**Minimal\* Risk Research, Quality Assurance or Evaluation Activity**

**PROTOCOL**

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| **IMPORTANT: Delete this text box before submitting this application.**This Protocol template can be used for Minimal\* Risk Research, Quality Assurance (QA), or Evaluation Activities with the appropriate deletion of elements that may not be applicable.Examples of activities this template can be used for are:1. The project involves the potential for no more than **minimal\* risk;** there is no risk of harm or discomfort; potential for minor burden or inconvenience. “Neither burden nor inconvenience should be considered a type of harm or discomfort and therefore should not be viewed as a risk.” Examples of burden and inconvenience are the time that will need to be given up to participate in the research, filling in forms and costs related to travel. The type of projects that might meet this level of risk are projects using:
	* Anonymous existing clinical data with no foreseeable risk; or
	* Existing research data for which consent has been provided for the secondary use; or
	* Non-identifiable or re-identifiable surveys or basic short interviews.

**OR**1. The proposed access is directly related to a **quality/evaluation activity** e.g., training or health service delivery evaluation,where the proposed investigators:
	* Have “rightful” access i.e., for clinical data as a treating clinician, head of department or junior medical staff under direct supervision from either of these persons, or for research data the Principal Investigator; AND
	* Are using non-identifiable data only, OR
	* For use of research data, the extended consent provided by the participant covers the secondary use of the data.

\*Minimal Risk Research has now replaced the previous terminology “Negligible Risk Research” in the NHMRC National Statement on Ethical Conduct of Human Research 2023 (and updates). Instructions for using this template: **Black text;** The recommended text.**Blue text;** Instructions for preparation of the document.**Brown text;** Sample text which you can use in your document**Green text;** For insertion of your own project specific information.**Red text;** Formatting alerts for finalising document.**Delete any instruction content and sample text that you do not want to use or does not apply to your application.** **Any sample text used MUST be changed to black font once the document is finalised.**  |

**PROJECT TITLE:**

**[INSERT FULL PROJECT TITLE]**

Principal Investigator (PI): [insert PI name, this person must have relevant research experience with at least 2 research publications, and ideally have a permanent position at Western Health. If the PI does not have 2 research publications, you will need to indicate that you have sought the advice of or have involved a biostatistician in the design and analysis plan of the project. Please include name, position and institution]

Position:

Institution:

Associate Investigators (AI): [insert AI name – this is anyone else formally involved in the project, their names, positions and institution. Duplicate as required]

Position:

Institution:

The project will occur at the following Western Health site(s): list *Western Health locations where the project activity will be taking place. E.g. Footscray Hospital, Sunshine Hospital, Williamstown Hospital, Sunbury Day Hospital [delete whichever site is not relevant and add any other Western Health sites involved that are not listed]*

# 1. Relevant background information and literature review

*Provide a brief background concentrating on the rationale for doing this project. You should explain why and how the project could conceivably lead to improved quality of care and to improved health outcomes at Western Health. This often involves stating the following:*

* *The nature and extent of the problem.*
* *The impediments to or opportunities for improved care.*

*The background should include:*

1. *A summary of the research question.*
2. *A literature review – this will help to provide justification for the project, and it can help to identify gaps in the literature.*
3. *A concise discussion of recent knowledge and research gaps.*
4. *Information about the outcome measure being used, including whether it has been validated.*
5. *A Bibliography/references.*

*Note: A literature review is not required for QA projects where the project will compare existing practice with a Western Health clinical standard/guideline, however you will be required to reference the standard/guideline. If an appropriate Western Health clinical standard/guideline is* ***not*** *available, then a literature review would be required to determine the appropriate clinical standard/guideline for comparison.*

# 2. Aim of the project

*Your project might have one or multiple aims and/or objectives. This section should articulate the research question. As you might be collecting a broad range of data and exploring multiple facets of a single problem, it is strongly suggested that you organise this section in terms of primary and secondary aims.*

