# WESTERN HEALTH LOW RISK ETHICS PANEL

###### QA/MRR Final Report Form

Approval of Quality Assurance (QA)and Minimal Risk (previously Negligible Risk) Type Research (MRR) projects via the expedited QA/MRR submission pathway is conditional upon the provision of a final report on completion of the project. **A brief summary of the project MUST accompany this report form for final reports.**

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| Date of Report: Enter date |  |

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| 1. **RESEARCH PROJECT DETAILS** | | | | | | | | | |
| **Project Number:** | | E.g.; QA2018.123 ERM ID12546 | | | | | | | |
| **Project Title:** | | Enter text | | | | | | | |
| **Principal Investigator:** | | Enter text | | | | | | | |
| **Study Contact/Coordinator:** | | Enter text | | | | | | | |
| **Study Site/s being reported:** | | Sunshine Hospital | | Footscray Hospital | | | | | Williamstown Hospital |
| Sunshine Radiation Therapy Centre  ☐ Melton Health  ☐ Grant Lodge Residential Aged Care | | Drug Health Services  ☐ Melton Health & Community Centre | | Bacchus Marsh Hospital  ☐ Bacchus Marsh Community Health Centre | | | | | Sunbury Day Hospital  ☐ Caroline Springs Community Health Centre |
| **Date of Original Approval:** | | Enter date | | | | | | | |
| **Reporting PeriodƗ:** Enter report start date to Enter report start date | | | | | | | | | |
| ƗThe reporting period is for the period from approval date until the end of the project. QA Approval is for a maximum of a two-year period unless you have obtained an extension of approval. E.g., November 2023 to November 2025. | | | | | | | | | |
| 1. **PROJECT PROGRESS** | | | | | | | | | |
| **QA Project Commencement/Initiation date:**  Enter date | | | | | | | | | |
| **Current status of research project:** Select one | | | | | | | | | |
| **Date of completion/Date of Abandonment:** | | | | | | Enter date | | | |
| **If project was abandoned, please provide reasons why:** | | | | | | Enter text | | | |
| 1. **SUMMARY OF FINDINGS Not applicable (project abandoned)** | | | | | | | | | |
| **Provide a brief** **summary of the research project below:**   * Summary of findings * Details of any publications accepted or in press * Details of any presentations given   Whether participants involved in the study have been informed of the results | | | | | | | | | |
| Enter text | | | | | | | | | |
| 1. **DATA ANALYSIS** | | | | | | | | | |
| **Status of Data Analysis?** Select one | | | | | | | | | |
| **Data Analysis Completion Date:**  Enter date | | | | | | |  | | |
| 1. **PROBLEMS ENCOUNTERED** | | | | | | | | | |
| **Have problems been encountered in the following areas?** | | | | | | | | | |
| * **Study Design:** | | | | | Yes No | | | | |
| * **Ethical Considerations:** | | | | | Yes No | | | | |
| * **Recruitment of Subjects:** | | | | | Yes No  N/A | | | | |
| * **Finances:** | | | | | Yes No | | | | |
| * **Facilities/Resources/Equipment:** | | | | | Yes No | | | | |
| * **Other(s)** | | | | | Yes | | | | |
| **If yes for any of the above, please provide details:** Enter text | | | | | | | | | |
| 1. **AMENDMENTS** | | | | | | | | | |
| **Was the research project conducted according to the study protocol?** | | | | | | | | | Yes No |
| **Were all conditions of QA approval met?**  **If no, please clarify below:** | | | | | | | | | Yes No |
| Enter text | | | | | | | | | |
| **Was the original project amended?**  **If yes, please include the number of amendments and a summary of the changes made to the project. E.g., Change to personnel, administrative changes, extension for approval** | | | | | | | | | Yes No |
| Enter date(s) as applicable | | | | | Enter text | | | | |
| Enter date(s) as applicable | | | | | Enter text | | | | |
| 1. **RECRUITMENT** | | | | | | | | | |
| **Not applicable**  **(Go to Q9)** | | | | | | | | | |
| **Recruitment target:** | Enter number | | **Recruitment to date:** | | | | | Enter number | |
| **Withdrawn to date:** | Enter number | | **Was recruitment on target?** | | | | | Yes  No | |
| **Provide reasons for participant withdrawal:** Enter text | | | | | | | | | |
| **If recruitment was not on target, provide an explanation:** Enter text | | | | | | | | | |
| 1. **ADVERSE EVENTS (AE) & SERIOUS ADVERSE EVENTS (SAE)** | | | | | | | | | |
| **Have there been any AEs or SAEs that have raised safety issues in relation to the research project, which occurred in the past 12 months or since the project was approved and are yet to be reported to the Office for Research?**  **\***If events that raised safety issues were not reported, please complete the AE & SAE Report Form | | | | | | | | Yes\* No | |

