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:** |