*If applicable you can also list a primary hypothesis +/- secondary hypotheses.*

*The primary hypothesis should include the primary outcome measure, and whether it is being compared to a gold standard or historical control. Alternatively, the project may be a pilot project, and not involve a comparison.*

# 3. The problem, procedure or practice being assessed

* *State what you are intending to do.*
* *What is the problem you have identified.*
* *What is the procedure or the practice that you are assessing?*

*i.e. Perhaps you have identified or anticipated a gap in the understanding or appreciation of clinicians with respect to completion of a particular assessment or task.*

*or*

*It may be that your project will assess compliance with a specific Western Health Clinical Standard. If this is the case, please explain and ensure you insert the name of the Clinical Standard.*

# 4. Outline of the benefits of the project

*If the project is assessing compliance with a known clinical standard, then the following likely benefits can be used, however, if these benefits are not relevant to your project, please provide relevant information about your specific project benefits.*

Sample Text: The benefits of this project are to:

1. Determine the level of compliance with a <insert clinical standard>.

2. Increase awareness and understanding among the clinicians of the <insert clinical standard> and its importance.

3. Improve the compliance with the <clinical standard>.

All of which will improve the quality of care provided to *<insert the patient cohort information>* Western Health.

# 5. Method of data attainment

## Study design:

*Outline what type of study this is, for example:*

*A retrospective audit: reviewing existing medical records, collected as part of routine care. (If this is the type of project you are considering please use the Clinical/Quality Audit Protocol Template)*

*A prospective audit: reviewing current and new medical records, collected as part of routine care. (If this is the type of project you are considering please use the Clinical/Quality Audit Protocol Template)*

*Cohort Study: Describe sources and methods that will be employed in the identification and recruitment of potential participants e.g., clinics, referring doctors, advertisements etc.*

*Cross-sectional Study: Describe the sources and methods that will be employed in the identification and recruitment of prospective participants (e.g., clinics, referring doctors, advertisements etc...) and retrospective data (e.g., medical records, registries, databases etc...)*

*Case-Control study: Describe how the cases will be identified and recruited to your study. Describe how controls will be identified and recruited (e.g., advertisements, letters from GP’s, family members, etc...), and describe how they will be matched to the cases. Provide a justification for how bias has been avoided.*

*Please note: You are not limited to using the examples provided as there are numerous other study designs not listed above, however you need to ensure that you are selecting an appropriate design for your study.*

## Ascertainment:

1. *How will you generate your list of cases for this project?*
* *This usually involves a search of a hospital database - for example a medical records department search of Diagnosis Related Group (DRG), or International Classification of Diseases-Version 10-Australian Modification (ICD-10 AM) codes* *or other suitable sources to identify patients with a certain diagnosis or a search of the pathology system to find a list of patients who have had a certain test or test result, or other hospital databases.*
1. *How will cases or records be identified (e.g., database, clinic waiting lists etc), including whether researchers usually have access to these environments.*

Sample Text: There are no foreseeable issues relating to patient or staff privacy. This is a retrospective project involving access to existing medical records and the research personnel reviewing these records would normally have access to these records. Consent will not be sought as the data accessed for this project is being used for a purpose related to that of its original collection and we will comply with the *NHMRC Ethical Considerations in Quality Assurance and Evaluation activities (March 2014)*.

1. *If this is a prospective project, and consent is being sought, how will participants be approached and recruited if applicable.*
* *Consider issues such as patient or staff privacy, and potential unequal relationships between researchers and participants. It is not appropriate to approach and recruit patients in waiting rooms without adequate privacy. However, it may be appropriate to have signs or leaflets in a waiting area for patients to voluntarily access. If applicable use provided sample text.*

Sample Text: This is a prospective project involving recruitment of participants and consent is being sought. All participants will be given a participant information sheet to read prior to providing their written consent. Access to existing medical records is also required and the research personnel reviewing these records would normally have access in their capacity as an employee of Western Health.

