**Barwon Health Reference Number:**  **ERM Reference Number:**

This document is designed to help research personnel reflect on their research conduct and comply with guidelines for responsible research conduct. The BH HREC advises the Principal Investigator (PI) discuss this form with **all members** of the study team. Please submit completed self-audit tool to RDU as an attachment to your Annual Progress Report in ERM, and retain a copy in your study files. Required for all BH HREC approved projects and clinical trials.

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| --- | --- | --- | --- |
| **Are all of the following *true* for your research project?** | **True** | **False** | **N/A** |
| If I left suddenly, my project could be completed or replicated because the project documentation is up to date, accessible, clearly ordered and comprehensible. The PI knows where to find all documentation and holds the passwords to the databases. |  |  |  |
| The study is being conducted in accordance with the HREC approved protocol. Any project modifications have been submitted to the reviewing HREC. |  |  |  |
| I have protocols in place to protect the welfare of participants and staff should there be an outbreak of COVID-19; and I have a plan to notify participants and staff of changes to study protocol should face-to-face research cease for a period (e.g. Study visits online). |  |  |  |
| I have obtained valid consent (signed/recorded/implied/waiver) for all participants (where applicable) and stored these securely. They are available for audit. |  |  |  |
| I have reported all safety events to the study sponsor, DSMB, reviewing HREC, RGO, and Riskman, as per Barwon Health ‘Guidelines for Research Safety Monitoring and Reporting’ |  |  |  |
| I have provided all study participants with a copy of the most recent Participant Information Sheet approved by the reviewing HREC. |  |  |  |
| I have provided a translator and/or a translated copy of the Participant Information Sheet in his/her own language to all non-English speaking participants. |  |  |  |
| I have received HREC approval for all advertising material that seek volunteers to participate in the study, including all media (printed, social/online, interview). |  |  |  |
| All questionnaires, data collection tools and images, have identifying information removed and are coded (re-identifiable). The ‘code-key’ is stored separately and securely. |  |  |  |
| All computer files containing study data are stored on a secure network drive, regularly backed up and are password protected. |  |  |  |
| All study data has been collected, transferred and stored securely in accordance with the protocol, research agreement and Barwon Health Data Management policies |  |  |  |
| Participants know who to contact if they have a question, complaint or an emergency. |  |  |  |
| Regular minuted meetings of the study team (including PI) and DSMB are held to discuss the progress of the study and review safety incidents. |  |  |  |
| Each investigator and coordinator have a current certificate of GCP training, if applicable. |  |  |  |
| All relevant competing interests have been declared to the RDU, including any that have arisen since the study was authorised. |  |  |  |
| All related research agreements are up to date and reflect current protocol version and research project activities. |  |  |  |

*If there are problems you can’t fix, seek advice from RDU on (03) 4215 3374 or* [*RDU@barwonhealth.org.au*](mailto:RDU@barwonhealth.org.au)

*or Research Quality Manager on (03) 4215 3040 or* [*natasha.savvides@barwonhealth.org.au*](mailto:natasha.savvides@barwonhealth.org.au)

Form completed by: Date:

(*Please print*)

Principal Investigator:

(*Please print*)