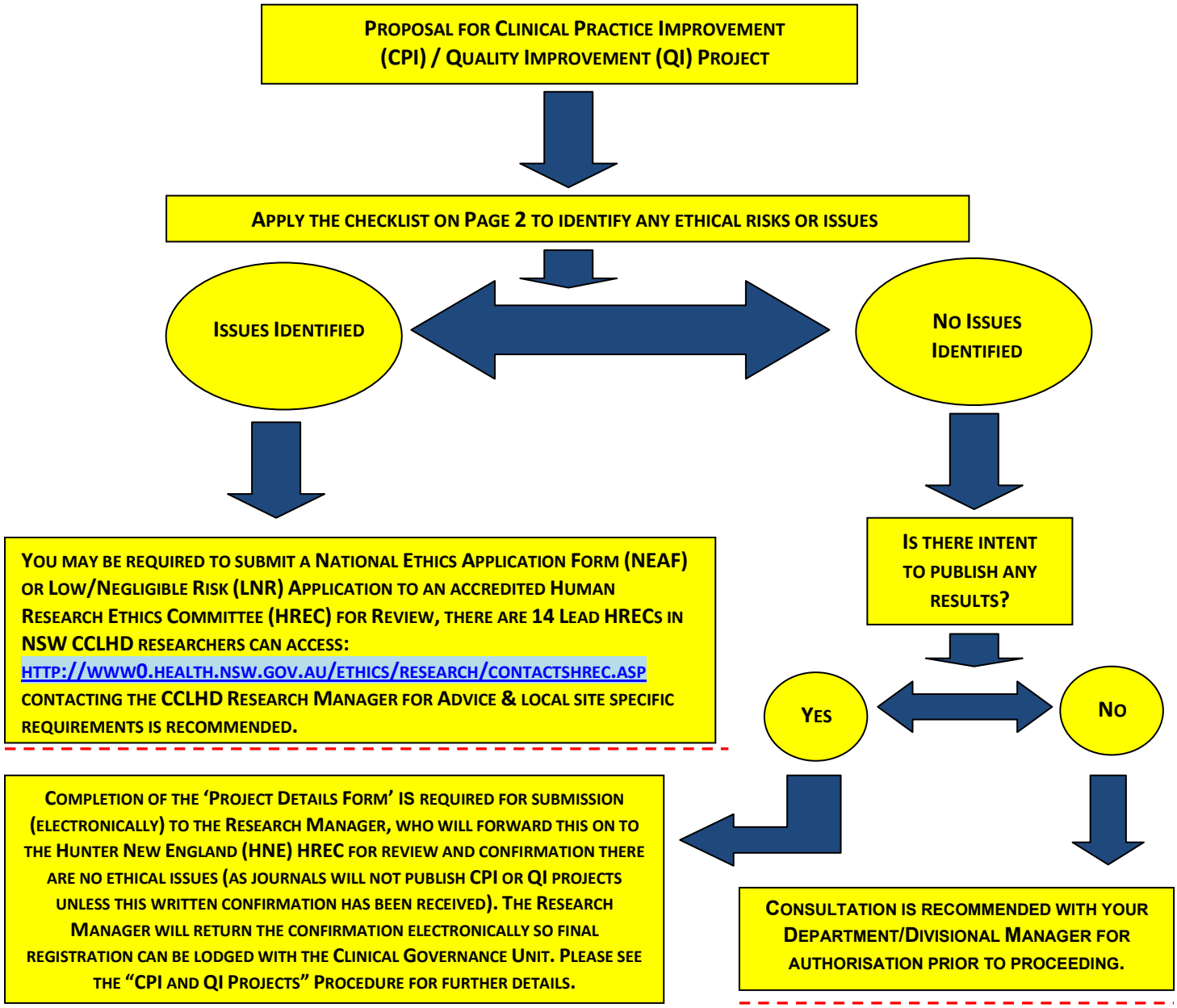
CENTRAL COAST LOCAL HEALTH DISTRICT (CCLHD)
Application Checklist – Clinical Practice Improvement (CPI), Quality Improvement (QI) Projects & Research

