1. Please DO NOT submit a cover letter with this form.
2. This form should be filled in electronically and submitted with the original SSA
3. Incomplete submissions may be rejected or result in delayed review.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Site:** | Click here to enter text. | | | **HREC Ref:** | | Click here to enter text. | |
| **Study Title:** | Click here to enter text. | | | | | | |
| **RESEARCH CO-ORDINATOR PERSONNEL** | | | | | | | |
| **Name of research co-ordinator:** | | | | | | | |
| **Research responsibilities at the site (list all tasks as per delegation log):**  **\*This section must be completed** | | | | | | | |
| Obtain informed consent  Subject selection/recruitment  Confirm eligibility (review inclusion/exclusion criteria)  Obtain medical history (source documents)  Perform physical exam  Conduct study visit procedure as outlined in the protocol  Make study related medical decisions  Assess AEs/SAEs  Dispense study drug  Perform drug accountability  Study drug storage and temperature monitoring | | | Sample collection  Sample processing and/or shipment  Evaluate study related test results  Use IWRS/IVRS  Make entries/corrections on CRFs  Sign off CRF  Maintain essential documents  Perform study-related assessments as per protocol  Other (specify):  Other (specify):  Other (specify): | | | | |
| **Are you currently employed by the site for the purpose of this research project?** Yes  No  ***If no, evidence of Insurance/Indemnity from your employer must be provided***  **If not employed by the site, list the external organisation and department at organisation:**  **If not employed by the site, is DCSI clearance required?** Yes  No  [**https://screening.dcsi.sa.gov.au/screening-process/types-of-screening**](https://screening.dcsi.sa.gov.au/screening-process/types-of-screening) | | | | | | | |
| **RESEARCH CO-ORDINATOR DECLARATION** | | | | | | | |
| *I declare that I have read the study protocol & understand my obligations and responsibilities, and that site I will not conduct any study related activities until I have been granted authorisation by the site Research Governance Office.*  **Signature:**  **Date:** | | | | | | | |
| **PRINCIPAL INVESTIGATOR DECLARATION** | | | | | | | |
| *I confirm that the study co-ordinator named on this form is appropriately qualified and will be trained in the administration of the approved study protocol.*  **Name:**  **Signature:**  **Date:** | | | | | | | |
| **OFFICE USE ONLY** | | | | | | | |
| **Received & Authorised**  **by Research Governance Officer (Name):** | |  | | | | | |
| **Signature:** | |  | | | **Date:** | |  |
| **RGO Comments:** | | | | | | | |