The Access Request (AR) form should be used by the Coordinating Principal Investigator (CPI) / Principal Investigators (PI) who responsible for the conduct of the research project. The AR form is to be used when the research project requires access to participants (patient and/or public health service employees) and/or their data (medical and personal records of information) and/or tissue collections held within the authority of the Tasmanian public health service and the analysis of the data collected is conducted off-site and does not involve the conduct of research activities at any facilities, locations or services (**site**) under the control of the public health service.

The AR form is for research project that requires one or more of the following:

* participant recruitment through posters, leaflets, handouts, and email letter of invitation (but not recruitment through direct contact with potential participants or enrolment);
* distribution of surveys and questionnaires through the Health Service (but not collation and analysis of responses at that Health Service); and
* access to data or tissue held at the Health Service (but not processing or analysis at that Health Service).

HREC approval must be from either a constituted HREC; or Non-HREC level alternative committed constituted with a HREC; or a NHMRC certified HREC (operating under the national approach to single ethical review).

This form, including any supporting documents and attachments, must be submitted to the Research Governance Officer (RGO) for assessment. The research project **must not** commence at the site until authorisation is granted by the Chief Executive (or an appropriate equivalent).

| **1** | **RESEARCH PROJECT** |
| --- | --- |
| 1.1 | Project Reference Number:  |       |
| 1.2 | Project Title: |       |
| 1.3 | Short Title: |       |
| 1.4 | Protocol Number: |       |
| 1.5 | Research Type *(select one):*  | Biospecimen Analysis Research [ ] Survey/Interview/Focus Group Research [ ] Data Linkage Research [ ] Data Request – Other [ ] Other *(details below)* [ ]  |
| 1.6 | *(If Other – Other selected at 1.5)* Specify Details of Clinical Trial:  |       |
| 1.7 | Health Service Site(s):  | Royal Hobart Hospital [ ] Launceston General Hospital [ ] North West Regional Hospital [ ] Mersey Community Hospital [ ] Ambulance Tasmania [ ] Department of Health [ ] Other *(details below)* [ ]  |
| 1.8 | *(If Other selected at 1.7)* Specify Details of Health Service Site:  |       |
| 1.9 | Address: |       |
| 1.10 | Suburb / Town: |       |
| 1.11 | State:  |       |
| 1.12 | Postcode:  |       |
| 1.13 | Anticipated Site Start Date *(dd/mm/yyyy)*: |        |
| 1.14 | Anticipated Site Finish Date *(dd/mm/yyyy)*: |        |

| **2** | **HREC APPROVALS** |
| --- | --- |
| 2.1 | Lead HREC Name:  |       |
| 2.2 | Lead HREC Reference:  |       |
| 2.3 | Lead HREC approval letter attached:  | Yes [ ] No *(approval is pending)* [ ]  |
| 2.4 | Other HREC approval required:  | Yes [ ] No [ ] n/a [ ]  |
| 2.5 | Other HREC Name: |       |
| 2.6 | Other HREC Reference: |       |
| 2.7 | Other HREC approval letter attached: | Yes [ ] No *(approval is pending)* [ ]  |

| **3** | **INVESTIGATORS** |
| --- | --- |
| **3.1** | **Principal Investigator**  |
| 3.1.1 | First Name: |       |
| 3.1.2 | Surname: |       |
| 3.1.3 | Position: |       |
| 3.1.4 | Department: |       |
| 3.1.5 | Email: |        |
| 3.1.6 | Phone (Mobile): |       |
| 3.1.7 | CV and GCP attached:  | Yes [ ] No [ ]  |
| **3.2** | **Associate Investigator** *(add more tables as required)* |
| 3.2.1 | First Name: |       |
| 3.2.2 | Surname: |       |
| 3.2.3 | Position: |       |
| 3.2.4 | Department: |       |
| 3.2.5 | Email: |        |
| 3.2.6 | Phone (Mobile): |       |
| 3.2.7 | CV and GCP attached: | Yes [ ] No [ ]  |
| **3.3** | **Student Investigator**  |
| 3.3.1 | First Name: |       |
| 3.3.2 | Surname: |       |
| 3.3.3 | Email: |        |
| 3.3.4 | Phone (Mobile): |       |
| 3.3.5 | University:  |       |
| 3.3.6 | Academic school/course: |       |
| 3.3.7 | Supervisor Name: |       |
| 3.3.8 | Supervisor Email: |       |
| 3.3.9 | Supervisor Phone (Mobile): |       |

| **4** | **RESEARCH PARTICIPANT DETAILS** |
| --- | --- |
| 4.1 | Type of access to participants *(select all that apply)*:  | Access to participants – patients [ ] Access to participants – staff [ ] Access to patient medical records [ ] Access to patient tissue / biological samples [ ] Access to data / linked data [ ]  |
| 4.2 | Planned number of participants? Or if the project involves access to records or samples, number required: |       |
| 4.3 | Type of Promotional / Advertising / Recruitment Material  | Poster [ ] Leaflet / Flyer / Handout [ ] Invitation Letter / Email [ ] Other [ ]  |
| 4.4 | Promotional / Advertising / Recruitment Material or Other document attached: | Yes [ ] No [ ] n/a [ ]  |

