# **WESTERN HEALTH SELF-AUDIT REPORT FORM**

Please complete this Self-Audit and submit with your Progress Report.

Failure to provide a satisfactory Self-Audit will result in a detailed short audit review of your project.

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| Date: Enter date |

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| 1. **RESEARCH PROJECT DETAILS** | | | | | | | |
| **Project Number:** | E.g. 41234; HREC/18/WH/123; QA2018.123 | | | | | | |
| **Project Title:** | Enter text | | | | | | |
| **Principal Investigator:** | Enter text | | | | | | |
| **Study Contact/Coordinator:** | Enter text | | | | | | |
| **Sponsor:** | Enter text | | | | | | |
| **Study Site/s being reported:** | Sunshine Hospital | | | Footscray Hospital | Williamstown Hospital | | |
| Melton Health/Community Services  Sunshine Radiation Therapy Centre | Drug Health Services  Bacchus Marsh Hospital/Community Health Centre | | | ☐ Caroline Springs Community Health Centre | Sunbury Day Hospital | | |
| **Date of Original Approval:** | Enter date | | | | | | |
| **Reporting PeriodƗ:** Enter report start date to Enter report start date | | | | | | | |
| ƗThe reporting period is for the twelve months preceding the annual due date for progress reports which is 01 May. For example, if your project was approved on 14 November 2022, the first year’s progress report would be from 14 November 2022 to 01 May 2023, then 01 May 2023 to 01 May 2024. If the project was approved between January to April in any year then Annual Progress Reports do not need to be submitted until 01 May the following year. | | | | | | | |
| Are you submitting this Self-Audit Form with your  Annual Progress Report  Final Progress Report? | | | | | | | |
| 1. **SELF AUDIT** | | | | | | | |
| Please complete **ALL** points. Are all of the following true for your research project? If you select “False” to any of the points, please provide an explanation in the Additional Self- Audit comments. | | | | | | | |
| **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 are 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 Protocol, safety profile of the investigational product, or any other safety information regarding the study where applicable.  This training has been documented in the Training Log. | | | | | | | Choose an item. |
| Approaches to potential participants have been made only by the individuals with full knowledge of the study protocol and of the risks and inconveniences associated with participation (and approved by an ethics committee). | | | | | | | Choose an item. |
| All essential documents are stored either electronically or hard copies in the Site File or Trial Master File. | | | | | | | Choose an item. |
| There is a regular meeting of the study team including the Principal Researcher/s to discuss the progress of the study and a record of these meetings is maintained on the training log. | | | | | | | Choose an item. |
| **ETHICS AND GOVERNANCE** | | | | | | | |
| I am conducting the study in accordance with the protocol approved by a HREC. Any amendments or changes in personnel have been reported to the committee and the relevant documents updated. | | | | | | Choose an item. | |
| **Current approved Protocol:**  Version: Click to insert version number  Dated: Please insert date | |
| I have received ethics committee 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 ethics committee/research governance office. | | | | | | Choose an item. | |
| **PARTICIPANT INFORMATION AND CONSENT FORM** | | | | | | | |
| I have obtained signed consent forms from all participants (where applicable) and stored these securely. They are available for audit. | | | | | | | Choose an item. |
| Participants know who to contact if they have a question, complaint or an emergency. | | | | | | | Choose an item. |
| I have provided all study participants with a copy of the Participant Information Sheet approved by the approving ethics committee. | | | | | | | Choose an item. |
| A copy has been added to the medical records as required by internal procedures | | | | | | | Choose an item. |
| All participants (where applicable) have been invited to complete the Clinical Trials Participant Experience Survey. | | | | | | | Choose an item. |
| All participants (where applicable) have been informed of the Australian Charter of Healthcare Rights. | | | | | | | 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 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 at all times. | | | | | | | 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 in place to ensure no unauthorised access. | | | | | | | Choose an item. |
| Any data files being sent outside of the Western Health (WH) network is through a WH endorsed secure platform.  Please describe your data transfer method and secure platform used below: | | | | | | | Choose an item. |
| Enter text | | | | | | | |
| **Additional Self-Audit comments:** | | | | | | | |
| Enter text | | | | | | | |
| 1. **RECRUITMENT AT WH SITE** | | | | | | | |
| Not applicable, no participants involved. Go to section 4. | | | | | | | |
| **Recruitment target:** | | | Enter number | | | | |
| **Recruitment to date:** | | | Enter number | | | | |
| **Withdrawn to date:** | | | Enter number | | | | |
| **Is recruitment on target?** | | | Yes  No | | | | |
| **Provide reasons for participant withdrawal:** Enter text | | | | | | | |
| **If recruitment is not on target, provide an explanation:** Enter text | | | | | | | |
| 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 Low Risk Ethics Panel/reviewing Human Research Ethics Committee.  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) and Western Health Research Code of Conduct (2023) or as amended. | | | | | | | |
| **Principal Investigator (or delegate):** | | Enter text | | | | | |
| **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 Progress Report Form and project summary (if final report) via email to [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. 51234 Progress Report 01Jan20; QA2020.123 Progress Report 01Jan20; HREC19WH123 Final Report 01Jan20