1. *What research resources will be required to complete the project?*

* *Consideration must be given to whether the time commitments of researchers will be within or outside their normal duties, and whether the department will be adversely affected by the commitment.*

Sample Text: This project is fully supported by <insert name of relevant department/institution>. It will be supported by <internal funds/external funding (delete whichever is not relevant) > and the appropriate arrangements have been made to achieve the project objectives. This project will not adversely affect this or any other Western Health department. All resources required for the conduct of this project have been considered and accommodated.

## Inclusion Criteria:

1. *What cases will be eligible for inclusion?*
2. *What type of patients will you be seeking information from?*
* *For example, age>18yrs with diagnosis of COPD*

## Exclusion Criteria:

1. *What types of patients will be excluded from the study?*
* *For example, Records will be excluded if the maternal age is <18 years of age.*

## Timing and Duration of Study:

1. *How many records do you expect to include?*
2. *What is the timeframe you have set to complete this project?*

Sample Text: All <insert specific information for example (COPD)> presentations to the <insert department, ward, service area for example (Emergency Department)> between <insert dates for example (July 2022- July 2023)>, and it is anticipated there will be <insert Number> cases, we expect to complete our data collection in <insert timeframe, for example (6 months)>, commencing in <insert date for example (August 2024)> until <insert date for example (January 2019)>.

## Data Collection and identification:

1. *Describe the data collection method.*
2. *Who will collect the data?*
3. *Does this person usually have access to this information?*
4. *Describe who else will have access to the collected data.*
* *Generally, this will only be members of the research team and a statistician.*
1. *Describe what happens if there is a data breach, where will it be reported?*
2. *When will it be collected?*
3. *How will it be collected?*
* *Historically, data collection has usually been done using a paper form called a Case Record Form (CRF) However, increasingly, and most commonly source data is available in an electronic format and it can therefore be entered directly onto an electronic database such as REDCap or downloaded in a non- identifiable format from an existing Western Health electronic data system in a format ready for analysis.*
* *It does remain good practice to utilise a case report form (either paper or electronic) for collection of data from the source. [Design a CRF that ensures ease of collection and extraction of data. Ensure formatting of the CRF is clear and consistent, allowing data collectors or participants to easily navigate the form.]*
* *Data can also be entered directly onto a REDCap, which is a secure data platform utilised by Western Health. The data is encrypted; password protected and on the Western Health server. For utilisation of REDCap a project specific database will need to be created on the platform and similarly, you will need to ensure the database is set up to accommodate an ease of collection, entering and extraction of data.*
* *Please Note: It has been a requirement since 01 July 2020 data that for all Investigator Lead projects initiated at Western Health Data must be stored on the Western Health REDCap account. To obtain a login please email Frank.Pham@wh.org.au*
* *An exemption to the use of REDCap can be requested in certain situations such as when you are directly exporting data from an existing Western Health data system such as RISKMAN, EMR, Medical Imaging etc and the exported file is in a format ready for analysis and the data is either in a non-identifiable or re-identifiable format.*
* *REDCAP must be used if you are planning to distribute an online survey or questionnaire. You will need to ensure the preamble at the beginning of the survey provides enough information about it.*
1. *State whether collected and stored data will be in identifiable, re-identifiable or non-identifiable form.*
* *Identifiable data is data that includes enough information to easily identify the participant. Information could include names, addresses, hospital unit record numbers or dates of birth. This form of data is rarely required, and is not justifiable for a Quality Assurance project, and if required will escalate an application to full ethical review; either low or high risk depending on the nature of the information collected, how it is collected, and the sensitivity of this information.*
* *Re-identifiable data is data that is not readily identifiable, but can be re-identified if necessary. Usually this occurs through a coding process, where each participant has been assigned a unique study code, and their UR number is not on the data collection sheet/form. All collected data contain only the participant study code. A separate log that contains identifying details and the key to match the study codes is then kept in a separate secure location. Keeping data in a re-identifiable format ensures that a separate and deliberate step is required to link collected data to participants.*

Sample Text *(if using paper case report forms and electronic database)*: The information will be collected in a re-identifiable format. All the data collected will be entered onto the project case report form and issued with its own unique project identification number. A master identifier list with the patient UR and the corresponding project identification number dataset will be kept separately in a password protected file accessible only to the research personnel involved with the project. All paper case report forms will be stored securely in a locked cabinet located in the <insert name, of department, principal Investigator, or wherever the data will be kept> department office and will only be accessible to authorised research personnel. All electronic data sets will be stored in password protected files in the shared drive of computers within Western Health / REDCap account.  *[if NOT using REDCap delete and state what file type]*. These computer files are only accessible to authorised research personnel.

