This template can be used for CLINICAL/QUALITY AUDIT or QUALITY IMPROVEMENT(retrospective or prospective) submissions. *Please make sure that you delete any text that is not be applicable.*

**Please check against definition of Clinical/Quality Audit below before proceeding with this template.**

**IS YOUR CLINICAL AUDIT:**

|  |  |  |
| --- | --- | --- |
| ***A retrospective/prospective medical record review which:*** | **YES** | **NO** |
| * 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* |  |  |
| * 1. *Designed and conducted to produce information to inform delivery of best care; and* |  |  |
| * 1. *Data is accessed, collected and used by a suitably qualified RHC employees or Accredited Practitioners who, in the course of employment, would normally have access to such information/medical records; and* |  |  |
| * 1. *Data collected is re-identifiable or non identifiable data and not of a sensitive nature; and* |  |  |
| * 1. *Data accessed is being used for a purpose related to that of its original collection; and* |  |  |
| * 1. *Data collected is not beyond that which is collected in routine clinical care; and* |  |  |
| * 1. *Has been instigated by a Ramsay Health Care staff member or Accredited Practitioner;* |  |  |
| * 1. *The data collected and analysed for the QA/QI activity will be stored on a Ramsay Health Care computer and password-protected; and* |  |  |
| * 1. *It is NOT a research project but is still intended for publication or presentation at a conference* |  |  |

If you have answered **NO** to any of the above questions, your proposed activity **does not** meet the definition of a Clinical/Quality Audit. It will need to be considered as either a Negligible risk or Low Risk Research Project and submitted for ethical review to the appropriate Ramsay Health Care HREC. Your project will need to incorporate the appropriate consenting obligations as per the National Statement on Ethical Conduct in Human Research that are applicable to such research projects.

This should be submitted via REGGS. More information can be found on the Ramsay Research Website <https://www.ramsayhealth.com.au/Ramsay-Research>.

Instructions for using this template.

Instructions for preparation of the document are in**blue text***.* Sample text which you can use in your document is in **green text.** **Red 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.**

If it is planned that the audit will be regularly repeated, consideration should be given to establishing a databank. Please contact the HREC if you would like more information about this.

|  |  |
| --- | --- |
| **Project Details** | |
| Name of Hospital Site(s) |  |
| Department |  |
| **Department Manager Approval:** | |
| Name of Manager: |  |
| Date Discussed (attach email or other evidence of support) |  |
| **Investigators** | |
| Principal Investigator Name  Position:  Institution:  Email: |  |
| Associate Investigator Name  Position:  Institution:  *Duplicate to add additional AI as required* |  |
| Reason for Audit (*e.g., incident, complaint, general or scheduled review, evaluation etc.)* |  |
| Is Audit/Survey related to a previous Audit/Survey or part of a previous Quality Improvement? |  |
| When will the Audit start and finish? |  |

**CLINICAL/QUALITY AUDIT TITLE [INSERT FULL AUDIT TITLE]**

**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.*

Ensure that you name the current standard or Guideline that you are comparing against and include this as supporting documentation with your Application.

## 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 Ramsay Health Care.

## 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. If your audit includes medical record review, state whether this will occur on the ward during patient admission or retrospectively by a request to Health Information Services?
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) eg Medical Record Review at ward level, Audit system, Survey Monkey, Google Forms etc
     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 database or other electronic database, which will need to be encrypted; password protected and stored on a hospital computer.
   * Any information stored on a USB data storage device must be in a non-identified format only.

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 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 Ramsay Health Care HOSPITAL NAME. These computer files are only accessible to 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 research personnel involved with the audit. All electronic data sets will be stored in password protected files in the shared drive of computers within Ramsay Health Care HOSPITAL NAME. These computer files are only accessible to authorised 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 Ramsay Health Care employee.*
2. *Describe how the data (paper and/or electronic) will be stored and secured.*
3. *At Ramsay Health Care, 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:

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 research personnel. Electronic datasets will be stored securely within the Ramsay Health Care server as a password protected excel file or Access database *[delete whichever is not relevant]*.

*For audits 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. 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 Ramsay Health Care 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.*

**8. Dissemination of Information**

*Outline how you will be communicating the results of your Audit and to whom. If you are intending on presenting this Audit as a Poster or paper for a Conference please include this in your dissemination process.*

**CONFIDENTIAL**

This document is confidential and the property of Ramsay Health Care

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 NHMRC National Statement on Ethical Conduct in Human Research 2023 and the ICH Guidelines for Good Clinical Practice (2016)*.*

* NHMRC Ethical considerations in quality assurance and evaluation activities (2014)
* NHMRC National Statement on Ethical Conduct in Human Research, 2023
* NHMRC Australian Code for the Responsible Conduct of Research (2018)
* NHMRC Guidelines approved under Section 95A of the Privacy Act 1988 (2014)
* Australian Privacy Principles February 2013 (amended January 2014); <https://www.oaic.gov.au/privacy/australian-privacy-principles>
* Health Records Act (2001)