Quality Assurance project – Application Form

Please complete this application form for Quality Assurance (QA) project approval. Do not use this Application form for **research** project applications.

## SECTION 1: PROJECT OVERVIEW

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| * 1. Project Title
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| * 1. Project Summary – provide an overview of the proposed project
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| * 1. Details of the Project Lead
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| Name | Appointment | Department | Email | Phone |
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| * 1. Details of Additional Personnel involved in this project
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| Name | Appointment | Department | Email | Phone |
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## SECTION 2: ETHICAL CONSIDERATIONS

If you answer “yes” to any of the questions in Section 2, the project likely does not meet the criteria for QA project and a full HREC review is required.

### Consent

* 1. Will the activity possibly breach the following National Privacy Principle 2.1 (a)?

NPP 2.1(a) An organisation must not use or disclose personal information about an individual (without consent) for a secondary purpose unless both of the following apply:

1. the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;
2. the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose.

[ ]  Yes – The project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.2

* 1. Do you require *written* consent from participants for this project?

Consider whether it is acceptable to provide a participant information sheet to study participants without the requirement for written consent

[ ]  Yes – The project does not meet the QA criteria and a full HREC review is required.

[ ]  No – Proceed to Q2.3

### Risks and Burdens

* 1. Does the proposed project pose any risk for participant beyond those of their routine care/business? Note: Risks include not only physical risks but also psychological, spiritual and social harm or distress (e.g. stigmatisation, or discrimination).

[ ]  Yes– the project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.4

* 1. Does the proposed project impose a burden on participants beyond that experienced in their routine care / business? Note: Burdens may include intrusiveness, discomfort, inconvenience or embarrassment e.g. persistent phone calls, additional hospital visits or lengthy questionnaires.

[ ]  Yes – The project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.5

### Privacy and Confidentiality

* 1. Is the proposed activity to be conducted by a person who does not normally have access to the patient’s records for clinical care, or a directly related secondary purpose e.g. Practitioners or Health Information Staff?

[ ]  Yes – the project does not meet the QA criteria and a full HREC review is required

[ ]  No – proceed to Q.2.6

*Note:*

*The involvement of a clinical student who is a member of the team in a clinical setting is acceptable. However, the involvement of a student external to the clinical team requires further consideration.*

*The review of medical records by anyone who would not normally have access to information contained therein, unavoidably compromises the privacy of individuals. However, authorised audit of records is an extremely valuable quality assurance activity. Provided the individual reviewing the records is bound by legislation or a professional code of ethics, the access can be considered a directly related secondary purpose, and would be deemed to meet the reasonable expectations of the patient, this question can be answered in the negative.*

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| Please state the position of the person who will have access to the records. (e.g. AMS student, ward pharmacists, etc.) |
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* 1. Does the proposed project risk breaching the confidentiality of any individual’s personal information, beyond that experienced in the provision of routine care/business?

[ ]  Yes – The project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.7

### Overlap with Research (which requires HREC review)

* 1. Does the proposed project involve any clinically significant departure from the routine care provided to the patients?

[ ]  Yes – The project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.8

* 1. Does the proposed project involve randomisation, the use of a control group, or a placebo?

[ ]  Yes – The project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.9

* 1. Does the proposed activity seek to gather medical, health or sensitive information about the patient beyond that collected in routine clinical care?

[ ]  Yes – the project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.10

### Broader Implications

* 1. Does the proposed project potentially infringe the rights, privacy or professional reputations of carers, health care providers or institutions?

[ ]  Yes – The project does not meet the QA criteria and a full HREC review is required

[ ]  No – Proceed to Q2.11

### Budget

* 1. How will the project be funded?

[ ]  External funds – the project does not meet the QA criteria and a full HREC review is required

[ ]  Internal funds – funding already held in a RMH Cost Centre

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| Provide the Cost Centre number and a budget for the project outlining details such as the hourly cost and number of hours per each member of staff on the study. |
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## SECTION 3 - PROJECT / PROTOCOL OUTLINE

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| * 1. What is/are the aim/s of the project?
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| * 1. What is the problem, procedure or practice that will be assessed / quantified?
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| * 1. What is/are the likely benefit/s of conducting this project?
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| * 1. Method: What activities will you undertake to gather the required information to meet the aims of the project?
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| * 1. Will participants be involved in the project? **[ ]  Yes [ ]  No**  (If yes provide details)
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| * 1. Are you seeking verbal or implied consent from participants?

**[ ]  Verbal** **[ ]  Implied (e.g. via the return of a survey) [ ]  No – consent not required**Provide details of the consent process, & submit a copy of the participant information.  |
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| * 1. What information will be collected, and from where / whom?

