This form is for amendments to the governance of the research project as they involve changes to the conduct of the research project at the site. This form should be used by the Coordinating Principal Investigator (CPI) and/or Principal Investigators (PI) (for single-site) or Principal Investigators (PI) (multi-site) who responsible for the conduct of research project at the health service site. All supporting documents should be submitted with the amendment form to the RG Office for review and authorisation.

| **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 [ ] 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: | IQVIA RDS Pty. Limited |
| 1.9 | Type of Amendment *(select all that apply)*: | Change to Project Investigators *(Go to Section 2)* [ ] Change to Project Documentation *(Go to Section 3)* [ ] Change to Project Budget *(Go to Section 4)* [ ] Change to Project Sponsor *(Go to Section 5)* [ ] Change to Project Site Authorisation date *(Go to Section 6)*  [ ] Other *(Go to Section 7)* [ ]  |

| **2** | **CHANGE TO INVESTIGATORS** |
| --- | --- |
| 2.1 | Investigator Change *(select all that apply)*: | Adding Investigator *(Go to section 2.2)* [ ] Removing Investigator *(Go to section 2.3)* [ ]  |
| **2.2** | **Adding New Investigator (*add additional tables as required)*** |
| 2.2.1 | New Investigator Role: | Principal Investigator [ ] Associate Investigator [ ] Site Coordinator/Contact person [ ] Student Other [ ]  |
| 2.2.2 | First Name: |       |
| 2.2.3 | Surname: |       |
| 2.2.4 | Position: |       |
| 2.2.5 | Department: |       |
| 2.2.6 | Email: |        |
| 2.2.7 | Phone (Mobile): |       |
| 2.2.8 | CV and GCP attached:  | Yes [ ] No [ ]  |
| 2.2.9 | Conflict of Interest Declarations attached: | Yes [ ] No [ ] n/a [ ]  |
| 2.2.10 | If training, certification, accreditation or credentialing is required, evidence attached: | Yes [ ] No [ ] n/a [ ]  |
| 2.2.11 | New Investigator has agreed to be involved in this project? (*Declaration required Section 7.1)* | Yes [ ] No [ ]  |
| **2.3** | **Removing Current Investigator**  |
| 2.3.1 | Outgoing Investigator Role: | Principal Investigator [ ] Associate Investigator [ ] Site Coordinator/Contact person [ ] Student/Other [ ]  |
| 2.3.2 | First Name: |       |
| 2.3.3 | Surname: |       |
| 2.3.4 | Position: |       |
| 2.3.5 | Department: |       |
| 2.3.6 | Email: |        |
| 2.3.7 | Phone (Mobile): |       |
| 2.3.11 | The Head of Department/Divisional Director/Manager (or equivalent) has been advised of the change to Investigators? *It is the responsibility of the PI to advise their relevant manager of Investigator changes. (Declaration required Section 7.5)* | Yes [ ] No [ ]  |
| 2.3.12 | Has the CPI / Sponsor been advised of the change to Investigators? *It is the responsibility of the PI to inform the CPI/Sponsor of any project team member changes.* | Yes [ ] No [ ]  |

| **3** | **CHANGE TO PROJECT DOCUMENTATION** |
| --- | --- |
| 3.1 | Change to documentation *(select all that apply)*: | Protocol [ ] Participant Information and Consent Form (PICF) [ ] Promotional / Advertising Material [ ] Research Agreement [ ] Sub-Agreements / Tele-Trial Agreement [ ] Biosafety, Chemical & Radiation Safety Requirements [ ] Other [ ]  |
| 3.2 | *(If Other selected at 3.1)*Specify Details:  |       |
| 3.3 | Reason for change to project documentation: |       |
| 3.4 | Was the change a result of a safety event | Yes *(details below)* [ ] No [ ]  |
| 3.5 | *(If Yes selected at 3.4)*Specify Details:  |       |
| 3.6 | Amended Documents attached: | Yes *(attached)* [ ] No *(details below)* [ ] n/a [ ]  |
| 3.7 | *(If No selected at 3.4)*Specify Details: |       |
| 3.8 | Does the amendment require HREC approval?  | Yes *(attached)* [ ] No *(details below)* [ ] Other - HREC approval Pending [ ]  |
| 3.9 | *(If No selected at 3.8)*Specify Details: | Changes are to the Sponsor and Budget |
| 3.10 | HREC approval attached:  | Yes *(attached)* [ ] No *(not attached)* [ ] Other - HREC approval Pending [ ]  |
| 3.11 | *(If No selected at 3.10)*Specify Details: |       |

| **4** | **CHANGE TO PROJECT BUDGET**  |
| --- | --- |
| 4.1 | Does the amendment impact on services being provided by the research department or a supporting department?  | Yes *(details below)* [ ] No [ ] n/a [ ]   |
| 4.2 | Does the amendment require adjustment to the overall project cost?  | Yes *(details below)* [ ] No [ ] n/a [ ]   |
| 4.3 | *(If Yes at 4.1 & 4.2)*Specify Details:  |       |
| 4.3 | Updated Financial Analysis or Supporting Department quotation attached: | Yes *(attached)* [ ] No *(not attached)* [ ] n/a [ ]  |
| 4.4 | *(If No selected at 4.3)*Specify Details: |       |
| 4.5 | Does the amendment require adjustment to the Research Agreement, Sub-Agreements / Tele-Trial Agreement? | Yes *(details below)* [ ] No [ ] n/a |
| 4.6 | Updated research agreement Sub-Agreements / Tele-Trial Agreement attached: | Yes *(attached)* [ ] No *(not attached)* [ ]  |