Sample Text *(if using electronic dataset only)*: The information (data) will be collected in a re-identifiable format. All the data collected will be entered onto the project database and issued with its own unique project identification number. A master identifier list/key with the patient UR and the corresponding project identification number dataset will be kept separately in a password protected electronic file accessible only to the research personnel involved with the project. All electronic data sets will be stored in password protected files in the shared drive of computers within Western Health / REDCap account. *[if NOT using REDCap delete and state what file type]*. These computer files are only accessible to authorised research personnel.

* *Non-identifiable data is data that cannot be re-identified. An anonymous survey is an example of non-identifiable data.*

Sample Text: The data will be collected in a non-identifiable manner. The dataset will be allocated a project reference number, but there will be no master re-identifier list. There is no identifiable data being collected.

Or

This project is administering an anonymous survey; therefore, the dataset is non-identifiable.

*Justification must be included in the protocol for the choice of data privacy level. Quality Assurance activities must collect re-identifiable or non-identifiable information.*

# 6. Consent

1. *The Requirement for Consent should be adequately acknowledged. [Only a Human Research Ethics Committee (HREC) accredited by the NHMRC can grant a waiver of consent (See The National Statement on Ethical Conduct in Human Research (2023; and updates) (National Statement) Section 2.3.9-2.3.12). The Western Health Low Risk Ethics Panel cannot grant a waiver of consent as it is not an accredited HREC.]*
2. *Quality Assurance/Improvement Activities require review oversight but will not be subject to a full ethics review.*
* *With this in mind, a waiver for consent is not permissible as the project will not be reviewed by a fully constituted HREC. Therefore, please state why consent is not required for your project if this is appropriate.*
* *If the project is accessing information from a database or patient medical records and it is to be collected retrospectively or prospectively in either a re-identifiable or non-identifiable manner by personnel who would usually have access to the data then consent is not required. However, it is also pertinent and an NHMRC requirement to justify why you are not going to obtain consent.*
* *For more information, please refer to the National Statement Chapter 2.2, General Requirements for Consent.*

*State what form of consent will be obtained from project participants/subjects. Describe the method of consent or select one of the sample texts outlined below.*

*There are different methods of consent, including:*

* *Written informed consent: involving a discussion by researchers with a participant and using a signed consent form such as the Western Health Participant Information and Consent template form.*

Sample Text: All eligible potential participants will be provided with a Participant Information and Consent Form. This form will provide them with information about what their participation involves and outline the risks and benefits. They will be asked to read this and will have the opportunity to ask any questions. They will be advised that participation is voluntary, and they may withdraw at any time, and if they do not wish to participate it will not adversely affect their treatment or relationship with Western Health. A copy of the Participant Information and Consent Form is included as an appendix to this protocol.

* *Implied consent: for example, inferring that participants are happy to take part in a project by them completing a survey. In these situations, the survey should provide a brief explanation of the project at the top, including the fact that it has been approved by an ethics body (if applicable).*

Sample Text: All eligible potential participants will be provided with a copy of the <survey or questionnaire> along with an <information sheet or an information statement> explaining what is required, and that participation is voluntary, and their consent is implied as they have completed the <questionnaire or survey>. The information sheet/statement is included as an appendix to this protocol.

or

All potential participants will be sent an invitation email/letter inviting them to complete an anonymous online survey. The email/letter will explain the project and why they have been asked to participate. It will also include a contact for enquiries if the participant has any concerns. The email/letter will provide a link to the survey. A copy of the sample email text is included as an appendix to this protocol.