THE FOLLOWING FLOWCHART AND CHECKLIST HAS BEEN PRIMARILY DESIGNED TO ASSIST CENTRAL COAST LOCAL HEALTH DISTRICT (CCLHD) STAFF IN IDENTIFYING WHEN A CLINICAL PRACTICE IMPROVEMENT (CPI) OR QUALITY IMPROVEMENT (QI) PROJECT ENTAILS ETHICAL 'RISKS'. IF ANY OF THE ANSWERS TO THE QUESTIONS ON PAGE 2 ARE ANSWERED "YES", FURTHER ADVICE SHOULD BE OBTAINED FROM THE CCLHD RESEARCH MANAGER ABOUT THE NEED FOR ETHICAL REVIEW AND COMPLETION OF THE APPROPRIATE APPLICATION. IF THE ANSWERS TO THE QUESTIONS ARE ALL 'NO' CONSULTATION IS RECOMMENDED WITH YOUR DEPARTMENT/DIVISIONAL MANAGER FOR AUTHORISATION PRIOR TO PROCEEDING. ANY QUESTIONS ABOUT COMPLETING A CPI OR QI THAT DOES NOT INVOLVE 'ETHICAL RISKS' SHOULD BE DIRECTED TO THE CLINICAL GOVERNANCE UNIT OR APPROPRIATE DEPARTMENT/DIVISIONAL MANAGER.



ETHICAL RISKS & ISSUES CHECKLIST			
1.(a) Is the aim of the project 'new knowledge'? If so, does it: **(b)** Involve any of the following; blinded tests, a randomised controlled trial, no bias, include all possible data, a fixed hypothesis or one large test?	☐ **Yes** ☐ **Yes** **Comment:**	☐ **No** ☐ **No**	☐ **Possibly** ☐ **Possibly**
2. Does the proposal pose any risks for participants beyond those of their routine care, treatment or activity?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
3. Does the proposal impose a burden on participants beyond that experienced in their routine care, treatment or activity?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
4. Does the proposal seek to gather information beyond that collected in routine care or service?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
5. Is the proposed activity to be conducted by a person who does not normally have access to the client's health or other records for care or a directly related secondary purpose?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
6. (a) Is the proposed activity covered by the National Privacy Principles (NPPs) of the Commonwealth Privacy Act 1988 (i.e. is a private sector organisation involved in the collection, use or disclosure of information)?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
(b) If yes, is the consent from participants inadequate or is the activity inconsistent with NPP 2.1(a)?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
(c) You should note that the activity must be reviewed by an HREC if the activity involves the collection of health information (by an organisation in the private sector) under NPP 10.3(d)(iii) for the purposes of: ☐ *Research* relevant to public health or public safety ☐ *Compilation or analysis of statistics* relevant to public health or public safety ☐ *Management, funding or monitoring* of a health service or if; the activity involves the **use** or **disclosure** of health information (by an organisation in the private sector) under NPP 2.1(d)(ii) for the purposes of: ☐ *Research* relevant to public health or public safety ☐ *Compilation or analysis of statistics* relevant to public health or public safety	***Please Note if you answered "yes" to question 6(a), but answered "no" to part (b) and did not tick any of the boxes for part (c), then you can count this as an overall "no" to this question.*** ☐ **Yes** ☐ **Yes** ☐ **Yes** ☐ **Yes** ☐ **Yes** **Comment:**	☐ **No** ☐ **No** ☐ **No** ☐ **No** ☐ **No**	☐ **Possibly** ☐ **Possibly** ☐ **Possibly** ☐ **Possibly** ☐ **Possibly**
7. Does the proposal involve randomization or the use of a control group or placebo?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
8. Does the proposed activity potentially infringe the rights, privacy or professional reputation of carers, health providers or institutions?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
9. Does this activity involve the collection of identifiable or potentially identifiable information for the management or evaluation of health services?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**
10. Is there intent to publish?	☐ **Yes** **Comment:**	☐ **No**	☐ **Possibly**

Important Information:

Please note that the definition of research as per the National Statement on Research (2009) excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.

This document has been put together as a guide only if you have any questions regarding an application for Research please contact:
Amanda Jackson, Research Manager- PH:(02) 4320 3218 - E-mail: ccresearch@nsccahs.health.nsw.gov.au

CENTRAL COAST LOCAL HEALTH DISTRICT (CCLHD)

Project Details Form – Clinical Practice Improvement (CPI), Quality Improvement (QI) Projects

If all of the questions on Page 2 can be answered "no", then the proposal does not require consideration by an HREC, only fill out this section if you intend to publish any project results or if you are unsure as to whether the project would qualify as a Clinical Practice Improvement (CPI) or Quality Improvement (QI) Project.