| **5** | **SPONSOR DETAILS**  |
| --- | --- |
| 5.1 | Name of Sponsor: |       |
| 5.2 | Sponsor Type:  | Collaborative / Cooperative Research Group [ ] Private / Not for Profit Organisation [ ] Investigator Initiated [ ] Other *(details below)* [ ]  |
| 5.3 | *(If Other selected at 5.3)*Specify Details: |       |
| **5.4** | **Research Agreement or Other Agreement** |
| 5.5 | Is there a Medicines Australia Collaboration Research Agreement / Clinical Data Research Agreement /Other Agreement? *(select one)* | MA CTRA – Collaborative Research Group [ ] Research Collaboration Agreement [ ] Clinical Data Research Agreement [ ] Other Non-Standard Agreement [ ] None [ ]  |
| 5.6 | If there is a Research Agreement or Other Agreement is this attached: | Yes [ ] No *(details below)* [ ]  |
| 5.7 | *(If No – not attached selected at 4.8)* Specify Details: |       |

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| --- | --- |
| **6** | **SUPPORTING DEPARTMENT DETAILS** *(add more tables as required)* |
| 6.1 | Supporting Department: |       |
| 6.2 | Supporting Department approvals attached: | Yes [ ] No [ ] n/a [ ]  |
| 6.3 | Are there any costs for the Supporting Department to provide the service? | Yes [ ] No [ ] n/a [ ]  |
| 6.4 | Does this project require the health service to invoice? | Yes [ ] No [ ] n/a [ ]  |
| 6.5 | Total Project Cost: |       |

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| --- | --- |
| **7** | **CONFIRMATION OF SUPPORTING DEPARTMENT / HEAD OF DEPARTMENT / DIVISIONAL DIRECTOR SUPPORT OR EQUIVALENT** *(add more tables as required)* |
| * I have read the research project application named above and associated research information.
* I have discussed this research project, and the resource implications for this department, with the Principal Investigator.
* I support this research project being carried out using such resources as documented HREC application and protocol.
 |
| 7.1 | Comments: |       |
| 7.2 | Name: |       |
| 7.3 | Signature: |       |
| 7.4 | Date (dd/mm/yyyy): |       |

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| --- | --- |
| **8** | **INVESTIGATOR DECLARATIONS** *(add more tables as required for each investigator listed)* |
| * I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
* I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC).
* I accept responsibility for the conduct of this research project according to the principles of the *NHMRC National Statement on the Ethical Conduct in Human Research* (2018) and the *Australian Code for the Responsible Conduct of Research* (2018) and *Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95).
* I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
* I undertake to conduct this research in accordance with relevant legislation and regulations.
* I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC, RGO and NHMRC.
* I will adhere to the conditions of approval stipulated by the HREC and RGO and will cooperate with RGO and HREC monitoring requirements.
* I will inform the HREC, the RGO and the delegated department or Divisional Head if the research project ceases before the expected date.
* I will discontinue the research if the HREC withdraws ethical approval or the authorising authority at the site withdraws authorisation.
* I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the RGO, the sponsor or an independent body for audit and monitoring purposes.
* This information will be used for reporting purposes and managed according to the principles established in the *Privacy Act 1988* (Cwth) and relevant laws in the States and Territories of Australia.
 |
| 8.1 | Name: |       |
| 8.2 | Signature: |       |
| 8.3 | Date *(dd/mm/yyyy)*: |       |

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

OFFICE USE ONLY

| **9** | **SITE AUTHORISATION** |
| --- | --- |
| **9.1** | **Research Governance Officer**  |
| 9.2 | SSA Submission Validation Date *(dd/mm/yyyy)*: |        |
| 9.3 | The governance review for this project has been completed for this site.  | Yes [ ] No [ ]  |
| 9.4 | RGO recommendation for site authorisation:  | Recommended for Site Authorisation [ ] Not recommended for Site Authorisation [ ] Requires CE/ED Consideration [ ]  |
| 9.5 | *(If Not Recommended or Requires Consideration selected at 7.4)*Comments or Site Specific Conditions for CE/ED Consideration: |       |
| 9.6 | SSA Submitted for Authorisation Date *(dd/mm/yyyy)*: |       |
| 9.7 | Name: |       |
| 9.8 | Signature: |       |
| **9.9** | **Authorisation by Chief Executive (or Executive Director/Delegate)**  |
| 9.10 | CE/ED Decision:  | Authorised [ ] Not Authorised [ ]  |
| 9.11 | Comments or Site Specific Conditions for Authorisation: |       |
| 9.12 | SSA Authorisation Date *(dd/mm/yyyy)*: |       |
| 9.13 | Name: |       |
| 9.14 | Signature: |       |

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| --- |
| *If you require assistance or have feedback regarding the use of this form, please contact* *research.governance@health.tas.gov.au* |