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| SAC HREC Ethics Exemption Evaluation form |
| This is not an ethics application form and is to be used if you are requesting an evaluation of your project, to confirm it is exempt for ethics approval |

**Instructions**

The Office for Research advises that any projects that are classified as Continuous Improvement (CIP), Quality Assurance (QA)/ Quality Improvement (QI), audit, service design or negligible risk projects may not require ethical review by the Southern Adelaide Clinical Human Research Ethics Committee.

An activity whose primary purpose is to monitor or improve the quality of service is considered Continuous Improvement, Quality Improvement, Service Improvement. The project must only occur within SALHN, and data collected must remain within SALHN.

If the project is being conducted as part of / towards a degree or any part is external to SALHN, an ethics application is required.

Providing the intention of your project fits within this framework, ethics review is not required.

Accessing patient data for publication only purposes is not appropriate. Accessing patient data should always be for the purpose to monitor or improve the quality of service.

Examples of this type of work are:

* Review a current system and/or process e.g., revised procedure, form or care pathway, reconfiguration of services, redevelopment.
* New Improvement e.g., Continuous improvement project, new process, new equipment.
* Audit/Survey e.g., Clinical indicator, key performance indicator, consumer survey, safety systems audit, a NSQHS Audit, Gap Analysis.

These projects can be achieved via any of the below pathways: benchmarking and clinical variation, Patient Reported Outcome Measures and clinical quality registries.

CIP/ QA/ QI activity must comply with the *National Statement on Ethical Conduct in Human Research* and *The Australia Code for Responsible Conduct of Research.*

Please complete this evaluation form, providing the details of your project and email to Health:SALHNofficeforresearch@sa.gov.au

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| **Date**: |
| Project Team |
| **Project lead** (Please note students cannot be the project lead)  **Name:**  **Position:**  **Directorate:**  **Department:**  **Email address:** |
| **Associate project team member/s**  **Name:**  **Position:**  **Directorate:**  **Department:**  **Email address:** |
| Project overview: |
| **Project title:** |
| **Please provide a summary of the project:** (please provide a brief overview of the project and why you are doing it) |
| **What will the results of this project be used for?** (Please select all that apply)  Publication  Conference presentation  To determine if any improvements can be made to departmental service or delivery / guidelines / protocols.  Department presentation  Setting up a database or registry |
| **Background** (how did you develop the idea for this project?) |
| **Literature review** (Please provide a literature review / or an evidence base for this project. If you need support with completing this, please contact [fmc.library@sa.gov.au](mailto:fmc.library@sa.gov.au) |
| **Methodology** (clearly describe the specific procedures or techniques that will be used to obtain your outcomes that demonstrate how this qualifies as quality improvement) |
| **Are there any SA Health guidelines, standards or protocols being used in this audit to compare against current practice?**  Yes – please detail which ones are being used:  No  **Are you using any of the below NSQHS Standards (2nd edition)** *(please select all that apply)*   |  |  | | --- | --- | | ☐1. Clinical Governance | ☐5. Comprehensive Care | | ☐2. Partnering with Consumers | ☐6. Communicating for Safety | | ☐3. Preventing & Controlling Healthcare-Associated Infection | ☐7. Blood Management | | ☐4. Medication Safety | ☐8. Recognising & Responding to Acute Deterioration |   *For further information on standards please refer to the following website:* <https://www.safetyandquality.gov.au/> |
| **Aims** (what do you intend achieve with this project?) |
| **Outcomes** (what do you anticipate this project will achieve) |
| Data management |
| **The data is:**  retrospective  prospective - please justify why prospective collection data is required:  de-identified.  identifiable - Please justify why identifiable data it is required: |
| **Where is the data being collected from?** (i.e., medical records, department database) |
| **What format will the data or information be stored?** i.e., spreadsheet, case report form |
| **Where will the data be stored** and what security measures are in place to protect it during the project? It is not appropriate to store patient data on a USB, SSD, email, Microsoft Teams, a personal computer or google docs. |
| **What conditions can the data be accessed or granted to others?**  **Will the data be shared outside of SALHN?** |
| **What security measures are in place to protect the data after the project?**  **Is the data being used to create a Registry or database?** |
| Declarations |
| **Applicant**  I recognise that a research activity that is exempted from ethics committee review must comply with the *National Statement on Ethical Conduct in Human Research* and *The Australia Code for Responsible Conduct of Research*.  I confirm the information provided in this form is true and correct.  **Applicant:**  **Date**:  Signature: |

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| **Head of Department**  I recognise that a research activity that is exempted from ethics committee review must comply with the *National Statement on Ethical Conduct in Human Research* and *The Australia Code for Responsible Conduct of Research*.  I confirm the information provided in this form is true and correct.  **Name:**  **Date**:  Signature: |

**Polices and guidelines:**

* The SALHN Four Fields of Enquiry – Continuous Improvement
* Australian Commission on Safety and Quality in Health Care – standard 1.8/1.9/1.28
* SA Health Research Governance Policy Directive v3.2 dated 30.07.2020
* Health Care Act 2008
* The National Statement on Ethical Conduct in Human Research 2007, updated 2018
* The Australia Code for Responsible Conduct of Research