CLINICAL INNOVATION AND AUDIT APPLICATION FORM

MQ Health
MACQUARIE UNIVERSITY
HEALTH SCIENCES CENTRE

Introductory Remarks

Clinical innovation (CI) is widely accepted as a "good" - something that should be encouraged and facilitated in the public interest. For example, the "best practice guidelines" recently published by the Royal College of Surgeons of England [1] states that;

"*Surgeons are innovators. The advancement of surgery is set against a backdrop of continuous development and, in the past 50 years, surgical innovations have transformed the way clinical care is delivered*."

Quality Assurance, which involves continuously assessing the effectiveness of the care provided, is an important means of maintaining high quality health-care delivery at MQ Health. The role of the Clinical Innovation and Audit Committee is to provide oversight for both innovations and Quality Assurance activities, including clinical audits, and approval for individual projects proposed by persons affiliated with MQ Health.

When completed this form, combined with all other associated documents should be emailed as a single document (pdf file), to ***clinical.innovation@mqhealth.org.au***

SECTION 1: THE PROJECT

1.1. Project Title

1.2. Classification of the Procedure

- (●) Surgical/medical/clinical innovation ***(Please complete Section 3)***
- ( ) Clinical audit or Quality Assurance (QA) Activity (e.g. clinical chart review, survey or case report ***(Please skip Section 3 and complete Section 4)***
- ( ) Unsure ***(Please send your query to clinical.innovation@mqhealth.org.au to arrange advice about your project)***

1.3. Project Summary (Maximum 350 words, alternatively you can attached the project synopsis using the **CIAC Template**)

SECTION 2: PERSONNEL

2.1. Name of Applicant

2.2. Applicant and collaborating staff details

(Please complete Appendix A to provide the required information about the applicant and any staff who will be collaborators in the project. MQ Health has determined that a Macquarie University or MQ Health affiliation is required for all proposed activities)

SECTION 3: CLINICAL INNOVATION

Explanatory Notes

To the extent that it is experimental, and involves human subjects, clinical innovation (CI) has ethical implications, and both individual practitioners and MQ Health require some oversight of the process. It is particularly relevant in the earlier phases of innovation, identified by Barkun[1] in the IDEAL framework (Idea, Development, Exploration, Assessment, Long-term study). Activities qualify as clinical innovation if what is proposed involves any technique, or the use of any instrument or device, that deviates significantly from established practice, and is new to the either the operating surgeon, clinician or to MQ Health. Oversight is required to ensure;

i) that the outcomes of the change are likely to outweigh its known, or reasonably predictable, risks,
ii) that the outcomes will be assessed and recorded adequately, and
iii) whether special preparation should be undertaken by the surgeon and/or the surgical team prior to proceeding.

For minor changes in practice ("variations") documented approval of your Head of Clinical Program or Clinical Discipline is all that is required. The CIAC has been implemented to provide oversight and approval for CI in its early stages (i.e. I, D and E of IDEAL) at MQ Health.

In order to satisfy the CIAC process you will need to;

- be clear about what you are trying to do,
- identify the outcomes are you aiming for, and how will you bring them about,
- establish a coherent theoretical basis, and how it relates to what you propose, and
- be able to describe the intervention in a way that allows it to be evaluated and/or replicated by others.

The issues of the cost-effectiveness and any wider implementation of the innovation are best addressed by means of formal research requiring HREC approval.

3.1. Describe how the proposed innovation involves a significant departure from routine care. *(Maximum 150 words)*

[1] Barkun JS, Aronson JK, Feldman LS, Maddern GJ, Strasberg SM, Collaboration B. Surgical Innovation and Evaluation Evaluation and stages of surgical innovations. Lancet 2009;374:1089-96. https://www.phc.ox.ac.uk/publications/117090

3.2. Has the proposed innovation been performed or introduced elsewhere previously?

○ Yes ◉ No If yes, please attach relevant supporting documentation

3.3. Please indicate the number of cases anticipated to be performed per year at MQ Health

3.4. Do you propose to involve and external expert or supervisor (protor)?

○ Yes ○ No If yes, please enter the relevant details in Appendix A

3.5. Does your innovation carry either significant, or unknown, risks?

○ Yes ○ No If yes, a written patient information statement is strongly advised.
(see Section 6 for advice about patient information statements)

PLUS
if yes, please provide details (+/- references) and how you will review outcomes before any subsequent procedures are performed. *(Maximum 150 words)*

3.6. The outcomes of your innovation must be recorded. Please attach your Data Management Plan (DMP)
(See Section 5 for advice about Data Management Plans)

3.7. The outcomes of your innovation must be reported to your specialty governance structure or M&M Committee. Please provide details of how this will be done *(Maximum 150 words)*

SECTION 3(b): LEARNING CURVES

Explanatory Notes
Depending on the complexity of the procedure, learning curves are known to have a deleterious effect on morbidity and mortality for a surgeon's first twenty to fifty cases. And the outcomes are distinctly poorer in the early part of the curve. As a result, would-be innovators need to take proportional steps to minimise the curve's effects on their patients, and it is a responsibility of the oversight process to ensure that they have done so.

