This form is to monitor the progress of the research project at the site and is due on the date of the ethics approval (not the site authorisation date). This form should be used by the Site Principal Investigator (PI) (or their delegate) who responsible for the overall conduct of the research project at the health service site. All supporting documents should be submitted to the RG Office. For multisite projects, the PI must also provide a copy of the Site Progress Report to the Lead CPI for submission to the Lead HREC.

| **1**  | **RESEARCH PROJECT** |
| --- | --- |
| 1.1 | Project Reference Number:  |       |
| 1.2 | Project Title: |       |
| 1.3 | Site Principal Investigator: |       |
| 1.4 | Health Service Site *(select one)*:  | Royal Hobart Hospital [ ] Launceston General Hospital [ ] North West Regional Hospital [ ] Oral Health Services [ ] Ambulance Tasmania [ ] Department of Health [ ] Other [ ]  |
| 1.5 | *(If Other selected at 1.4)* Specify Details of Health Service Site:  |       |
| 1.6 | Lead HREC Name |  |
| 1.7 | Other HREC Name:  |       |
| 1.8 | Other HREC Approval Date: *(dd/mm/yyyy)*: |  |
| 1.9 | Site Authorisation Date: *(dd/mm/yyyy)*: |       |
| 1.10 | Site Commencement Date:*(dd/mm/yyyy)*: |       |

| **2** | **SITE REPORT**  |
| --- | --- |
| 2.1 | Report period start date:*(dd/mm/yyyy)*: |       |
| 2.2 | Report period end date:*(dd/mm/yyyy)*: |       |
| 2.3 | Summary of progress: |       |
| **2.4** | **SITE INVESTIGATORS**  |
| 2.4.1 | Are there any other investigators at this site?  | Yes [ ] No [ ] n/a [ ]  |
| 2.4.2 | Have any investigators changed in the past 12 months or since the previous report?  | Yes (*details below)* [ ] No [ ] n/a [ ]  |
| 2.4.3 | *(If Yes selected at 2.4.2)* Was an Amendment Form completed?  | Yes [ ] No *(if No, complete an Amendment Form)* [ ]  |
| 2.4.4 | *(if No selected at 2.4.3)*Attach Amendment Form: | Yes [ ] No [ ]  |
| **2.5** | **PARTICIPANTS** |
| 2.5.1 | Type of access to participants *(select all that apply)*: | Access to participants – patients [ ] Access to participants – staff [ ] Access to patient medical records [ ] Access to samples (eg biobank) [ ] Access to data / linked data [ ]  |
| 2.5.2 | Date of First Participant Recruitment? *Or if the project involves access to records or use of samples, Actual Date provided* *(dd/mm/yyyy)*: |        |
| 2.5.3 | Planned number of participants at this site: |       |
| 2.5.4 | Number of participants recruited (*or records accessed, or samples provided*) since Date of First Participant Recruitment: *(cumulative total):* |       |
| 2.5.5 | Number participants withdrawn:  |       |
| 2.5.6 | Reason for withdrawal:  | Safety Concerns [ ] Participant Complaint [ ] Other *(details below)* [ ]  |
| 2.5.7 | *(If Other selected at 2.5.6)*Specify Details: |       |
| 2.5.8 | Current status of the project at this site  | Active – Recruiting [ ] Active – Not Recruiting [ ] Closed – Follow-up Continuing [ ] Inactive – Temporary Halt [ ] Other *(details below)* [ ]  |
| 2.5.9 | *(If Other selected at 2.5.8)*Specify Details: |       |
| 2.5.10 | Is site participant recruitment on target | Yes [ ] No *(details below)* [ ] n/a [ ]  |
| 2.5.11 | *(If No selected at 2.5.10)*Specify Details: |       |
| 2.5.12 | Expected date of site closure/ completion*(dd/mm/yyyy)*: |       |
| 2.5.13 | Does the project require extension of site authorisation | Yes *(if Yes, complete an Amendment Form)* [ ] No [ ]  |
| 2.5.14 | *(If Yes selected at 2.5.13)*Attach Amendment Form  | Yes [ ] No *(if No, complete details below)* [ ]  |
| 2.5.15 | *(If No selected at 2.5.14)*Specify Details: |       |
| **2.6** | **INSURANCE** |
| 2.6.1 | Is a current certificate of insurance available? | Yes [ ] No *(if No, complete details below)* [ ] n/a [ ]  |
| 2.6.2 | *(If Yes selected at 2.6.1)*Attach current certificate of insurance  | Yes [ ] No *(if No, complete details below)* [ ] n/a [ ]  |
| 2.6.3 | *(If No selected at 2.6.1 & 2.6.2)*Specify Details: |       |
| **2.3** | **AUDIT AND REPORTING** |
| 2.3.1 | Has the research project undergone an audit in the past 12 months? | Yes *(details below)* [ ] No [ ]  |
| **2.4** | **AUDIT DETAILS**  |
| 2.4.1 | *(If Yes selected at 2.3.1)*Type of Audit:  | Short Audit [ ] Self-Audit [ ] Other *(e.g. Commercial Sponsor)* [ ]  |
| 2.4.2 | Date of Audit *(dd/mm/yyyy)*: |       |
| 2.4.3 | Auditing organisation: |       |
| 2.4.5 | Is there a report from the audit? | Yes *(details below)* [ ] No [ ] n/a [ ]  |
| 2.4.6 | *(If Yes selected at 2.4.5)*Attach Audit report: | Yes [ ] No [ ] n/a [ ]  |
| **2.4.7** | **AMENDMENTS AND SAFETY REPORTS** |
| 2.4.8 | Have all reporting requirements been met including Amendments and Safety Reports? | Yes [ ] No *(details below)* [ ]  |
| 2.4.9 | *(If No selected at 2.4.7)* Specify Details:  |       |
| 2.4.10 | Were there any Amendments or Safety Reports submitted since approval or the last site progress report? | Yes *(details below)* [ ] No [ ]  |
| 2.4.11 | *(If Yes selected at 2.4.10)* Specify Details: |       |
| 2.4.12 | If this project involves a device, is a system for tracking participants being maintained? | Yes [ ] No *(details below)* [ ]  |
| 2.4.13 | *(If No selected at 2.4.12)* Specify Details: |       |
| 2.4.14 | Have there been any participant complaints regarding the conduct of the project? | Yes *(details below)* [ ] No [ ]  |
| 2.4.15 | *(If Yes selected at 2.4.11)* Specify Details: |       |

