This form should be completed by the Principal Investigators (PI) responsible for the research project at the health service site. All supporting documents should be submitted with the form to the RG Office, for either the closure of a specific site (Closing a Single Site) or the completion of the project at all sites (Closing the Project).

| **1**  | **RESEARCH PROJECT** |
| --- | --- |
| 1.1 | Project Reference Number:  |       |
| 1.2 | Project Title: |       |
| 1.3 | Coordinating Principal Investigator / 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 | Sponsor Name: |       |
| 1.9 | Australia New Zealand Clinical Trial Registry Universal Trial Number (UTN): |       |
| 1.10 | If research project is registered on additional registries, specify details *(including reference numbers and how to access registry eg website address)*: |       |

| **2** | **SITE DETAILS** |
| --- | --- |
| 2.1 | Actual Site Start Date *(dd/mm/yyyy)*: |        |
| 2.2 | Actual Site Finish Date *(dd/mm/yyyy)*: |        |
| 2.3 | Recruitment Status: | Closed, follow-up continuing [ ] Closed, follow-up complete [ ] Completed [ ] Early Termination [ ] Withdrawn [ ]  |
| 2.4 | Date of First Participant Recruitment *(dd/mm/yyyy)*: |        |
| 2.5 | Date of Last Participant Recruitment *(dd/mm/yyyy)*: |        |
| 2.6 | Total Number of Participants: |       |
| 2.7 | Total Revenue: |       |
| 2.8 | Total Project Cost: |       |
| 2.9 | Did the project cost exceed the estimated budget?  | Yes *(details below)* [ ] No *(complete section 2.12)* [ ]  |
| 2.10 | *(If Yes selected at 2.8)* Specify details that led to the budget exceeded the expected budget? |       |
| 2.11 | Specify how the Department has managed to recoup budget overspend? |       |
| 2.12 | *(If Yes selected at 2.9)* Specify what will happen to the residual funds at completion of project? | Yes *(details below)* [ ] No *(details below)* [ ]  |
| 2.13 | Was there any equipment or physical assets supplied during the project? | Yes *(details below)* [ ] No [ ]  |
|  | *(If Yes selected at 2.11)* Specify what will happen to the equipment at completion of project? |       |
| 2.14 | Specify details of where retained residual funds and/or equipment been recorded eg Gift Registry, Asset Registry, etc? |       |

| **3** | **REPORTING** |
| --- | --- |
| 3.1 | Have all reporting requirements been met including amendments and safety reports? | Yes [ ] No [ ]  |
| 3.2 | *(If No selected at 3.1)* Specify Details:  |       |
| 3.3 | If this project involves a device, is a system for tracking participants being maintained? | Yes [ ] No [ ]  |
| 3.4 | *(If No selected at 3.3)* Specify Details: |       |
| 3.5 | Have there been any complaints regarding the conduct of the project? | Yes [ ] No [ ]  |
| 3.6 | *(If Yes selected at 3.5)* Specify Details: |       |

| **4** | **RECORDS** |
| --- | --- |
| 4.1 | Who is the owner of the research project participant records? |       |
| 4.2 | What is the final disposition of the participant records? |       |
| 4.3 | How will the participant records be stored prior to final disposition? |       |
| 4.4 | Who is responsible for costs of archiving and storage of participant records? |       |
| 4.5 | Who is the owner of the research project administrative records? |       |
| 4.6 | What is the final disposition of the administrative records? |       |
| 4.7 | How will the administrative records be stored prior to final disposition? |       |
| 4.8 | Who is responsible for costs of archiving and storage of administrative records? |       |
| 4.9 | If the research project administrative records are identifiable (or potentially identifiable), specify how privacy and confidentiality will be maintained: |       |

| **5** | **SAMPLES** |
| --- | --- |
| 5.1 | Will any samples of body fluid or tissue be retained at the completion of the project? | Yes [ ] No [ ]  |
| 5.2 | *(If Yes selected at 5.1)* Specify Details:  |       |
| 5.3 | Who will manage / control access to the samples?  |       |
| 5.4 | Who will have access to the samples? |       |
| 5.5 | Who is responsible for costs of storage of the samples? |       |