You should ensure that you have secured the authorisation of the Head of each department with which you are utilising resources. Health Information Services (HIS) have a specific authorisation form required for completion. If you require any access to medical records /patient histories please refer to Q 3.9 below.  |
| **[ ]  Cardiology [ ]  Dermatology [ ]  Emergency** **[ ]  HIS [ ]  Intensive Care [ ]  Radiology** **[ ]  Other:**   |
| Provide further details, including specifics of what data will be collected, where, how & by whom. |
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| * 1. Will you require Pathology to extract data from their laboratory system for this project?

**[ ]  Yes [ ]  No**If yes, provide details below, including specifics of what data will be collected, where, how & by whom. Please contact RMH Pathology Research Support MHPathSupport@mh.org.au to request assistance from Pathology. Data required prior to November 2017, that was previously on CIS, is no longer accessible. To access you will need to request data from Pathology directly.  |
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| * 1. Will you require assistance obtaining data extracts from EMR and/or Health Intelligence (examples: longitudinal data > 12 months, interfaces with external data repositories/multiple sources, variables not included in existing EPIC reports, data for external reporting or analysis)

**[ ]  Yes [ ]  No**If yes, please raise a [Service Now request](https://rchauprod.service-now.com/phssp?id=sc_cat_item&sys_id=d7d780b7db709454bf135e97f49619ec&referrer=popular_items) with details of the data extract (eg. target population, variables, time range, time-series data, aggregate or individual data) and **and notify us of the ticket number below.** |
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| * 1. Will you be accessing information that already exists within the organisation? (e.g. Medical Records, Departmental Databases, Test Results)

**[ ]  Yes [ ]  No**  If Yes, please provide detailsIf you are accessing **paper** **only** medical records/patient histories you must consult with HIS first and submit the HIS QA Request Form with this application available from the RMH website at: <https://www.thermh.org.au/research/office-for-research/quality-assurance> NOTE: The HIS QA Request Form is no longer required when accessing medical records via EMR/ECM. |
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| * 1. How will the data be collected, kept and subsequently destroyed? Attach a copy of any data collection tools with your QA submission.
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| * 1. How will the data be labelled on the data collection tool and/or electronic storage?

*Important: Data should be collected in a non-identifiable manner, i.e. anonymous (no label or a label that is not linked to the participant) or a re-identifiable manner, i.e. coded (with a unique code/ project number, not the UR #) if it is necessary to be able to re-identify the data)* |
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| 3.14 Statistical Analysis: How will the data collected be assessed and results validated? Provide your statistical analysis plan. The Office for Research will not accept QA submissions without this information. |
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| * 1. 3.15 Will a permanent database of information be created and kept that may be used for any other projects?

**[ ]  Yes [ ]  No**If yes, please contact the Office for Research for the RMH Databank Registration Form.  |

## SECTION 4: GOVERNANCE CONSIDERATIONS

### External Organisations

All projects involving two or more organisations, i.e. RMH and at least one other external entity, a Research Collaboration Agreement is required.

The Melbourne Academic Centre for Health (MACH) Research Collaboration Agreement template is available from the Office for Research website: <https://www.thermh.org.au/research/office-for-research/quality-assurance>

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| * 1. Does this project involve any other organisation outside of The Royal Melbourne Hospital?

**[ ]  Yes [ ]  No** If no, proceed to **Section 5: Declaration**If yes, provide the names of any external organisations involved in this project and explain the nature of their involvement. If yes, an agreement is completed as part of the QA application process |
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| * 1. Will any data or results be provided to an external organisation?

**[ ]  Yes [ ]  No** If Yes, provide details – Exactly what data will be provided, to whom, how will it be shared, etc. Note: These data must be protected, e.g., coded, or de-identified, to protect patient/ participant identity.  |
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| * 1. Is this project being conducted at other sites?

**[ ]  Yes [ ]  No**Note: The Melbourne Health HREC provides acknowledgement for RMH sites only. If you are conducting this project at other sites, please ensure that the other sites also obtain appropriate approvals for their involvement in the study including QA and governance (where appropriate.)  |
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## SECTION 5: DECLARATION

### Declaration by Project Lead

As the project lead, I recognise that this quality assurance activity, which is exempt from ethics committee review, must still comply with the *National Statement on Ethical Conduct in Human Research* and *The Australian Code for Responsible Conduct of Research*.’

I confirm that to the best of my knowledge, and based on the answers I have provided in this form, this project meets the criteria for quality assurance activity.

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| Name: |  |
| Signature: |  |
| Date: |  |

Submit you QA Application form along with all required documentation as per the instructions on the RMH website at under the heading The Application Process: <https://www.thermh.org.au/research/office-for-research/quality-assurance>

Thank you