The SSA form must be completed for each public health service site where the research is to be conducted. The SSA form should be completed by the Principal Investigator (or delegate) who is responsible for the conduct of the research project at the site. This SSA form, including any supporting documents, must be submitted to the Research Governance Officer (RGO). The research project **must not** commence at the site until formal site authorisation is granted by the Chief Executive.

| **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):*  | Action Research [ ] Biospecimen Analysis Research [ ] Data Linkage Research [ ] Epidemiological Research [ ] Ethnographic Research [ ] Observational Research [ ] Survey/Interview/Focus Group Research [ ] Textual Analysis Research [ ] Interventional / Clinical Trial Research [ ]  |
| 1.6 | *(If Interventional/Clinical Trial Research selected at 1.5)*Specify Interventional / Clinical Trial Type *(select one)*: | Clinical Trial – Drug [ ] Clinical Trial – Device [ ] Clinical Trial – Drug and Device [ ] Clinical Trial – Biological Product [ ] Clinical Data / Quality Registry [ ] Clinical Non-Interventional Research [ ] FTIH/FTIP Clinical Trial – Drug [ ] FTIH/FTIP Clinical Trial – Device [ ] FTIH/FTIP Clinical Trial – Drug and Device [ ] Clinical Trial – Other *(details below)* [ ]   |
| 1.7 | *(If Clinical Trial – Other selected at 1.6)* Specify Details of Clinical Trial:  |       |
| 1.8 | Clinical Trial Phase *(select one)*:  | Phase 1 [ ] Phase 2 [ ] Phase 3 [ ] Phase IV [ ] FTIH (First Time in Human) [ ] FTIP (First Time in Patient) [ ] Not Applicable [ ]  |
| 1.9 | Health Service Site *(select one)*:  | Royal Hobart Hospital [ ] Launceston General Hospital [ ] North West Regional Hospital [ ] Oral Health Services [ ] Ambulance Tasmania [ ] Department of Health [ ] Other *(details below)* [ ]  |
| 1.10 | *(If Other selected at 1.9)* Specify Details of Health Service Site:  |       |
| 1.11 | Address: |       |
| 1.12 | Suburb / Town: |       |
| 1.13 | State:  |       |
| 1.14 | Postcode:  |       |
| 1.15 | Anticipated Site Start Date *(dd/mm/yyyy)*: |        |
| 1.16 | Anticipated Site Finish Date *(dd/mm/yyyy)*: |        |

| **2** | **HREC APPROVALS** |
| --- | --- |
| 2.1 | Is this project a single centre or multi-centre project? | Single-Centre [ ] Multi-Centre [ ]  |
| 2.2 | If it is a multi-centre project, is the project multi-centre project inter-jurisdictional (across various the States) or intra-jurisdictional (within Tasmania)? | Inter-jurisdictional *(complete sections 2..4-2.6)* [ ] Intra-jurisdictional |
| 2.3 | If it is a multi-centre project, is there a Lead HREC?  | Yes [ ] No [ ]  |
| 2.4 | Lead HREC Name:  |       |
| 2.5 | Lead HREC Reference:  |       |
| 2.6 | Lead HREC approval letter attached:  | Yes *(attached)* [ ] No *(approval is pending)* [ ]  |
| 2.7 | Other HREC approval required:  | Yes *(attached)* [ ] No *(approval is pending)* [ ] n/a [ ]  |
| 2.8 | Other HREC Name: |       |
| 2.9 | Other HREC Reference: |       |
| 2.10 | Other HREC approval letter attached: | Yes *(attached)* [ ] 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** | **Site Coordinator / Contact Person** |
| 3.3.1 | First Name: |       |
| 3.3.2 | Surname: |       |
| 3.3.3 | Position: |       |
| 3.3.4 | Department: |       |
| 3.3.5 | Email: |        |
| 3.3.6 | Phone (Mobile): |       |
| **3.4** | **Student Investigator**  |
| 3.4.1 | First Name: |       |
| 3.4.2 | Surname: |       |
| 3.4.3 | Email: |        |
| 3.4.4 | Phone (Mobile): |       |
| 3.4.5 | University:  |       |
| 3.4.6 | Academic school/course: |       |
| 3.4.7 | Supervisor Name: |       |
| 3.4.8 | Supervisor Email: |       |
| 3.4.9 | Supervisor Phone (Mobile): |       |
| **3.5** | **Conflict of Interest**  |
| 3.5.1 | Affiliations or financial interests of Investigators (including family members) or the site may have in the research project or research outcomes?  | Yes [ ] No [ ]  |
| 3.5.2 | Type of Interest to Declare *(select all that apply)*:  | Board Appointment [ ] Bonus [ ] Conference and Travel [ ] Consultancy [ ] Direct Payment [ ] Equipment [ ] Milestone Payment [ ] Patent [ ] Recruitment Incentive [ ] Shares / Options [ ] Other *(details below)* [ ]  |
| 3.5.3 | *(If Other selected at 3.7)* Specify Details of Type of Interest to Declare:  |       |
| 3.5.4 | Conflict of Interest Declarations attached: | Yes [ ] No [ ] n/a [ ]  |
| **3.6** | **Credentialing / Training**  |
| 3.6.1 | Do any of the project members require training, certification, accreditation or credentialing for the conduct of this research (*eg phlebotomy, IATA training for transporting biological samples*): | Yes *(details below)* [ ] No [ ] n/a [ ]  |
| 3.6.2 | *(If Yes selected at 3.11)* Specify Details of training, certification, accreditation or credentialing requirements: |       |

