|  |
| --- |
| **IMPORTANT: Delete this text box before submitting this application.**  **This template applies to all CLINICAL/QUALITY AUDIT (retrospective or prospective) submissions only with the appropriate deletion of elements that may not be applicable.**  **Please check against definition of Clinical/Quality Audit below before proceeding with this template.**  Instructions for using this template.  Recommended text is in plain black type.  Instructions for preparation of the document are inblue text*.*  Sample text which you can use in your document is in brown text.  Green text appears in sections for insertion of your own Audit specific information.  **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.**  **DEFINITION OF A CLINICAL AUDIT**   1. ***A retrospective or prospective medical record review; which,***    1. ***Relates specifically to reviewing/measuring against current standards, systems or processes of care with the aim of improving outcomes for patients or improving service delivery; and***    2. ***Designed and conducted to produce information to inform delivery of best care; and***    3. ***Data is accessed, collected and used by a suitably qualified WH employee who in the course of employment would normally have access to such information/medical records; and***    4. ***Data collected is re-identifiable or non-identifiable data and not of a sensitive nature; and***    5. ***Data accessed is being used for a purpose related to that of its original collection; and***    6. ***Data collected is not beyond that which is collected in routine clinical care; and***    7. ***Has been instigated by Western Health; and***    8. ***It is NOT a research project but nonetheless may be intended for publication or presentation at a conference.***   If your proposed activity does not meet the definition of a Clinical/Quality Audit as per the above terms, then it will need to be considered as either a Quality Assurance (QA), Minimal\* Risk Research (MRR) (use the QA/MRR/Evaluation protocol template) or a Low Risk Project and submitted for ethical review to the Low Risk Ethics Panel. You must incorporate the requisite consenting obligations that are applicable to such research projects and use alternate submission forms which can be assessed on our website.  If it is planned that the audit will be regularly repeated, consideration should be given to establishing a databank. *More information can be accessed* [*here*](http://www.westernhealth.org.au/EducationandResearch/Research/Pages/default.aspx)  *\*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.* |

**CLINICAL/QUALITY AUDIT TITLE**

***[INSERT FULL AUDIT TITLE]***

Principal Investigator: *[insert PI name]*

Position:

Institution:

Associate Investigators: *[insert AI name]*

Position:

Institution:

*Duplicate to add additional AI as required*

The project will occur at the following Western Health site(s):*list Western Health locations where the project activity will be taking place. Eg. Footscray Hospital, Sunshine Hospital, Williamstown Hospital, Sunbury Day Hospital [add other Western Health sites if applicable or delete whichever site is not relevant]*

**1*.* Relevant Background Information**

*The background gives the information on why you are conducting the audit e.g. assessing your clinical practice. If you are looking critically at clinical care you need to identify and reference evidence of good clinical practice standards/guidelines on which to base your assessment.*

**2. Aim of the Audit**

1. *To review a local standard of care compared to current recognised standards, systems or processes of care, with the aim of improving outcomes for patients or improving service delivery. AND/OR*
2. *The Audit may also be conducted to provide data to inform the development of clinical standards and guidelines, especially if no higher level of evidence is available, or to guide further review of clinical practice.*

## 3. Outline Of The Benefits Of The Audit

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

Sample Text: The benefits of this audit are to:

1. Review current practice and 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 standards of patient care and compliance with the <clinical standard>.

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

## 4. Audit Design:

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

Sample Text: This is a retrospective audit reviewing existing medical records to <insert objectives>

And/or

Sample Text: This is a prospective audit reviewing current and new patient medical records for patients <admitted or presenting> with <insert relevant information>

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 2013- July 2014)>, 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 2020)> until <insert date for example (January 2020)>.

**5. 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?
   * Describe who else will have access to the collected data.
     1. Generally this will only be members of the research team and a statistician.
4. When will it be collected?
5. How will it be collected?
   * Most commonly, data collection will be collected on an Audit Form (paper and/or electronic)
     1. Design an Audit Form that ensures ease of collection and extraction of data. Ensure formatting of the Audit Form is clear and consistent, allowing data collectors to easily navigate the form.
   * Alternatively data can be entered directly onto an Excel or Access or REDCap database or other electronic database, which will need to be encrypted; password protected and stored on a hospital computer. Western Health now has a REDCAP database platform and from 01 July 2020 the use of Western Health REDCap database platform will be mandatory for all Western Health Investigator Initiated projects. To obtain access to this platform email Frank.Pham@wh.org.au for a login.
   * Any information stored on a USB data storage device must be in a non-identified format only.
   * 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 in either a non-identifiable or re-identifiable format.

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 audit case report form and issued with its own unique audit identification number. A master identifier list with the patient UR and the corresponding audit identification number dataset will be kept separately in a password protected file accessible only to the WH research personnel involved with the audit. 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 WH authorised research personnel.

Sample Text *(if using electronic dataset only)*: The information will be collected in a re-identifiable format. All the data collected will be entered onto the audit database and issued with its own unique audit identification number. A master identifier list with the patient UR and the corresponding audit identification number dataset will be kept separately in a password protected electronic file accessible only to the WH research personnel involved with the audit. All electronic data sets will be stored in password protected files in the shared drive of computers within Western Health. These computer files are only accessible to authorized WH research personnel.

* *Non-identifiable data is data that cannot be re-identified. For example; An anonymous survey or data extracted without allocation of a code number and the use of a master re-identifier list to re-identify the data.*

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

**6. Data Storage**

1. *Describe who owns the data; this is generally the Principal Investigator in their capacity as a Western Health employee.*
2. *Describe how the data (paper and/or electronic) will be stored and secured.*
3. *At Western Health audit 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 (Health Records Act (2001); Schedule 1, Health Privacy Principles; Section 4, 4.2b (ii)).*

*The standard statement below can be used if preferred and it is relevant to your audit.* *For further information, consult the Australian Code for the Responsible Conduct of Research Section 2.1.1.*

Sample Text is for use if the statement is true for your situation otherwise state the actual arrangements: ie if you are not using paper forms, then revise the statement to reflect where electronic files will be stored.

The Principal Investigator will be responsible for the secure storage of the data collected in this audit. The paper Audit 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 WH research personnel. Electronic datasets will be stored securely within the Western Health server as a password protected excel file/REDCAp Database *[delete whichever is not relevant]*.

*For audits where data is collected in a re-identifiable format, the following statement must also be included: however if not using paper forms delete the reference to them and ensure content of statement is true for your situation.*

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. Paper Audit Forms/Datasets will also be stored separately to any paper master identifier lists, which will maintain the security of the information.

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

All data will be kept for a minimum of twelve months from completion of the audit. 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.

**7. Statistical analysis**

*Consultation with a statistician is recommended if you are unsure of the most appropriate method of sampling for your audit.*

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

**CONFIDENTIAL**

This document is confidential and the property of Western Health

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 Clinical/Quality Audit. The audit will be conducted in compliance with all stipulations of this protocol, the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014), and the NHMRC National Statement on Ethical Conduct in Human Research (2023; and updates) and the ICH Guidelines for Good Clinical Practice (2016)*.*

Please use this [Link](http://www.westernhealth.org.au/EducationandResearch/Research/General%20Information/Pages/Standard-Operating-Procedures.aspx) access the relevant documents below for more information as 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)
* Australian Privacy Principles February 2013 (amended January 2014)
* Health Records Act (2001)
* Wesern Health Research, Ethics and Goverannce Procedure (2022)
* Western Health Research Code of Conduct (2023)
* WH Databank Registration Form
* WH Data Management in Research (Guidelines)