing your activity.

As noted above, some Quality Improvement Activities can have research elements with significant ethical implications; and some research studies can also result in quality improvement as a secondary outcome. The flowchart on the following page may help you in determining whether your activity is Quality Improvement or Research. If you are still unsure, please contact the CGU or the Research Ethics Office before you commence any application.

Research activities are reviewed by the Human Research Ethics Committee and/or its sub-committees and are subject to their own approval processes administered through the Research Ethics Office.

For further information on research approval processes, please contact the Research Ethics Office on 9845 1253, via email (SCHN-ethics@health.nsw.gov.au) or visit the Human Research Ethics Internet site.

Flowchart: How to determine whether an activity is Quality Improvement or Research



Ethical Considerations in relation to Quality Improvement Activities

If the purpose of a Quality Improvement Activity is *not directly related* to the patients' illness or routine care, it may be considered as being burdensome to them and this may cause additional discomfort or inconvenience to the patient and/or their family members. Some examples of this are where additional investigations are required or sensitive information is collected. Further, there is a need to ensure that privacy and confidentiality is maintained at all times when collecting information from or about a person participating in the activity.

To ensure that these, among other ethical concerns are considered, staff who are initiating a quality improvement activity are asked a series of questions in CHARLI to help the CGU assess whether an activity is ethically acceptable. These questions are located in the '*Ethical Review Tab'* and accessed via the Activity Menu in CHARLI. The questions are:

- Does this activity involve or affect any other areas of the Hospital beyond the team?
- Will you be conducting a survey/questionnaire?
- Will you be conducting an interview or focus group?
- Will you be involving consumers in any other way apart from surveys/interviews/focus groups? Consumers can include patients, families, staff and external groups.
- Will you be conducting a case note / chart review / audit (this includes all audits, not just audits of Medical Records)?
- Will you be conducting any observations?
- Will you collect or use identified data (includes identified information collected as part of surveys, audits etc.)?
- Will the activity require additional treatments/procedures/diagnostic tests for patients beyond what is considered current routine clinical care?
- Will your activity involve the introduction of a new treatment/procedure/equipment to the Hospital?
- Will you share the data you collect with another organisation?
- Are you thinking of presenting or publishing this activity beyond the Hospital?

When the person entering the activity into CHARLI answers 'yes' to any of these questions, CHARLI will automatically flag the activity for ethical review by a Clinical Governance Unit reviewer.

Ethical Review of Quality Improvement Activities by the Clinical Governance Unit (CGU)

The CGU has been delegated by the Human Research Ethics Committee (HREC) to review and provide approval for Quality Improvement activities that have ethical implications; i.e. where "yes" has been selected to any of the questions under the Ethical Review Tab in CHARLI. The SCHN Quality Improvement review committee has an agreement with the SCHN HREC, as per the NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2018) section 5.1.20 (c), to undertake an ethical review and approval of SCHN improvement activities submitted for ethics review through the CHARLI database. Where a Quality Improvement Ethics number (QI Ethics number) is assigned, CGU forward these improvement projects to the HREC executive for review and ratification.

A QI Ethics number will only be granted for quality improvement activities whose project methodology has been deemed to be ethically acceptable. This QI Ethics number should be quoted when submitting for publication and presentations.

Note: Retrospective ethics approval cannot be given for activities that have already been conducted.

As part of the ethical review process conducted by the CGU each activity referred to the CGU by CHARLI is allocated to a CGU Reviewer. The CGU Reviewer ensures that the methodology of the activity is ethically acceptable and meets the minimum requirements as established in the *National Statement.*

The review also aims to ensure that any potential ethical implications have been removed, or at the least minimised to protect the:

- Interests of the patients, carers, and staff who are the subject of the Quality Improvement Activity
- And to minimise any risk to the Hospital in carrying out the activity.

The CGU Reviewer will contact the activity's Team Leader to discuss any aspects that require further information, including, for example:

- Who is on the team
- The methodology to be used
- How the activity will be evaluated

The CGU reviewer will also review any activity instruments to be used, including audit tools, surveys, interviews or focus groups questions.

Once the review has been completed and a decision made, the outcome will be formalised at the weekly Improvement Project Review meetings attended by CGU reviewers. The outcome will fall into one of the following categories:

- Ethically approved, with a QI Ethics number - The activity has appropriately addressed any ethical concerns and will proceed to the next stage of approval in CHARLI (approval by the person(s) the activity is "Reporting To")

- Ethically approved, with no QI Ethics number - The activity has been reviewed by the CGU and found to have no ethical concerns and will now proceed to the next stage of approval in CHARLI (approval by the person(s) the activity is "Reporting To")
- Modifications Required – Revisions are required to the activity in CHARLI to reflect outcomes of discussions between the CGU Reviewer and the Activity Team Leader. Once these revisions have been made, the activity will need to be resubmitted for approval
- Modifications required and Activity put on hold- The CGU reviewer has been unable to contact the Team and the activity has been put on hold until contact is made.
- Review Only - The activity has already commenced and significantly progressed. As the CGU are unable to provide retrospective approval, the activity will proceed to the next stage of approval in CHARLI (approval by the person(s) the activity is "Reporting to") without a QI Ethics number.
- Not approved - The activity will be cancelled in CHARLI. This outcome will only be used in the following circumstance:
    - The activity is a research activity and requires review by the Human Research Ethics Committee or its sub-committee
    - The team agrees, following detailed discussion with the CGU, when the activity is not ethically acceptable, nor can be revised as such, and therefore the activity cannot reasonably proceed.