| **6** | **DATA COLLECTIONS** |
| --- | --- |
| 6.1 | Does this project involve accessing Tasmanian Department of Health data collections? | Yes [ ] No [ ]  |
| 6.2 | *(If Yes selected at 6.1)* Specify which data collections:  |       |
| 6.3 | Specify the current status of the data provided: |       |
| 6.4 | Has a new data collection (databank) been established as a result of this project? | Yes [ ] No [ ]  |
| 6.5 | *(If Yes selected at 6.4)* Where will the data be stored? |       |
| 6.6 | Who will have access to the data? |       |
| 6.7 | How will security of storage of the data collection be maintained |       |
| 6.8 | How long will the data be stored in individually identifiable or potentially identifiable form |       |
| 6.9 | What will happen to the data at the expiration of the prescribed storage period? |       |
| 6.10 | Have any other projects used this data collection for research? |       |

| **7** | **PRIVACY** |
| --- | --- |
| 7.1 | Did a Commonwealth agency(s) collect, use or disclose personal information for your project? | Yes [ ] No [ ]  |
| 7.2 | Has the name of the agency(s) been recorded? |       |
| 7.3 | Have the number of records involved been recorded? |       |
| 7.4 | Was the information in a format where individuals are not identifiable? |       |

| **8** | **OUTCOMES** |
| --- | --- |
| 8.1 | What have been the accomplishments/benefits from the project? *Discuss whether the original aims were met, benefits to the public and individual participants, knowledge gained from the project, unexpected benefits not foreseen.* |       |
| 8.2 | Have there been any difficulties encountered? *Discuss any issues regarding: meeting the original aims, recruitment and consent; confidentiality; data security; safety (eg. non-compliance, significant safety issues, Suspected Unexpected Serious Adverse Reactions or Unanticipated Serious Adverse Device Effects), amendments (eg changes to project documentation, personnel or funding) or complaints.* |       |
| 8.3 | How will the research outcomes be translated into practice, policy or further research? *Discuss any future research proposals, policy changes, presentations, publications or creation of new databanks.* |       |
| 8.4 | How will participants be informed of the outcomes of the project? *Please note any information regarding outcomes should be approved by the reviewing HREC.* |       |
| 8.5 | Publications – current, planned, number, authorship, by CPI/Sponsor, by me, representation, peer review, conferences/abstracts/posters.  |       |
| 8.6  | Is there any Intellectual Property that has been developed or could be developed through the conduct of this project?  |       |

|  |  |
| --- | --- |
| **9**  | **DECLARATIONS**  |
| **9.1** | **HEAD OF DEPARTMENT / DIVISIONAL DIRECTOR SUPPORT OR EQUIVALENT (add more tables as required)** |
| * I have read the final research report for the above referenced project.
* I have discussed this research outcomes with the Principal Investigator and Investigators.
* I will ensure my staff involved in this project have fulfilled all contractual obligations as per the research agreement and will continue to abide enduring contractual obligations as per the research agreement for this project.
 |
| 7.1 | Comments: |       |
| 7.2 | Name: |       |
| 7.3 | Signature: |       |
| 7.4 | Date (dd/mm/yyyy): |       |
| **9** | **CPI / PI DECLARATION** *(add more tables as required)* |
| * The information provided above is complete and correct.
* Any data/samples accessed or obtained for the purposes of this project will not be used for any other project or released to any third party not specified in the original or amended application.
* I am aware that this report will be provided to the HREC and RGO and may also be released to others in accordance with the original terms of approval for this project.
* I have fulfilled all contractual obligations as per the research agreement and will continue to abide enduring contractual obligations as per the research agreement for this project.
 |
| 9.1 | Name: |       |
| 9.2 | Position: |       |
| 9.3 | Signature: |       |
| 9.4 | Date *(dd/mm/yyyy)*: |       |

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

OFFICE USE ONLY

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