**Goulburn Valley Health** [](http://gvhintranet.gvhealth.local/department/CommunityEngagement/Logos/GVHealth%20Logo%20Vert%20(A).jpg)

# Research Governance Unit

**QUALITY ASSURANCE ACTIVITY / AUDIT**

**APPLICATION FORM**

**Approval No: GVH ………./……..**

**Please note: This application is to be submitted in typed form only. Handwritten applications will not be accepted.**

**All sections must be completed.**

**Project Details**

|  |  |
| --- | --- |
| Project title |  |
| Commencement date |  |
| Funding Source |  |

**Principal Investigator**

|  |  |
| --- | --- |
| Title and Name |  |
| Position |  |
| Department |  |
| Institution |  |
| Mailing address |  |
| Phone |  |
| Email |  |

**Additional contact person (if relevant)**

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment |  |
| Department |  |
| Institution |  |
| Mailing address |  |
| Phone |  |
| Email |  |

**Description of proposed activity**





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| **1. Rationale and Objectives** |
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| **2. Methodology - Including how QA activity will be conducted, timelines, number of participants/records, data collection and analysis. Please use simple, non clinical language.** | |
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| **3. CONSENT** | |
| *Will written informed consent be obtained from participants? If yes, please include a copy of the Information Sheet/Consent Form for review.* |  |
| *Will verbal and/or implied consent be obtained from participants?* |  |

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| **4. RISKS AND BURDENS**  The risk and/or burden to participants must be negligible for QA activities. Risk and/or burden include extensive interviews, lengthy questionnaires, persistent reminders, and/or intrusive/personal questions. | |
| *Does the proposed QA activity impose any additional burden, harm or risk, beyond those associated with routine care?* |  |

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| --- | --- |
| **5. PRIVACY AND CONFIDENTIALITY**  Participants records (medical records, databases, data/tissue banks) used for QA activities may only be accessed by those with usual access (through routine clinical care or professional practice) or by those with a directly related secondary purpose. | |
| *Will participant records/information be accessed by those with routine access through clinical care/professional practice* ***OR*** *by those with a secondary purpose which is directly related to the patient’s clinical care?* |  |
| *Will the confidentiality of participant records/information be maintained at all times?* |  |

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| **6. OVERLAP WITH RESEARCH**  QA activities **must not** involve a deviation from normal standard care, and must not include the assessment of safety/efficacy of a new intervention or device. Any requirement for additional testing, blood or tissue collection, physical or psychological testing, or longer interviews are not considered quality assurance. Similarly, QA activities **must not** involve randomisation, or the use of control groups/placebo. | |
| *Does the proposed QA activity involve any clinically significant departure from the routine clinical care provided to patients?* |  |
| *Does the proposed QA activity involve randomisation, control groups, or the use of placebo?* |  |
| *Does the proposed QA activity seek to gather information about the participant beyond that collected as part of routine care?* |  |

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| **7. PRIVACY AND DATA STORAGE** | |
| *Are the rights, privacy, and professional reputation of any persons or institutions involved free from any risk of infringement?* |  |
| *Will all data collected for as part of the proposed activity non-identified?* |  |
| *Will the storage of such information be securely held within the department for a minimum period of 7 years, in a non-identified format?* |  |
| *Will all data/information be published in a non-identified format?* |  |

*\*Please attach any further information that you wish to submit, to this application (optional)\**

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| 8. Principal Investigator Declaration |

I confirm that the information provided in this application is true and correct and that I agree to adhere to all relevant legislation and guidelines during conduction of this activity

**Signature:**

**Date:**

|  |
| --- |
| 9. Head of Department Declaration |

I confirm that I support the conduct of this study by the Principal Investigator within the department that I manage.

**Name:**

**Department:**

**Signature:**

**Date:**