* *Consent will not be sought:*

*For QA/QI and Evaluation projects where appropriate justification has been provided; data can be collected without consent: This process may be approved if the activity meets specific criteria; where the data collected is in either a non-identifiable, or re-identifiable format and is not of a sensitive nature. The Ethical review bodies require an explanation of why a no consent process is required and justifiable. The statement below is a good example of justification for when no consent is applicable for when the specific project meets these criteria. If this is relevant to your project, please include the statement. If not, delete irrelevant text and include the appropriate/relevant information regarding why you are not obtaining consent from the persons whose data you are collecting.*

Sample Text: This project will comply with the *NHMRC Ethical Considerations in Quality Assurance and Evaluation activities (March 2014)*.  Consent will not be sought as the data accessed for this project is being used for a purpose related to that of its original collection (ascertaining quality of care) and will be collected by clinicians and/or researchers/quality monitors who would normally have access to the data.

Specifically, we address each of the criteria that must be met in the *National Statement Section 2.3.10* when consent is not being sought:

* 1. This study carries no more than minimal risk, as it is a retrospective/prospective *[delete whichever is not relevant]* study of data that already exists and seeking consent would be inconvenient for patients and may raise concerns that they did not receive high quality care.
	2. The benefits from this research justify any risks of harm associated with not seeking consent. This assumes that patients seeking care from Western Health are likely to expect that as a health care provider, Western Health participates in ongoing quality assurance practices to improve health care provision.
	3. It is impractical to obtain consent, due to the high volume of patients and feasibility challenges of contacting patients who may have moved or changed contact details or are deceased since their admission.
	4. There is no known reason for thinking that patients would not have consented, had they been given the opportunity, as this activity will not/does not change the quality of care they have/have not received, nor does it require any ongoing input from the individual whose data is accessed.
	5. There will be sufficient protection of their privacy.
	6. There is an adequate plan for protection of confidentiality of data (see section regarding data collection and identification privacy and storage of data)
	7. It is highly unlikely that the results would have any significance for an individual participant’s welfare. In the case pooled results have significance for participants’ welfare, appropriate measures will be made to disseminate the results, and made available to the public sphere by publication on the Western Health website and/or local news media.
	8. The possibility of commercial exploitation of derivatives of the data will not deprive the participants of any financial benefits to which they would be entitled.
	9. The request to not obtain consent is not prohibited by state, federal, or international law.

*Researchers are advised to consult with experienced researchers from within their department or contact the Office for Research if they are unsure of the appropriate consent to consider or would like to clarify the level of consent required for their project.*

# 7. Permanent database

*If it is planned that the project will be regularly repeated, consideration should be given to establishing a databank. A databank can be used to hold repeated project data. If the stored data is to be used later for a new project, a separate approval will need to be sought from an ethics body for the new project. Although a yearly report of the databank is required for ongoing ethics approval, there is no requirement to obtain new ethics approval for each episode of data collection. From 01 July 2020 all databanks will need to utilise the Western Health REDCap system*

*For more information, please refer to the National Statement 2023, Section 3 Ethical considerations in the design, development, review and conduct of research; Chapter 3.1The Elements of Research; Element 4: Collection, Use and Management of Data and Information.*

Sample Text: An electronic databank/database will be created, as it is intended to use this dataset for further projects. A separate application will be submitted for review prior to this databank being accessed for future projects. We have enclosed a databank registration form. The databank name is <insert name>, and the custodian of the databank is <insert name>.

Sample Text: A permanent databank/database will not be established. The dataset is only intended to be used for this project only. It will be kept for the required timeframe as outlined in section 8, data storage.