| **4** | **RESEARCH TRIAL DETAILS** |
| --- | --- |
| **4.1** | **Recruitment**  |
| 4.1.1 | 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 [ ]  |
| 4.1.2 | Planned number of participants at this site: |       |
| **4.2** | **Participant recruitment details** |
| 4.2.1 | Participant Information and Consent Form (PICF) for this site attached: | Yes [ ] No [ ] n/a [ ]  |
| 4.2.2 | Promotional / Advertising Material for this site attached:  | Yes [ ] No [ ] n/a [ ]  |
| **4.3** | **Therapeutic Goods Association (TGA)**  |
| 4.3.1 | Is the project being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Scheme: | Clinical Trial Notification (CTN) [ ] Clinical Trial Exemption (CTX) [ ] n/a [ ]  |
| 4.3.2 | TGA Reference Number:  |       |
| 4.3.3 | CTN or CTX attached:  | Yes [ ] No [ ] n/a [ ]  |
| **4.4** | **Australia New Zealand Clinical Trial Registry (ANZCTR)**  |
| 4.4.1 | Is the research project registered with the Australia New Zealand Clinical Trial Registry (ANZCTR)? | Yes [ ] No [ ] n/a [ ]  |
| 4.4.2 | ANZCTR Universal Trial Number (UTN): |       |
| 4.4.3 | If research project is registered on additional registries, specify details *(including reference numbers and how to access registry eg website address)*: |       |
| **4.5** | **Clinical Trial Research Agreement or Other Agreement** |
| 4.5.1 | Is there a Medicines Australia Clinical Trial Research Agreement (CTRA) / Medical Technology Association of Australia Clinical Investigation Research Agreement (CIRA) / Other Non-Standard Agreement? *(select one)* | MA CTRA – Standard [ ] MA CTRA – Collaborative Research Group [ ] MA CTRA – Contract Research Organisation acting as Local Sponsor [ ] MA CTRA – Phase IV Collaborative Research Group [ ] MA CTRA – Phase IV Contract Research Organisation acting as Local Sponsor [ ] MTAA CIRA – Standard [ ] Other Non-Standard Agreement [ ] None [ ]  |
| 4.5.2 | CTRA/CIRA or Other Non-Standard Agreement attached: | Yes [ ] No *(details below)* [ ]  |
| 4.5.3 | *(If No – not attached selected at 4.17)* Specify Details: |       |
| **4.6** | **Sub-Agreements / Tele-trial Agreement** |
| 4.6.1 | Is there any other sub-agreement or tele-trial agreement? | Yes *(details below)* [ ] No [ ] n/a [ ]  |
| 4.6.2 | Other sub-agreement or tele-trial agreement attached: | Yes [ ] No *(details below)* [ ]  |
| 4.6.3 | *(If No selected at 4.6.2)* Specify Details: |       |
| **4.7** | **Indemnity** |
| 4.7.1 | Is there a Medicines Australia Standard Form of Indemnity or Medical Technology Association of Australia Standard Form of Indemnity? *(select one)* | MA Standard Form of Indemnity for Clinical [ ] TrialsMTAA Standard Form of Indemnity for Clinical [ ] Investigationn/a [ ] Other *(details below)* [ ]  |
| 4.7.2 | *(If Other selected at 4.7.1)* Specify Details: |       |
| 4.7.3 | If an indemnity is required, is the relevant indemnity selected attached: | Yes [ ] No [ ]  |
| **4.8** | **Insurance** |
| 4.8.1 | Name of Insurer: |       |
| 4.8.2 | Certificate of Currency Expiry Date *(dd/mm/yyyy)*: |        |
| 4.8.3 | Certificate of Currency attached:  | Yes [ ] No [ ] n/a [ ]  |
| **4.9** | **Intellectual Property** |
| 4.9.1 | Is there a possibility of significant new IP being developed? | Yes [ ] No [ ]  |
| 4.9.2 | Is there an agreement stating arrangements for the use of IP? | Yes *(details below)* [ ] No [ ] n/a [ ]  |
| 4.9.3 | (*If Yes selected at 4.9.2)*Agreement for use of IP attached: | Yes [ ] No [ ]  |
| **4.10** | **Biosafety, Chemical and Radiation Safety Requirements**  |
| 4.10.1 | Does the project requires any of the following approvals *(select all that apply)*:  | Institutional Biosafety Committee (IBC) notification [ ] Licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms [ ] Committee approval of chemical safety (drugs/pharmacy committee) [ ] NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment [ ] Application for a licence to the NHMRC Licensing Committee to conduct embryo research [ ] Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) assessment [ ] n/a [ ]  |
| 4.10.2 | *(If any item selected at 4.10.1)*Approvals attached: | Yes [ ] No [ ]  |

