**SELF AUDIT TEMPLATE FOR USE BY RESEARCHERS**

This checklist is provided to assist researchers in conducting their own audit of their study documentation. The documents listed here provide a framework which may need to be adapted to suit specific project requirements. Nevertheless each point should be reviewed in the context of the study under review and not dismissed without consideration.

1. **Useful Resources:**

The web-links that follow provide information and education on the principles and guidelines that should underpin all human research conducted at CAHS. Knowledge and application of these principles and guidelines will assist researchers in ensuring their research is conducted to the highest possible standard. Specific information required for each project should be sought and considered during the design phase of the project using all resources available, including personal contact with other experts, supporting departments and research administration. It is the researcher’s responsibility to ensure that all information relating to the conduct of the study is updated regularly and any changes are implemented appropriately with supporting documentation. If you require assistance, please organise an appointment to meet with the research administrative team via the Research Ethics/RGO office.

* 1. National Statement [National Statement on Ethical Conduct in Human Research 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)
  2. NHMRC [Guidance on GCP Good Clinical Practice (GCP) in Australia | Australian Clinical Trials](https://www.australianclinicaltrials.gov.au/researchers/good-clinical-practice" \l ":~:text=Australia%20has%20adopted%20international%20guidelines,which%20ones%20apply%20in%20Australia.)
  3. TGA: [Guideline for Good Clinical Practice – Annotated with TGA comments](https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice)
  4. TGA: [Australian clinical trial handbook | Therapeutic Goods Administration (TGA)](https://www.tga.gov.au/resources/resource/guidance/australian-clinical-trial-handbook)
  5. Safety Reporting : [Guidance: Safety Monitoring and reporting in clinical trials involving therapeutic goods](https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods)
  6. CAHS Research Policy Framework
  7. CAHS Research Policy Framework - Investigator Responsibilities Procedures
  8. [Australian Code for the Responsible Conduct of Research 2018](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)
  9. [WA Health Research Governance Policy and Procedures](https://www.health.wa.gov.au/About-us/Policy-frameworks/Research/Mandatory-requirements/Research-Governance-Policy)
  10. [CAHS Research Website](https://cahs.health.wa.gov.au/Research/For-researchers)
  11. [CAHS Research Intranet site](https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/research/Pages/default.aspx)
  12. Research Governance Service (RGS) [RGS - Home](https://rgs.health.wa.gov.au/Pages/Home.aspx); under research information on the home page of the RGS.
  13. [Research Skills Seminar Series](https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/research/educationandtraining/Pages/default.aspx)
  14. Link to intranet for [CAHS Research Toolkit templates and additional references](https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/research/researchers/Pages/default.aspx)

1. **The Study Master File (SMF)**

The study master file (SMF; aka trial master file (TMF)) is the collection of essential documents which allows the conduct of a clinical trial to be reconstructed and evaluated. It is basically the story of how the trial was conducted and managed. It should enable both the conduct of a study and the quality of the data produced to be evaluated. The SMF may be maintained in hard copy or electronically; or a combination of both. It is noted that delegation logs and enrolment logs should be “active” documents maintained and updated in hard copy in “real time” they can be filed electronically at the completion of the research but originals should be maintained and archived as appropriate.

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| **STUDY SITE FILE – SELF AUDIT CHECKLIST FEBUARY 2024** | | |
| **Study (or Site) Master File** | **Yes/No** | **Comment** |
| Has all documentation been placed together in either one or a series of files that can be easily accessed by all study team members who need to do so? (this should include lab manuals/work flows etc.) |  |  |
| **HREC and Governance Approvals** | **Yes/No** | **Comment** |
| Do you have a copy of the signed and dated letter(s) of approval from the HREC? |  |  |
| Do you have a copy of signed and dated letter(s) of approval from the relevant institutions where the study will be conducted? |  |  |
| Are all the key documents listed correctly in the appropriate approval letters? |  |  |
| Have there been any changes/updates to the study documentation that should have been reviewed by the HREC and/or Governance Office? Do you have letters of approval for all these documents? |  |  |
| **Key Documents** | **Present In Study Master File?**  **( Y/N)** | **Comment** |
| Are the following key documents (including updated or revised versions) contained in the SMF? |  |  |
| i. Protocol |  |  |
| ii. Participant Information and Consent Form (PICF) templates |  |  |
| iii. Investigational Drug/Device Brochure (if required) |  |  |
| iv. Case Record/Report Form (templates) |  |  |
| v. Questionnaires (templates) |  |  |
| vi. Recruitment Tools/Advertising Materials/Guidance Notes that are given to potential and actual participants |  |  |
| vii. Approval Documentation: |  |  |
| * HREC (including any amendments) |  |  |
| * Governance Approvals (at all sites and including any amendments) |  |  |
| * CTN/CTA (if required) |  |  |
| viii. Correspondence with HREC and/or Governance office (including annual reports) |  |  |
| ix. Confirmation that the study has been registered on a clinical trials web site |  |  |
| x. Relevant correspondence both within the project team and more broadly as appropriate |  |  |
| xi. Procedure for reporting and assessing adverse events and other safety issues including DSMC Charter/Process documents |  |  |
| xii. Procedure for handling and storing clinical trial materials (including blinding and unblinding procedures (if applicable) |  |  |
| xiii. Procedures for collecting, handling, storing and analysing biological samples |  |  |
| xiv. Procedures for accessing, entering, storing, amending, analysing and reporting data |  |  |
| xv. Signed and dated CVs of all project staff qualifications |  |  |
| xvi. Budget and financial documentation |  |  |
| **Real Time Records of Study Activities** | **In Study Master File?**  **( Y/N)** | **Comment** |
| Does the SMF contain the following documentation that will enable you to track; in real time, study activities? |  |  |
| i. participant screening log |  |  |
| ii. participant enrolment log |  |  |
| iii. participant withdrawal log |  |  |
| iv. contact information for study staff |  |  |
| v. study staff participation, training (including GCP) and experience |  |  |
| vi. delegation of duties to study staff |  |  |
| vii. distribution and handling of trial materials (including dispensing logs) |  |  |
| viii. suitability and certification of all facilities involved in the project |  |  |
| ix. deviations/violations of the protocol and study procedures |  |  |
| x. adverse events |  |  |
| xi. self auditing and monitoring |  |  |
|  |  |  |
| **Participant Specific Documentation** | **In Study Master File?**  **( Y/N)** | **Comment** |
| Does the SMF contain : |  |  |
| i. original signed and dated PICFs for all participants |  |  |
| ii. case record/report forms (including questionnaires completed by participants) for all participants |  |  |
| iii. all safety reports (individual as well as summaries of events) |  |  |

Self Audit of Study Site File was completed by: *Researchers Name* Date: DD Month YY

Reviewed by Principal Investigator:  *Researchers Name*  Date: DD Month YY