*The databank registration form is available on the Office for Research internet or intranet pages.*

# 8. Data Storage

1. *Describe who owns the data; this is generally the Principal Investigator in their capacity as a Western Health employee. Describe who is the custodian and steward of the data.*
2. *Describe how the data and associated records (emails etc) will be stored and secured.*
3. *At Western Health this type of project data must be stored securely for a minimum of 12 months, or if it is intended to publish the data then it must be stored for 5 years from decision to publish or 5 years from decision not to publish. All data and records that are disposed after this time must be done through a disposal process.*
4. *Collection, Use and Disclosure of Health Information: Identifiable (including potentially identifiable) health information cannot be transferred outside of WH without consent from participants e.g. must remain within the WH server; it cannot be transferred onto REDCap or other applications. This is a requirement of the Health Records Act (Vic) 2001 and the Privacy Act (1998) and Privacy and Data Protection Act 2014.*

*The standard statement below can be used if preferred and it is relevant to your project.* *For further information, consult the Australian Code for the Responsible Conduct of Research (2018) (the 2018 Code) and the topic guide Management of Data and Information in Research.*

*[This Sample Text is for use if the statement is true for your situation otherwise state the actual arrangements]:*

The Principal Investigator will be responsible for the secure storage of the data collected in this project. The paper case report forms will be stored securely in a locked office in the *<insert department name/or location of department>* and will only be accessible to authorised research personnel. *[delete previous sentence if it is not relevant] Electronic* datasets will be stored securely within the Western Health server as a password protected excel file on the Western Health REDCap Account. *[delete whichever data file type is not relevant]*

*For projects where data is collected in a re-identifiable format, the following statement must also be included:*

A data re-identification key file will be stored as an encrypted file separate to the file containing the data. This will be a password protected file stored on a hospital server computer. *[the next sentence must be deleted if not relevant to your project] Paper* Case Report Forms will also be stored separately to any paper master identifier lists, which will maintain the security of the information.

*The statement below should be included as standard information.*

All data will be kept for a minimum of 12 months from completion of the project. All Datasets will be kept for a period of five years from publication or for five years from subsequent decision not to publish. The data will then be destroyed in a secure confidential manner according to the Western Health and National Guidelines at the time of destruction.

# 9. Statistical analysis

*Describe the statistical or qualitative analysis of the data.*

*When analysing your data, you will generally want to try to reach conclusions about:*

* *The general pattern of actual practice.*
* *The degree to which actual practice (results of audit) is meeting the standards set.*
* *Those cases for which it is clinically acceptable for the standards not to be met; and*
* *The limitations of the project.*

*Analysing audit data does not usually require complex statistical tests, although these may be necessary in certain situations. The type of data you have collected will determine the type of analysis employed. If you are unsure of the most appropriate method of sampling for your project it is recommended to consult with a statistician.*

For assistance with biostatistics, please consult our Biostatistician: <http://www.westernhealth.org.au/EducationandResearch/Research/Research%20Facilitation/Pages/Biostatistical-Consulting-Service.aspx>

# 10. Dissemination of results

*State whether you intend for the results of the project to be published or presented and if so, where.*

*Include in this section a statement that presented results will be pooled data only, or non-identifiable individual results.*

Sample Text: Results will be presented at peer group education sessions, within departmental reports and potentially published in peer-reviewed journals and at conferences. Only non-identifiable pooled results will be presented.

# CONFIDENTIAL

This protocol document is confidential and the property of [insert institution name]

No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the institution.

# STATEMENT OF COMPLIANCE

This document is a protocol for a Quality Assurance project. The project will be conducted in compliance with all stipulations of this protocol, the conditions of Western Health Low Risk Ethics Panel approval, the Western Health Research Code of Conduct (2023 and updates), NHMRC National Statement on Ethical Conduct in Human Research (2023 and updates) and the ICH Guidelines for Good Clinical Practice*.*

[Links](http://www.westernhealth.org.au/EducationandResearch/Research/General%20Information/Pages/Standard-Operating-Procedures.aspx) to relevant documents mentioned in this protocol template:

* NHMRC Ethical considerations in quality assurance and evaluation activities (2014)
* NHMRC National Statement on Ethical Conduct in Human Research (2023) - and updates
* NHMRC Australian Code for the Responsible Conduct of Research (2018) and topic guides
* Western Health Research Code of Conduct (2023)
* WH Databank Registration Form
* WH Data Management in Research (Guidelines)