This complaint report form should be used by the Site Principal Investigators (PI) (or delegate) responsible for the research project at the health service site. All supporting documents should be submitted with this form to the RG Office. The site RGO will advise whether the complaint should also be sent to the reviewing Human Research Ethics Committee (HREC).

| **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  Mersey Community Hospital  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: |  |

| **2** | **DETAILS OF COMPLAINT** | |
| --- | --- | --- |
| 2.1 | Complaint Received Date *(dd/mm/yyyy)*: |  |
| 2.2 | Complaint Format: | Verbal  Written |
| 2.3 | Details of Complaint: |  |
| 2.4 | Has the Complaint been resolved / closed with the Complainant? | Yes  No  n/a |
| 2.5 | Has this Complaint been reported in the Safety Reporting and Learning System (SRLS)? | Yes  No  n/a |
| 2.6 | SRLS ID Number(s): |  |
| 2.7 | Has this Complaint been reported to the Lead HREC, Other HREC or Sponsor? | Yes  No  n/a |
| 2.8 | What immediate actions were taken in response to the Complaint? |  |
| 2.9 | What corrective or preventative actions were or will be taken in response to the Complaint? |  |
| 2.10 | Will there be changes to the Protocol in response to the Complaint? | Yes *(complete an Amendment Form)*  No  n/a |
| 2.11 | Will there be changes to the Participant Information and Consent Form (PICF) in response to the Complaint? | Yes *(complete an Amendment Form)*  No  n/a |
| 2.12 | Supporting documentation attached: | Yes *(attached)*  No – pending  n/a |

| **3** | **COMPLAINANT DETAILS** | |
| --- | --- | --- |
| 3.1 | Complainant is anonymous: | Yes |
| 3.2 | How is complainant connected to research project? | Participant  Carer / Guardian of Participant  Staff or employee of health service  Other |
| 3.3 | *(If Other selected at 3.2)*  Specify Details: |  |
| 3.4 | Title: |  |
| 3.5 | First Name: |  |
| 3.6 | Surname: |  |
| 3.9 | Email: |  |
| 3.10 | Phone (Mobile): |  |
| 3.11 | Address: |  |
| 3.12 | Suburb / Town: |  |
| 3.13 | State: |  |
| 3.14 | Postcode: |  |
| 3.15 | Any other relevant information: |  |

| **4** | **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 subject to any changes subsequently approved). * The project is being conducted in compliance with 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). | | |
| 4.1 | Name: |  |
| 4.2 | Position: |  |
| 4.3 | Signature: |  |
| 4.4 | 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](mailto:research.governance@health.tas.gov.au) |

OFFICE USE ONLY

| **5** | **ACTIONS** | |
| --- | --- | --- |
| 5.1 | Complaint Report Validation Date *(dd/mm/yyyy)*: |  |
| 5.2 | Actions: |  |
| 5.3 | Name: |  |
| 5.4 | Position: |  |
| 5.5 | Signature: |  |
| 5.6 | Date *(dd/mm/yyyy)*: |  |