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| **Protocol / study number:** |  | **Sponsor:**  |  |
| **Principal Investigator:** |  | **Site number:** |  |
| **Site name:** |  |  |  |

**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.**

**Principal Investigator (PI)**

By signing, I confirm/acknowledge that the tasks listed below will only be delegated to appropriately trained, skilled and qualified staff. I will remain responsible for the overall study conduct and reported data and I will ensure study oversight. All associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations and have not performed any study tasks prior to appropriate delegation and completion of appropriate training. Mechanisms are in place to ensure that site staff receives the appropriate information and training throughout the study and that a 2-way communication channel exists between staff and self. Any changes in staff or delegation in staff will be recorded in a timely manner.

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| **Name of PI** | **PI’s Signature** | **Study Task(s)** | **PI Initials** | **Start Date** | **End Date**✝ |
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**Task Key:**

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| 1. Obtain informed consent \* | 12. Sample collection |
| 2. Subject selection/recruitment\* | 13. Sample processing and/or shipment |
| 3. Confirm eligibility (review inclusion/exclusion criteria)\* | 14. Evaluate study-related test results \* |
| 4. Obtain medical history (source documents) | 15. Use IWRS/IVRS  |
| 5. Perform physical exam\*  | 16. Make entries/corrections on (e)CRFs |
| 6. Conduct study visit procedure as outlined in the protocol\* | 17. Sign- off (e)CRFs\* |
| 7. Make study-related medical decisions\* | 18. Maintain essential documents |
| 8. Assess AEs/SAEs\* | 19. Perform study-related assessments as per protocol \* |
| 9. Dispense study drug\* | 20. Complete company- specific log (if applicable) |
| 10. Perform drug accountability | 21. Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 11. Study drug storage and temperature monitoring | 22. Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

\*These tasks may only be performed by qualified individual as permitted by local law, medical or standard of care practices, or applicable required training as per job description or designation.

✝Complete only if PI ends prior to the completion of the study. Refer to ‘Optional Section’ below.

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| **Name** | **Signature** | **Initials** | **Study Role** | **Key Study Task(s)** | **Start Date** | **PI Initials and Delegation Start Date** | **End Date** | **PI Initials and Delegation End Date** |
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| **Comments:**  |
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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 persons.

**Optional Section** *(use only if applicable)*

**CHANGE OF PRINCIPAL INVESTIGATOR**

**Outgoing Principal Investigator’s declaration:** As the outgoing Principal Investigator for the above-mentioned clinical trial, I formally transfer all Principal Investigator responsibilities to Dr. , qualified by education, training and experience to take over this study role.

I confirm that I have performed an appropriate study handover which has included a review of the study protocol and procedures, the structure and functioning of the study team and auxiliary services within and outside of the site, and the interactions and tasks related to the Sponsor, Contract Research Organisation (CRO) and other third-party service providers.

**Incoming** **Principal Investigator’s declaration:** As the incoming Principal Investigator for the above-mentioned clinical trial, I formally agree to assume all responsibilities from the outgoing Principal Investigator, Dr. . I have been fully informed regarding the study protocol and procedures, the structure and functioning of the study team and auxiliary services within and outside of the site, and the interactions and tasks related to the Sponsor, CRO and other third-party service providers.

[ ]  **I agree with the delegation of tasks as done by the outgoing Principal Investigator** *(tick if applicable)*

**Date of transfer of responsibilities:**

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| --- |
| **Outgoing Principal Investigator** |
| PI’s name: |  | PI’s signature: |  | Date: |  |

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| --- |
| **Incoming Principal Investigator** |
| PI’s name: |  | PI’s signature (& initials): |  | Date: |  |

**References**

[TransCelerate information and guidance sheet for site signature and delegation of responsibilities log](http://www.transceleratebiopharmainc.com/wp-content/uploads/2015/04/TransCelerate-Site-Signature-DOR-Guidance-JUNE.pdf)