3.8. Have you taken steps to minimise the deleterious effect of the learning curve associated with your innovation?
(Such measures include; attendance at demonstrations and courses, trial procedures in simulators or "wet" labs, and the recruitment of a proctor or colleague to "back-stop" the planned procedure).

◯ Yes ◯ No Please explain your response (*Maximum 200 words)*

SECTION 3(c): ADVOCACY AND SPONSORSHIP

Explanatory Notes
Most clinical innovations are not sponsored by an independent third party. Surgeons offering the innovation are often advocates of the procedure and may also be sponsors. While a professional opinion that the proposed innovation is likely to be beneficial, is not problematic, if the surgeon proposing the clinical innovation is its inventor (and thus might have IP claims), is providing any support (whether financial or support in kind),or stands to benefit from its success, there are potential conflicts of interest that must be declared and managed appropriately.

3.9. Does the applicant have such a potential conflict of interest? (Examples include you potentially gaining intellectual property (IP) rights, or any direct or indirect future financial benefits resulting from the success of the innovation).

◯ Yes ◯ No If yes, a written patient information statement is strongly advised to provide details of the potential conflicts and how they will be managed (*Maximum 200 words)(See Section 6 for advice about patient information statements)*

SECTION 3(d): PROFESSIONAL FEES

Explanatory Notes
Charging fees for an innovative treatment (which, by definition, is not of proven efficacy) greater than those that would apply to standard care is ethically dubious and may prove to be illegal if questioned in common law. (It is illegal to charge patients for their participation in research.)

MQ Health practitioners who do not respect this principle may be the subject to notification to either AHPRA or the NSW HCCC.

3.10. Will the professional fees you charge for this innovation be greater than those that would apply to your provision of standard care?

◯ Yes ◯ No If yes, please provide a justification for your intention (*Maximum 200 words)*

Also, you must obtain, and document, informed financial consent before proceeding. In addition, a written patient information statement is strongly advised. *(see Section 6 for advice about patient information statements)*.

Thank you for completing Section 3. Please skip Section 4 and go to Section 5

SECTION 4: QUALITY ASSURANCE ACTIVITIES INCLUDING CLINICAL AUDIT

Explanatory Notes
Quality Assurance refers to activities designed to assess the coal-face efficacy of established health-care delivery processes. They may involve the review of medical records collected during normal healthcare delivery (clinical audit) or the generation of new health information such as surveys or questionnaires.

When the new health information is anonymous, the patients' willingness to complete the form is accepted as indicative of their consent. New health information that is not anonymous needs both the patients' consent and a data management plan.

The results of QA activities should be disseminated within the generating institution and may at times be worthy of wider dissemination.

4.1. Does your activity involve any departure from normal care?

○ Yes ○ No

If yes, this is not a QA activity, and you should contact clinical.innovation@mqhealth.org.au to arrange discussion of your project

4.2. Does your activity involve direct interaction with human participants? (*This may include patients, carers, health care providers and the institution involved).*

○ Yes ○ No

4.3. Is your activity restricted to a review of health information already collected in the course of normal care?

○ Yes ○ No

If yes, please enter the relevant details in Appendix A

If yes, does the person who will be collecting the data have legitimate access to medical records, either for clinical care or for a directly related secondary purpose?

○ Yes ◉ No

If no, please explain how the data will be collected *(Maximum 150 words)*.

4.4. Will your activity generate health, or sensitive, information beyond what would normally be collected in the course of routine clinical care?

○ Yes ◉ No

If yes, you need to provide copies of the data collection tools, (e.g. scripts of telephone interviews, surveys etc.) and a data management plan.

Outline your data management plan below (*Maximum 150 words).(See Section 5 for advice about data management plans).*

4.5. Will your activity impose any significant burden or risks on its participants?
(Burdens may include intrusiveness, discomfort, inconvenience or embarrassment. Risks include not only physical risks but also psychological, spiritual and social harm or distress).