| **5** | **RESEARCH TRIAL RESOURCE AND BUDGET** *(add more tables if required)* |
| --- | --- |
| **5.1** | **Sponsor**  |
| 5.1.1 | Name of Major Sponsor: |       |
| 5.1.2 | Major Sponsor Type:  | Commercial Sponsor [ ] Collaborative Research Group [ ] Institution [ ] University [ ] Investigator Initiated [ ] Other *(details below)* [ ]  |
| 5.1.3 | *(If Other selected at 5.3)*Specify Details: |       |
| 5.1.4 | Funding Source Type: | Commercial Sponsor [ ] Collaborative Research Group [ ] External Source eg NHMRC Grant [ ] Internal / Departmental (including in-kind) [ ] Other *(details below)* [ ]  |
| 5.1.5 | *(If Other selected at 5.5)*Specify Details: |       |
| 5.1.6 | Total estimated funding at all sites (*per patient or per year*):  |       |
| 5.1.7 | Total estimated funding at this site (*per patient or per year*): |       |
| 5.1.8 | Total FTE at this site:  |       |
| 5.1.9 | Approved Financial Analysis attached: | Yes *(attached)* [ ] No *(details below)* [ ] n/a [ ]  |
| 5.1.10 | *(If No – not attached selected at 5.1.9)* Specify Details: |       |
| **5.2** | **Supporting Department Approvals** *(add more tables as required)* |
| 5.2.1 | Supporting Departments involved in the conduct of the project:  | Pharmacy [ ] Imaging [ ] Pathology [ ] Medical Records [ ] Other *(details below)* [ ]  |
| 5.2.2 | Pharmacy approvals attached: | Yes [ ] No [ ] n/a [ ]  |
| 5.2.3 | Imaging approvals attached: | Yes [ ] No [ ] n/a [ ]  |
| 5.2.4 | Pathology approvals attached: | Yes [ ] No [ ] n/a [ ]  |
| 5.2.5 | Medical Records approvals attached: | Yes [ ] No [ ] n/a [ ]  |
| 5.2.6 | *(If Other selected at 5.2.1)*Other Supporting Department Details: |       |
| 5.2.7 | Other Supporting Department approvals attached: | Yes [ ] No [ ] n/a [ ]  |

|  |  |
| --- | --- |
| **6** | **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.
 |
| 6.1 | Name: |       |
| 6.2 | Signature: |       |
| 6.3 | Position: |       |
| 6.4 | 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

| **7** | **SITE AUTHORISATION** |
| --- | --- |
| **7.1** | **Research Governance Officer**  |
| 7.2 | SSA Submission Validation Date *(dd/mm/yyyy)*: |        |
| 7.3 | The governance review for this project has been completed for this site.  | Yes [ ] No [ ]  |
| 7.4 | RGO recommendation for site authorisation:  | Recommended for Site Authorisation [ ] Not recommended for Site Authorisation [ ] Requires CE/ED Consideration [ ]  |
| 7.5 | *(If Not Recommended or Requires Consideration selected at 7.4)*Comments or Site Specific Conditions for CE/ED Consideration: |       |
| 7.6 | SSA Submitted for Authorisation Date *(dd/mm/yyyy)*: |       |
| 7.7 | Name: |       |
| 7.8 | Signature: |       |
| **7.9** | **Authorisation by Chief Executive (or Executive Director/Delegate)**  |
| 7.10 | CE/ED Decision:  | Authorised [ ] Not Authorised [ ]  |
| 7.11 | Comments or Site Specific Conditions for Authorisation: |       |
| 7.12 | SSA Authorisation Date *(dd/mm/yyyy)*: |       |
| 7.13 | Name: |       |
| 7.14 | Signature: |       |

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