1. Principle Investigator:	
Name:	Department:
Position/Title:	Tel:
E-mail:	Mailing Address:
2. Associate Investigator/s: ***Please duplicate as necessary***	
Name:	Department:
Position/Title:	Tel:
E-mail:	Mailing Address:

3. Project Title:

4. Project Details:
Background:
Aim(s):
Methodology*:*

5. Privacy:

It is necessary for you to complete this part of the application form in order to ensure that you comply with the Health Records and Information Privacy Act. This enables the HREC to properly assess the protocol under the Act; and ensures the HREC meets its statutory obligations to report to the Privacy Commissioner on its activities under the Act.

5.1 Is there a requirement for the researchers to collect, use, or disclose information of a personal nature (either identifiable or potentially identifiable) about individuals without their consent:

- From Commonwealth departments or agencies? Yes ☐ No ☐
- From State departments or agencies? Yes ☐ No ☐
- From other third parties, such as non-government organisations? Yes ☐ No ☐

If you ticked yes to one or more of the above boxes, please state what information will be sought and how many records will be accessed

5.2 Is there a requirement for the researchers to collect, use, or disclose personal health information about individuals without their consent which is identifiable or potentially identifiable?

YES – go to question 5.3
NO – go to 5.6

5.3 Indicate the reason(s) why de-identified information cannot be used?

- ☐ The project involves linkage of data
- ☐ Scientific deficiencies would result if de-identified information was used
- ☐ Other

Please provide details

5.4 Why is it impracticable to obtain the consent of the individual to the collection, use or disclosure of their health information?

- ☐ The size of the population involved in the research.
- ☐ The proportion of individuals who are likely to have moved or died since the Health information was originally collected.
- ☐ The risk of introducing potential bias into the research, thereby affecting the generalisability and validity of the results.
- ☐ The risk of creating additional threats to privacy by having to link information in order to locate and contact individuals to seek their consent.
- ☐ The risk of inflicting psychological, social or other harm by contacting individuals with particular conditions in certain circumstances.
- ☐ The difficulty of contacting individuals directly when there is no existing or continual relationship between the organisation and the individuals.
- ☐ The difficulty of contacting individuals indirectly through public means, such as advertisement and notices.
- ☐ Other – ***Please provide details below.***

5.5 Explain why the collection, use or disclosure of this information is in the public interest, and why the public interest in the project substantially outweighs the public interest in the protection of privacy.

5.6 Will a study code be generated? If using potentially identifiable or identifiable information to code participant records, this must be included in the Consent Form (if applicable).

Yes ☐ if yes, please provide details
No ☐

5.7 Will the subjects be video/audio taped or will any other electronic medium be used?

Yes ☐
No ☐

5.8 How will the investigators protect the privacy of the participants and their personal details specifically relating to all patients that attend Central Coast Health sites (eg a locked filing cabinet)?

5.9 Storage & Security of Information relating to all Central Coast Health sites. Please complete the following:

Security of data storage:

Location of stored data:

Format of stored data:

Duration data will be kept:

Method of destruction of data:

5.10 Does the project involve the transfer within or outside Australia of a subject's personal information? (eg. date of birth, initials, name and/or address being transferred in a serious adverse event form or a Case Report Form)

Yes ☐
No ☐

Specify type of information (as detailed above)?

Where will the information be transferred from and to whom?

How will the patients' information remain confidential during the transfer process?

5.11 Please confirm that information which identifies individuals or from which an individual's identity can be reasonably ascertained, WILL NOT be published in any generally available publication?

Yes ☐ Confirmed published data will not identify participants. As the Publication of identifiable data is not permissible under the Act.

Declaration

I have discussed the proposed activity with the CCLHD Research Manager and have been advised to submit the proposal to the Hunter New England (HNE) Human Research Ethics Committee (HREC) for advice on whether this project would qualify as a Clinical Practice Improvement (CPI)/Quality Improvement (QI) Project or whether a full application for research would be required.

I understand should any changes be made to the original activity as outlined above that I should contact the CCLHD Research Manager for advice on whether or not a full research application would be subsequently required.
I will also advise the CCLHD Research Manager of any changes in writing so these can be communicated to the HNE HREC.

Signatures:		
Department Head Signature:	Name (printed)	Date
Principle Investigator:	Name (printed)	Date
Associate Investigator/s: ***Please duplicate as necessary***	Name (printed)	Date
Director, Clinical Governance/Delegated Representative:	Name (printed)	Date