Self-audit for researchers

This self-audit has been designed to assist our researchers in being able review their current research project/s at any time to ensure the research is still compliant with the HREC approved protocol, the National Statement, and the Australian Code for Responsible Research.

Self-audits do not need to be submitted to the HREC and copies should be kept in the master site file.

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| **Items for consideration** | **Yes** | **No** | **NA** |
| If I left suddenly, the project could be completed or replicated because the documentation for the project is up to date, accessible, clearly ordered and easy to understand.  The Principal Investigator knows where to find all relevant documentation and has been provided with the passwords to the databases, documents and other password protected computer files/group drives/web applications. |  |  |  |
| I am conducting the study in accordance with the protocol approved by the lead HREC. Any changes have been reported to the lead HREC as amendments and the relevant documents updated. |  |  |  |
| All safety events have been reported to the study sponsor, lead HREC and site RGOs. |  |  |  |
| The annual report has been submitted on the anniversary of the approval date to the lead HREC and acknowledged report to site RGOs. |  |  |  |
| Have any risks been identified with the research?  Has a risk register been created to document all risks and how they will be managed? |  |  |  |
| Signed consent forms have been obtained from all participants (where applicable) and are stored securely.  I am using the correct version of the PICF. |  |  |  |
| All participants have been provided with a copy of their PICF approved by the lead HREC and signed where applicable. |  |  |  |
| I have provided a translator and/or a translated copy of the PICF in his/her own language to all non-English speaking participants. |  |  |  |
| I have received HREC and site approval for all public advertising material that seeks volunteers to participate in the research. |  |  |  |
| Approaches to potential participants have been made only by the individuals with full knowledge of the study and as outlined in the study protocol.  Potential participants have been advised of the risks and inconveniences associated with participation. |  |  |  |
| All questionnaires have the identifying information removed after processing and are then coded (re-identifiable). The ‘code-key’ is stored separately and securely. |  |  |  |
| All computer files containing study data are stored on a secure network drive where they are regularly backed up.  All computer files containing study data are protected by passwords |  |  |  |
| Standard operating procedures have been created to outline the process for completing common tasks and procedures |  |  |  |
| All documents have a current version number and date to assist with document management |  |  |  |
| No personal identifying information has been transferred to portable drives including USB sticks or portable computers. |  |  |  |
| Participants know who to contact if they have a question, complaint or an emergency. |  |  |  |
| There is a regular meeting of the study team including the Principal Investigator to discuss the progress of the study. A record of these meetings is maintained. |  |  |  |
| GCP training is current and a certificate of completion has been retained for each investigator and coordinator. |  |  |  |
| All relevant competing interests have been declared to the site governance office including any that have arisen since the study was authorised. |  |  |  |

**Resources:**

The SALHN Office for research has:

* A training resource page on our website, that contains links and information on training for Good Clinical Practice, The National Statement and research process.
* An integrity and monitoring page that contains handy resources such as a Standard Operating Procedure and risk register template.

**Items to be addressed:**