(●) Yes ( ) No — If yes then you will need to obtain informed consent for what you propose

4.6. Will a permanent database of information be created and kept for further use for QA or other projects?

( ) Yes ( ) No — If yes, provide details below about where it will be stored, its intended use(s) and who will be the custodian of your data. *(Maximum 150 words)*

Please outline how the results of your activity will be disseminated (e.g. in-house or more widely published) *(Maximum 150 words).*

Note that CIAC approval will normally satisfy your ethics approval requirements for publication in peer-reviewed journals and/ or presentation at a conference as a QA activity.

SECTION 5: DATA MANAGEMENT PLAN (DMP)

Advice about data management plans

In preparing a data management plan you should consider and describe the following.

- The nature of the data to be produced by the project.
- Who will be responsible for the overall management of the data.
- How, when and where the data will be acquired.
- Whether the data you collect will be collated with any existing data, and if so, how the existing data will be acquired, and how it will be combined.
- Exactly how the data will be processed.
- How the data will be stored, including security, protection and back-up.
- When and how the data will be destroyed or archived.

5.1. Have you prepared a written Data Management Plan?

( ) Yes ( ) No — If yes, please attach a copy
If no, outline a Data Management Plan below. *(Maximum 200 words)*

SECTION 6: PATIENT INFORMATION STATEMENT (PIS)

Advice about Patient Information Statements
It should be in plain language, as its purpose is to aid patients in coming to a decision about participating, to provide a vehicle for them for discussion with their loved ones, and a document to refer back to.

The commonly addressed issues are;

- The purpose of the project.
- Description of innovation/ new surgical procedure.
- Clinical team
- Why the patient has been invited to participate.
- What participation will involve.
- The evidence about innovation/ new surgical procedure (or lack thereof)
- Whether participation involves (increased) risks.
- What the benefits are likely to be *(for CI to be ethical, its prospects for benefits must outweigh its risks)*.
- What will happen with the results.

Reassurances are usually provided that;

- Patients' confidentiality will be protected.
- Participation is voluntary, and should they decide not to participate, it will not affect their on-going care.
- Participation will not cost them anything, nor will they be paid.

Contact details should be provided for;

- A project lead to enable the patients to discuss it further.

Include a signature block advising the patient has read and understood the PIS, and been given an opportunity to ask question

6.1. Have you prepared a written Patient Information Statement?

◯ Yes ◯ No If yes, please attach a copy

SECTION 7: CONSENT PROCESS

7.1. Please identify the consent process (specific to the project or activity) that will be used.

◯ No consent is necessary. (e.g QA activity not involving interaction with participants)

◯ No consent other than the voluntary completion of an anonymous survey.

◯ Verbal consent only

◯ Participants will be provided with an information statement to acknowledge and retain.

◯ Verbal discussion supported by a standard surgical consent form.

◯ Verbal discussion supported by an acknowledged information statement and a standard surgical consent form.

◯ Other – please provide details below

SECTION 8: FUNDING AND HOSPITAL RESOURCES

8.1. Has or will the Clinical discipline hosting the proposd activity receive any income for this project ? (e.g. grant, fee for services, donation)

Yes ○ No ○

If yes, provide details of the budget and the funding source and how this income will be used *(Maximum 150 words)*

8.2. Does the proposed activity require use of hospital resources, beyond the standard of care? (e.g. operating room, equipment, storage space, laboratory)

Yes ○ No ○

If yes, please obtain separate financial approval from the MUH and Clinical Services Executive

8.3. Will hospital employees help collect project related data or conduct other project related activities?

Yes ○ No ○

If yes, please provide details, e.g. estimate hours of nurse or allied health staff time, etc.) *Note: Sign off from Nurse line manager or Allied Health Director is required*

SECTION 9: APPLICATION DECLARATION

☐ I declare that all information provided in this application and relevant attachments are true and correct

☐ I have read and I am familiar with the **Macquarie Code for the Responsible Conduct of Research** and the **National Statement on Ethical Conduct in Human Research (2018)**

APPLICANTS: NAME	SIGNATURE	DATE

SECTION 10: HEAD OF CLINICAL PROGRAM OR CLINICAL DISCIPLINE DECLARATION

☐ I confirm that I am comfortable with this activity being done within my Clinical Program/discipline

☐ I confirm that I have addressed the resource implications of the activity and am comfortable that the resources necessary to complete it are available for the work

☐ I confirm that the project has financial approval from the MUH Executive

	SIGNATURE	DATE
Clinical Program Head name:		
Nursing line Manager name:		
Director Allied Health name:		

CHECKLIST OF ATTACHMENTS

☐ Project Protocol

☐ Data Collection Tools

☐ Data Management Plan

☐ Patient Information Statement

☐ Appendix A - List of Personnel

☐ Other, please specify