| **5** | **CHANGE OF SPONSOR**  |
| --- | --- |
| 5.1 | Specify Details:  |       |
| 5.2 | Relevant Documents attached: | Yes *(attached)* [ ] No *(details below)* [ ] n/a [ ]  |
| 5.3 | *(If No selected at 7.2)*Specify Details: |       |
| 5.4 | Does the amendment require HREC approval?  | Yes *(attached)* [ ] No (*details below)* [ ] Other - HREC approval Pending [ ]  |
| 5.5 | *(If No selected at 7.3)*Specify Details: |       |
| 5.6 | HREC approval attached:  | Yes *(attached)* [ ] No *(not attached)* [ ] Other - HREC approval Pending [ ]  |
| 5.7 | *(If No selected at 7.5)*Specify Details: |       |
| 5.8 | Is a Deed of Variation or Deed of Novation required?  | Yes *(attached)* [ ] No *(details below)* [ ]  |
| 5.9 | Does the Insurance need to be updated? | Yes *(attached)* [ ] No *(details below)* [ ]  |
| 5.10 | Does the Medical Indemnity need to be updated? | Yes *(attached)* [ ] No *(details below)* [ ]  |
| 5.11 | *(If No selected at 5.8, 5.9, 5.10)*Specify Details: |       |

| **6** | **EXTENSION OF SITE AUTHORISATION** |
| --- | --- |
| 6.1 | Current Site Authorisation Approval Date *(dd/mm/yyyy)*: |       |
| 6.2 | Requested Extension of Site Authorisation Date *(dd/mm/yyyy)*: |       |
| 6.3 | Specify Details for Extension: |       |
| 6.3 | Is the Site Progress Report current? | Yes *(complete section 6.5)* [ ] No *(details below)* [ ] n/a [ ]  |
| 6.4 | Annual Progress Report last submitted date *(dd/mm/yyyy)*: |       |
| 6.5 | *(If No selected at 6.4)*Specify Details: |       |
| 6.6 | HREC approval attached:  | Yes *(attached)* [ ] No *(details below)* [ ] Other - HREC approval Pending [ ]  |
| 6.7 | *(If No selected at 6.7)*Specify Details: |       |

| **7** | **OTHER AMENDMENT** |
| --- | --- |
| 7.1 | Specify Details:  |       |
| 7.2 | Relevant Documents attached: | Yes *(attached)* [ ] No *(details below))* [ ] n/a [ ]  |
| 7.3 | *(If No selected at 7.2)*Specify Details: |       |
| 7.3 | Does the amendment require HREC approval?  | Yes *(attached)* [ ] No (*details below)* [ ] Other - HREC approval Pending [ ]  |
| 7.4 | *(If No selected at 7.3)*Specify Details: |       |
| 7.5 | HREC approval attached:  | Yes *(attached)* [ ] No *(not attached)* [ ] Other - HREC approval Pending [ ]  |
| 7.6 | *(If No selected at 7.5)*Specify Details: |       |

| **8** | **DECLARATIONS** |
| --- | --- |
| **8.1** | **NEW INVESTIGATOR DECLARATION** *(add more tables as required)* |
| * I will only start in 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 will 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 will 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 | Position: |       |
| 8.3 | Signature: |       |
| 8.4 | Date *(dd/mm/yyyy)*: |       |
| **8.5** | **HEAD OF DEPARTMENT / DIVISIONAL DIRECTOR DECLARATION** *(or equivalent)* |
| * I have read the research project amendment named above.
* All Investigators from my department involved in the research project have the skills, training and experience necessary to undertake their role.
* I have discussed this amendment, and the resource implications for this department, with the Principal Investigator.
* There are suitable and adequate facilities and resources for the research project to be continued at this site.
 |
| 8.6 | Comments: |       |
| 8.7 | Name: |       |
| 8.8 | Signature: |       |
| 8.9 | Date *(dd/mm/yyyy)*: |       |

|  |  |
| --- | --- |
| **8.10** | **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 RGO (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 RGO.
* 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).
 |
| 8.11 | Name: |       |
| 8.12 | Position: |       |
| 8.13 | Signature: |       |
| 8.14 | 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, including all Supporting Documents: research.governance@health.tas.gov.au |

OFFICE USE ONLY

| **9** | **AUTHORISATION** |
| --- | --- |
| **9.1** | **Research Governance Officer**  |
| 9.2 | Amendment Submission Validation Date *(dd/mm/yyyy)*: |        |
| 9.4 | RGO recommendation for site authorisation:  | Recommended for Site Authorisation [ ] Not recommended for Site Authorisation [ ] *(details below)*Requires CE/ED Consideration *(details below)* [ ]  |
| 9.5 | *(If Not Recommended or Requires Consideration selected at 10.4)* Details:  |       |
| 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 for Authorisation: |       |
| 9.13 | Name: |       |
| 9.14 | Signature: |       |
| 9.12 | Amendment Authorisation Date *(dd/mm/yyyy)*: |       |