|  |  |
| --- | --- |
| **3** | **BUDGET AND FINANCE**  |
| 3.1 | Total revenue to date: |       |
| 3.2 | Total expenditure to date: |       |
| 3.3 | Does the budget require amendment  | Yes *(if Yes, complete an Amendment Form)* [ ] No [ ]  |
| 3.4 | Does the contract require amendment  | Yes *(if Yes, complete an Amendment Form)* [ ] No [ ]  |

|  |  |
| --- | --- |
| **4** | **CPI /PI (or Delegate) DECLARATION** *(add more tables as required)* |
| * The information provided is complete and correct.
* The project is being conducted in keeping with the conditions of approval of the reviewing HREC and RG Office (and subject to any changes subsequently approved).
* The project is being conducted in accordance with the protocol. Any further changes to the project documentation, timeline, personnel or sites will be notified in writing to the reviewing HREC(s) and/or the relevant RG Office.
* I am aware that the health service reserves the right to monitor the progress of projects more intensively. This monitoring may include site visits, audits, interviews and/or documentation checks.
* I am aware that this report will be provided to the HREC and RG Office and may also be released to others in accordance with the original terms of approval for this project.
* Any significant protocol deviation or violation has been reported to the reviewing HREC.
* The project is being conducted in compliance with the *NHMRC National Statement on the Ethical Conduct in Human Research* (2018), Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016), the *Australian Code for the Responsible Conduct of Research* (2018) and *Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95).
 |
| 4.1 | Name: |       |
| 4.2 | Position: |       |
| 4.3 | Signature: |       |
| 4.4 | Date *(dd/mm/yyyy)*: |       |

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| --- |
| Once this form is fully completed and signed by all investigators submit to the Research Governance Officer: research.governance@health.tas.gov.au |

OFFICE USE ONLY

| **10** | **ACTIONS** |
| --- | --- |
| 10.1 | Final Report Validation Date *(dd/mm/yyyy)*: |        |
| 10.2 | Actions *(if any):* |       |
| 10.3 | Name: |       |
| 10.4 | Position: |       |
| 10.5 | Signature: |       |
| 10.6 | Date *(dd/mm/yyyy)*: |       |