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| 1. **SELF AUDIT** | | |
| Please complete ALL points. Are all of the following true for your research project? Please check all questions, failure to provide a satisfactory self-audit will result in a detailed short audit review of your project. | | |
| **QA STUDY OVERSIGHT** | | |
| The Principal Researcher knows where to find all relevant documentation and has been provided with the passwords to the databases.  The documentation for my project is up to date, accessible, clearly ordered and comprehensible. | | Choose an item. |
| All personnel were trained in the study protocol and Good Clinical Practice (GCP) prior to study involvement.  Training and delegation logs are completed and maintained for this protocol. Ongoing training for new personnel or for protocol amendments have been completed and documented as required. | | Choose an item. |
| I have informed all study personnel of any updates regarding the study protocol, and any matters relating to data collection, storage and publication. | | Choose an item. |
| Approaches to potential participants have been made only by the researchers with full knowledge of the study protocol and of the risks and inconveniences associated with participation (and approved by the Office for Research) | | Choose an item. |
| All essential documents are stored as per approved protocol.  (e.g., Electronically via WH SharePoint or REDCap and/or hard copies stored in a secure locked cabinet at WH premise only.) | | Choose an item. |
| **ETHICS AND GOVERNANCE** | | |
| I have conducted the study in accordance with the protocol approved by the Office for Research. Any amendments or changes in personnel have been reported to the Office for Research and the relevant documents updated. | Choose an item. | |
| **Current approved Protocol:**  Version: Click to insert version number  Dated: Please insert date | |
| I have received the Office for Research approval for all public advertising material that seeks volunteers to participate in the study. | Choose an item. | |
| I have reported all serious and unexpected adverse incidents to the Office for Research. | Choose an item. | |
| **PARTICIPANT INFORMATION AND CONSENT FORM (PICF)** | | |
| The project involved recruitment of participants and use of PICF  If not applicable, please go to next section (Data Integrity and Privacy) | | Choose an item. |
| I have obtained signed consent forms from all participants (where applicable) and stored these securely as per WH Organizational Guideline – “Data Management in Research”. They are available for audit. | | Choose an item. |
| Participants know who to contact if they have a question, an emergency or a complaint relating the study. | | Choose an item. |
| I have provided all study participants with a copy of the Participant Information Sheet approved by the Office for Research. | | Choose an item. |
| A copy has been added to the medical records as required by internal procedures. | | Choose an item. |
| **DATA INTEGRITY AND PRIVACY** | | |
| All computer files containing study data are protected by passwords. | | Choose an item. |
| All principal computer files containing study data are stored on a secure network drive, e.g., the WH SharePoint or WH REDCap where they are regularly backed up. | | Choose an item. |
| All paper-based case report forms/questionnaires/surveys etc. have the identifying information removed immediately after processing and are then identifiable only by a code. The ‘code-key’ or Master List is stored separately under lock and key or if electronic, in a separate password protected file on a secure network drive at all times and are only accessible by authorized study personnel. | | Choose an item. |
| Any personal identifying information has been removed before temporary storage or transfer to portable devices (including USB sticks or portable computers). These portable devices have adequate security measures (e.g., password protected) in place to ensure no unauthorised access. | | Choose an item. |
| **Additional Self-Audit comments:**  Enter text | | |

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| 1. **DECLARATION** | |
| I confirm that the information provided is accurate and true and that this project is being conducted as originally approved by the Western Health Office for Research.  I confirm that the project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (2023 and updates), ICH Guideline for Good Clinical Practice E6 (R2), Western Health Research Code of Conduct (2023) or as amended and is consistent with the NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (2014) guideline. | |
| **Principal Investigator (or delegate):** | Enter Principal Investigator Name |
| **Signature:** | **Date:** |
| **Email:** Enter email address | |
| **Telephone:** Enter contact number | |

**Useful link to WH GCP SOPS, Guidelines and policies:** <http://www.westernhealth.org.au/EducationandResearch/Research/General%20Information/Pages/Standard-Operating-Procedures.aspx>

Please send a signed electronic copy of this Final Report Form and the project summary or copies of any publications via the correspond tab in the ERM application. If you have any questions about reporting you can email [QAreview@wh.org.au](mailto:QAreview@wh.org.au) or [progressreports@wh.org.au](mailto:progressreports@wh.org.au).

**Mandatory electronic file name convention:**

To ensure the electronic copies submitted are easily identifiable, the format outlined below must be used for all electronic files. As shown in example below, include version numbers (if applicable) and dates in the file name.

Projects submitted with documents that do not follow the below naming convention/format will not be considered and will be returned via email to sender.

**Convention**: [Reference Number/ERM Project ID] [Document Name] [version number] [Date DDMMMYY]

E.g. 41234 Progress Report 01Jan20; QA2020.123 Progress Report 01Jan20; HREC19WH123 Final Report 01Jan20