Once CGU has completed its review, activities approved are automatically referred by CHARLI to the Reporting To person(s) to complete the next step in the process to be completed. SCHN team members will also receive an email notifying them of the outcome of the CGU review.

Further ethics review once the activity has commenced

Quality Improvement activities often need to be initiated quickly, for example, in response to an incident or complaint. This can mean that, whilst the aim of the activity is known at the outset, the tools required to undertake the activity may not be fully developed at the time the activity is initiated in CHARLI and review by the CGU occurs.

When this situation occurs, QI Ethics approval may be granted so that the team can commence the activity, with the condition that the team:

- Notifies their CGU reviewer of any changes to the project methodology (e.g. deciding to conduct a survey or deciding to collect prospective data as well as retrospective data) prior to its implementation so that the CGU reviewer has an opportunity to review and comment on the proposed amendment
- Sends to CGU for review any additional tools developed, for example, audit tools, surveys, interview and focus group questions, Information Sheets for participants etc. before they are implemented.

CGU will record these additional approvals against the activity, and the activity will again be referred to the HREC Executive Committee for ratification.

Electronic Surveys

CGU have an electronic survey account. Surveys for Quality Improvement activities can be created through the CGU account. Once the activity is approved through CHARLI CGU will send the log in details to the team leader. A condition of using the CGU electronic survey account is that you only view your own surveys unless you have explicit permission from the owner. Please remember that others can also see your survey and all staff are expected to abide by the Code of Conduct signed on employment.

Where surveys are created using another electronic tool, they will still be subject to the same review and approval process prior to being made available to consumers.

Maintaining and Monitoring Improvement Activities

It is important to keep the information in CHARLI up to date as the SCHN is required to report on improvement activities.

Once the activity is finished the Team Leader/Team Members must complete the activity in CHARLI. If the activity has not been finished and the Planned End Date in CHARLI has gone past the activity Planned End Date must be updated in CHARLI to indicate when the activity is now planned to be finished by.

It is also recommended that Area Heads review activities in CHARLI at regular intervals, e.g. every 3 months.

The following can assist with monitoring improvement activities:

- Search function in CHARLI
- Reporting function in CHARLI

Where an activity no longer meets a Departmental priority it is recommended that the activity is discontinued in CHARLI.

Where activities have been inactive for 14 months or more, CGU will cancel the activity in consultation with the team.

Responsibilities for Initiating, Approving, Documenting and Reporting on Quality Improvement Activities

Activity Team Leader

- Initiate a Quality Improvement Activity (including ongoing activities) in CHARLI.
- Enter Activity Progress Updates within the activity record in CHARLI as required.
- Complete the Quality Improvement activity in CHARLI once the activity is finished.

Area Heads or their delegate

- Review and approve Quality Improvement activities submitted in CHARLI as applicable.
- Ensure staff are aware of and utilise CHARLI for all Quality Improvement activities.
- Ensure that staff undertake Quality Improvement activities that are effective and contribute to achieving the strategic goals and objectives of the department.
- Ensure that information entered in CHARLI by their staff is correct and informative.
- Regularly monitor activities in CHARLI to ensure that information in CHARLI is kept up to date.

Clinical Governance Unit

- Review and approve Quality Improvement activities submitted in CHARLI that have minimal or suitably addressed ethical implications.
- Discuss with the Research Ethics Office or HREC representative any activities that have significant ethical concerns, or activities that may be considered research.
- Discuss with the Team Leader and/or Team member(s) how ethical concerns can be minimised by changing the activity methodology.
- Where required, request that the Team Leader and/or Team member(s) liaise with the Research Ethics Office to submit a Low / Negligible Risk ethics application.
- Submit to the Research Ethics Office, a report of Quality Improvement activities that have been approved by CGU for ratification by the HREC Executive Committee.
- Monitor activities in CHARLI and report to management on utilisation and other database statistics.
- Work with staff to ensure that the information in the database is of an appropriate quality.

Research Ethics Office

- Discuss with the CGU activities submitted via CHARLI that have significant ethical concerns which are unable to be minimised by changing the activity methodology, to determine how an activity should proceed for approval.
- Direct staff to the CGU who approach the Research Ethics Office with a Quality Improvement activity.

Continuous Improvement Resources

The CGU are available to assist staff undertaking '*Quality Improvement Activities'* and regular short and intensive training sessions are available by booking through My Health Learning. Details of training are located on the SCHN Education intranet page.

The CEC has a number of resources readily available including Quality Improvement tools, and publications such as Clinician's Guide to Quality and Safety.

Related Information – SCHN policies

- Access to Electronic Healthcare Records for Research, Improvement Activity or Case Study Purposes (2007-8113)
- Code of Conduct (2011-9004)
- Improvement activities: ethical review and approval process in CGU (2009-0026)
- Improvement Activities: Preparation of Papers in CGU for HREC Endorsement (2009-0064)
- Privacy Manual for Health Information (2015-9065)
- Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW (GL2007_020)
- Patient Safety and Clinical Quality Program (PD2005_608)

References

1. [1] National Statement on Ethical Conduct in Human Research, 2007, *National Health and Medical Research Council*

Appendix: Quality Improvement Activity lifecycle in CHARLI

The flowchart explains how an activity progresses through the different '*statuses*' in CHARLI