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| **ITCC Staff Signatures and Delegation Log** | | | |
| **Protocol / Study Number:** |  | **Sponsor Name:** |  |
| **Site Name:** |  | **Site Number:** |  |

**This form is to be completed by all personnel involved in the study**

**after receiving proper study training and prior to taking part in any study activities**

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| **Name of Principal Investigator (PI)** | **PI Signature1** | **PI Initials** | **Start** | **End** |
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1 My signature confirms/acknowledges that:

* The tasks listed below will only be delegated to appropriately trained, skilled and qualified staff.
* I will conduct the study in accordance with the protocol and remain responsible for the overall study conduct and reported data.
* I will ensure study oversight.
* I authorise the delegation of study tasks to personnel as listed below.
* I will ensure that all personnel assisting in the conduct of this study are informed about their obligations and have not performed any study tasks prior to appropriate delegation and completion of appropriate training.
* I will ensure that mechanisms are in place to ensure that site staff receive the appropriate information and training throughout the study and that a 2-way communication channel exists between staff and self.
* I will declare any actual or potential conflicts of interest to the relevant ethical review body.
* I will ensure that any and all changes in staff or delegated study tasks will be recorded in timely manner.

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|  | **Site Staff**  *\* This form is to be signed* ***contemporaneously*** *by PI and Staff \** | | | | | | | | | |
| **Name & Title** | | **Initials** | **Study Role** | **Key Study Task(s)**  *List all appropriate from the index below* | **Duration** | | **Staff Signature2 & Date** | **PI Signature & Date** | **CV3 (Y/N)** | **GCP4 (Y/N)** |
| **Start** | **End** |
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2 My signature confirms/acknowledges that I accept the assigned study task(s)

3 CV has been received by PI (new version is required annually)

4 Current Good Clinical Practice (GCP) training certificate has been received by PI (to be renewed prior to expiry date or every 3 years)

**Comments:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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|  | **Site Staff**  *\* This form is to be signed* ***contemporaneously*** *by PI and Staff \** | | | | | | | | | |
| **Name & Title** | | **Initials** | **Study Role** | **Key Study Task(s)**  *List all appropriate from the index below* | **Duration** | | **Staff Signature2 & Date** | **PI Signature & Date** | **CV3 (Y/N)** | **GCP4 (Y/N)** |
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|  | **Site Staff**  *\* This form is to be signed* ***contemporaneously*** *by PI and Staff \** | | | | | | | | | |
| **Name & Title** | | **Initials** | **Study Role** | **Key Study Task(s)**  *List all appropriate from the index below* | **Duration** | | **Staff Signature2 & Date** | **PI Signature & Date** | **CV3 (Y/N)** | **GCP4 (Y/N)** |
| **Start** | **End** |
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| **Study Roles and Key Tasks Index** | | | | | | | |
| * Identification of study roles includes but is not limited to **sub-investigators, study nurses, pharmacist (when appropriate) and data recorders**. * Identify key study tasks delegated by the Principal Investigator from the list below: | | | | | | | |
| **1** | Obtain Informed Consent | **9** | Review study-related test results (e.g. pathology, radiology etc) | **17** | Prepare/Dispense Investigational Product (IP) | **25** | Electronic data query completion |
| **2** | Review medical history | **10** | Confirm eligibility criteria (inclusion/exclusion) | **18** | Perform IP Accountability | **26** | Manage EC communications and submissions |
| **3** | Review medication history and collect concomitant medications | **11** | Perform safety assessments (assess AE/SAE causality) | **19** | Manage IP receipt and storage | **27** | Recruit study participants |
| **4** | Perform basic assessments (vital signs, weight) | **12** | Assist with AE/SAE recording | **20** | Deliver IP | **28** | Organise monitoring visits |
| **5** | Perform physical examination | **13** | Report SAEs | **21** | Administer IP | **29** | Maintain Essential Documents and Investigator Site File |
| **6** | Make study-related medical decisions | **14** | Prescribe study medication | **22** | Complete data collection worksheet entries, corrections, and queries | **30** | Study closure signature |
| **7** | Collect biological samples | **15** | Provide authorisation to randomise (e.g. prescription) | **23** | Sign eCRF | **31** | Archive functions |
| **8** | Handling/processing and shipment of biological samples | **16** | Randomise participants | **24** | Data entry into electronic data capture system (e.g. REDCap) | **32** | Other [please specify]\* |

\*Other tasks may be those that are study specific or are local regulatory requirements and have been identified by the Study Sponsor.

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| **Electronic Signature Declaration for Principal Investigator and Site Staff**   * My electronic signature as it applies to entering electronic data or signing records in sponsor-owned or sponsor-outsourced computer systems is the legally binding equivalent of my handwritten signature. * I will not share password(s) assigned to me for this study with any other person. |

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| **Principal Investigator’s End of Study Declaration**  I hereby confirm that the above information is accurate and complete, and that I authorised the delegation of study-related tasks to each individual as listed above. | | | |
| **Principal Investigator’s Signature** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Date** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |