**PLEASE REFER TO THE** [**GUIDANCE DOCUMENT**](http://www.transceleratebiopharmainc.com/assets/site-qualification-and-training/) **FOR DETAILED INSTRUCTIONS ON THE COMPLETION OF THIS FORM.**

THIS FORM IS TO BE COMPLETED FOR SITE PERSONNEL INVOLVED IN THE STUDY TO WHOM THE INVESTIGATOR HAS DELEGATED SIGNIFICANT STUDY-RELATED DUTIES. THE FORM IS TO BE **COMPLETED PRIOR TO** CONDUCTING STUDY RELATED TASKS.

THE PRINCIPAL INVESTIGATOR MUST ENSURE PERSONNEL DO NOT START THE DELEGATED STUDY-RELATED TASKS UNTIL CONFIRMING THAT THEY HAVE COMPLETED STUDY RELATED TRAINING APPROPRIATE TO THE ROLE AND TASK.

THE STUDY SITE IS REQUIRED TO MAINTAIN AN UP TO DATE VERSION OF THIS FORM IN ACCORDANCE WITH SPONSOR REQUIREMENTS.

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| **Name of Principal Investigator** | **Principal Investigator’s Signature\*** | **Principal Investigator’s Initials** | **Start Date**  **(dd/mmm/yyyy)** | **End Date**  **(dd/mmm/yyyy)** |
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\*My signature confirms/acknowledges that the information contained here is accurate and that:

* I will remain responsible for the overall study conduct and reported data.
* I will ensure study oversight.
* I will authorize the delegation of study-related tasks to each individual as listed.
* The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
* I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.
* I will ensure that site staff receives, in a timely manner, the appropriate information and training for delegated tasks.
* I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.

**CHANGE IN PI INSTRUCTIONS:** In the event that the Principal Investigator changes, an end date will be recorded above and a new log will be completed by the new Principal Investigator prior to commencing any study tasks. Both the original and the new log will be held by the site. Please see the guidance document for additional instructions.

Study Task Key:

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| 1. Manage IRB/EC communications & submissions | 11. Evaluate study related test results | 21. Administer IP |
| 1. Maintain essential documents | 12. Assess AE/SAE causality | 22. Other \* |
| 1. Receive/access safety notifications | 13. Report SAEs | 23. Other \* |
| 1. Screen/recruit study subjects | 14. Collect/process/ship biological samples | 24. Other \* |
| 1. Obtain informed consent | 15. Make (e)CRF entries, corrections and queries | 25. Other \* |
| 1. Perform physical exam | 16. Sign off on (e)CRF visit data | 26. Other \* |
| 1. Obtain medical/medication history | 17. Use IWRS/IVRS | 27. Other \* |
| 1. Confirm eligibility criteria (inclusion/exclusion) | 18. Manage IP receipt, storage, & temperature monitor | 28. Other \* |
| 1. Perform basic assessments (e.g. vital signs, weight, ECG) | 19. Prepare and dispense IP | 29. Other \* |
| 1. Make study related medical decisions | 20. Performs IP accountability | 30. Other \* |

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

(\*\*) Necessary training for task must be completed prior to performing a study task.

(\*\*\*) PI initials and delegation start date indicate date when delegation is authorized by PI. This date should not be after “start of task(s)” date.

| **Name** | **Signature**  My signature below indicates that I accept the study task. | **Initials** | Study Role | **Study Task(s)** (Select from key) | **PI initials and delegation start date \*\*\***  (dd/mmm/yyyy) | **Start of task(s)\*\***  (dd/mmm/yyyy) | **End of task(s)**  (dd/mmm/yyyy) | PI initialsand delegation end date (dd/mmm/yyyy) |
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| Example:  *Katarina Koordinator* | Katarina Koordinator | KMK | Study Coordinator | 1-3,7,10-17,19,20-23, 25,27 | **DMG** 31/MAY/2016 | 31/MAY/2016 | 30/JUN/2017 | **DMG** 30/JUN/2017 |
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**Comments**: Please check box if there are no comments

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I confirm that the information contained in this document is accurate and complete. (To be completed by the Principal Investigator at the end of the study).

**Principal Investigator Name:**   **Signature:** **Date**:

This section is intentionally left blank space for sponsor specific statements. Delete text if no sponsor specific statement needed.

| **Name** | **Signature**  My signature below indicates that I accept the study task. | **Initials** | Study Role | **Study Task(s)** (Select from key) | **PI initials and delegation start date \*\*\***  (dd/mmm/yyyy) | **Start of task(s)\*\***  (dd/mmm/yyyy) | **End of task(s)**  (dd/mmm/yyyy) | PI initialsand delegation end date (dd/mmm/yyyy) |
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*Instructions: Duplicate this page as needed to add additional site staff for delegation. Insert duplicated pages after pg. 3 of the form.*