## **Before Submission:**

* Use [the Level of Risk Checklist](https://www.easternhealth.org.au/images/Level_Of_Risk_2022.docx) to determine if your proposed activity is Quality Assurance/Audit.
* Discuss the project design and scope with your supervisors/peers.
* We recommend that proposals for all studies that involve patient contact, be presented/discussed with the relevant clinical unit prior to submission.
* Where appropriate discuss appropriate statistical analysis methods with a statistician.

## **Submission in Ethical Review Manager (ERM) website**

* Fill in this protocol template.
* Upload protocol, data collection sheets and/or questionnaire/survey.
* **Make sure all your submitted documents have a version number and date. This includes within the document (i.e. in the footer) and the document file name.**
* Please make sure to use the current Eastern Health Logo for any participant facing documents.
* Only ONE investigator can be the Principal Investigator.
* Please have ALL investigators sign the declaration in ERM.
* The Head of the Department and the Head of Supporting Departments (if any) are to sign the declaration in ERM to demonstrate endorsement of the project.
* Upon submission in ERM, please send a courtesy email to Ethics inquiries at ethics@easternhealth.org.au

# **Quality Assurance and Audit Activity Protocol**

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| * 1. **Overview**
 |
| Project Title | Click or tap here to enter text. |
| Department | Click or tap here to enter text. |
| Version number | Click or tap here to enter text. | Date | Click or tap to enter a date. |
| Is this a:(please tick what best describes your proposal) | [ ]  Clinical AuditSeeks to improve patient care through review of care against explicit standards. Designed to produce information to inform delivery of best practice. Analysis of existing data, possibly interview/questionnaires. |
| [ ]  Service Evaluation or Practice ReviewSystemic evaluation about a specific program or intervention OR systematic assessment of current practice without comparison against a set of standards. Evaluates current care. Uses existing data possibly interview/questionnaire. |
| [ ]  Satisfaction SurveySystematic collection of data from a sample of patients or staff to determine levels of satisfaction or knowledge about a service or process. |

## **Investigator Details**

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| * 1. **Principal Investigator**
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| Name & Title | Enter text. |
| Position | Enter text. |
| Department & Site | Enter text. |
| Email | Enter text. | Phone | Enter text. |
| Institute (tick all applicable) | [ ]  Eastern Health employee[ ]  Dual Appointment | [ ]  Other (please specify): Enter text. |

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| * 1. **Associate Investigators**
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| **Name & Title** | **Position** | **Relation to Eastern Health (tick all applicable)** |
|  |  | Current employee | Dual appointment | Student | Other (specify) |
| Enter text. | Enter text. |[ ] [ ] [ ]  [ ]  enter text. |
| Enter text. | Enter text. |[ ] [ ] [ ]  [ ]  enter text. |
| Enter text. | Enter text. |[ ] [ ] [ ]  [ ]  enter text. |
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| Enter text. | Enter text. |[ ] [ ] [ ]  [ ]  enter text. |

## **Project Overview**

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| * 1. **Brief Summary of the Audit/Evaluation activity in plain language ( no more than 100 words)**
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| Click or tap here to enter text. |

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| * 1. **Background** – Why are you conducting the project? What are the current clinical standards being compared to? What are you trying to assess? Etc.
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| Click or tap here to enter text. |

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| * 1. **Aim/Objective** - define clearly your clinical audit objectives, why you are doing the project and what you are hoping to achieve. What are the targets? Focus on the clinical importance.
 |
| Click or tap here to enter text. |

## **Project Design**

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| * 1. **Duration** – What is the planned duration of this project? NOTE a maximum of 2 years for QAs is allowed. If the project requires more than 2 years, consider applying for a Negligible/Low risk ethics application and contact the Eastern Health Office of Research Ethics for advice.
 |
| Click or tap here to enter text. |

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| * 1. **Sites at Eastern Health**
* Tick all applicable
 |
|[ ]  Angliss Hospital |[ ]  Turning Point |
|[ ]  Box Hill Hospital |[ ]  Wantirna Health |
|[ ]  Healesville Hospital & Yarra Valley Health |[ ]  Yarra Ranges  |
|[ ]  Maroondah Hospital |[ ]  Other: Click or tap here to enter text. |
|[ ]  Peter James Centre |[ ]  Other: Click or tap here to enter text. |
|[ ]  Spectrum Service |[ ]  Eastern Health Wide |

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| * 1. **Participant Records Details** (for projects involving collection of identifiable records)
* Description of target participants, e.g. age, diagnosis, treatment, service etc.
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| Click or tap here to enter text. |

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| * 1. **Participant Recruitment (if applicable)**
* Where, by whom and who will be asked to participate? Inclusion/Exclusion criteria. Consent procedure.
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| * 1. **Survey/Questionnaire (where applicable)** – please describe the survey and also include a copy of the survey in your submission. The survey will need to explain what the survey is, who is conducting it, that participation is voluntary, what will happen to the collected data and statement that completion of the survey implies consent.
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| Click or tap here to enter text. |

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| * 1. **Number of records and/or participants–** break down into groups if applicable. Justification of sample size.
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| Click or tap here to enter text. |

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| * 1. **Data Analysis -** What data you will be collecting and how the data will be collected.

Include a copy of the data collection template (e.g. Excel spreadsheet or REDCap) as an Appendix or as an additional document in your submission.The type of data collected will determine the analysis employed. Generally, audits/evaluations do not requires require complex statistical tests. The type of data you have collected will determine the type of analysis employed. |
| Click or tap here to enter text. |

## **Data Management**

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| * 1. **Data Management –** As consent is not normally obtained for audits it is especially important that measures are taken ensuring patient/participant privacy and confidentiality. Detailed information on collection and storage is required.

Please refer to the Eastern Health policies on Confidentiality and Privacy. |
| Who will collect the data? | Click or tap here to enter text. |
| Source of the data (EMR,CPF…) | Click or tap here to enter text. |
| What format will the data be collected? | [ ] Identifiable [ ] Re-identifiable [ ] Non-identifiable |
| What format will the data be stored? | [ ] Identifiable [ ] Re-identifiable [ ] Non-identifiable |
| Where will the data be stored? Electronic and paper based. | Click or tap here to enter text. |
| How long will the data be stored? | Click or tap here to enter text. |
| Who will have access? | Click or tap here to enter text. |
| Click or tap here to enter text. |

## **Dissemination of Results**

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| * 1. **Dissemination of Results –** Select all those that apply and provide information on what format the data will be shared. How will the privacy of participants be protected?
 |
| [ ]  Shared with the Department |
| [ ]  Shared within Eastern Health |
| [ ]  Presented at a Conference (provide details below) |
| [ ]  Journal Publication |
| [ ]  Student report/thesis (provide details below) |
| [ ]  Other (provide details below) |
| Click or tap here to enter text. |

## **References**

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| * 1. **References**
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| Click or tap here to enter text. |