**PLEASE REFER TO THE** [**GUIDANCE DOCUMENT**](http://www.transceleratebiopharmainc.com/assets/site-qualification-and-training/)**(Trans Celerate) FOR DETAILED INSTRUCTIONS ON THE COMPLETION OF THIS FORM.**このフォームの記入方法の詳細な手順は，ガイダンス文書(Trans Celerate)を参照する．

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.　このフォームは，治験責任医師が，試験関連の重要な業務を委任した，治験に関与する施設スタッフを特定するために記入するものである．フォームは試験関連業務を実施する前に完成する必要がある．

THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR ALL TASKS CONDUCTED AT THE STUDY SITE， THEREFORE THE PI COMPLETES THE SECTIONS INDICATED BUT THE PI IS NOT DELEGATED SPECIFIC TASKS IN THE TASK SECTION OF THE LOG.　治験責任医師は，試験実施施設で行われる全ての業務に責任があり，指定されたセクションを記入するが，業務のセクションでは特定の業務は委任されない．

THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL.　治験責任医師は，施設のスタッフが役割と業務に適したトレーニングを完了したことを確認する．

THE STUDY SITE IS REQUIRED TO MAINTAIN AN UP TO DATE VERSION OF THIS FORM IN ACCORDANCE WITH SPONSOR REQUIREMENTS.　試験実施施設は，依頼者の要件にあわせてこのフォームを最新版に更新し続ける必要がある．

**START OF STUDY DECLARATION　試験開始の宣言**: (to be completed at the start of the study　試験開始時に記入する)

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| --- | --- | --- | --- |
| **Name of Principal Investigator** | **Principal Investigator’s Signature\*** | **Principal Investigator’s Initials** | **Date (dd/mmm/yyyy)** |
|  | (日本語) |  |  |
| (英語) |  |

\*My signature confirms/acknowledges that the information contained here is accurate and that: 私は，ここに含まれた内容が正確であることを確認・承認し，署名する．

* I will remain responsible for the overall study conduct and reported data. 私は試験全体の実施と報告されたデータに責任を負う．
* I will ensure study oversight. 私は試験を確実に監督する．
* I will authorize the delegation of study-related tasks to each individual as listed. 私はリストに記載された試験関連の業務を各個人に委任することを許可する．
* The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role. リストに記載した試験業務は，私から役割に適した訓練受けた経験と資格のあるスタッフにのみ委任される．
* 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. 私は，試験の実施に協力する全てのスタッフへその責務に関する情報が提供されること，そして適切な委任と役割に適した試験の訓練が完了する前に，委任された試験関連のいかなる業務が行われていないことを保証する．
* I will ensure that site staff receives, in a timely manner, the appropriate information and training for delegated tasks. 私は，施設のスタッフが，委任された業務のための適切な情報入手と訓練が迅速に行えるようにする．
* I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner. 私は，スタッフや委任された試験関連業務の全ての変更を迅速に記録する．

END OF STUDY DECLARATION　試験終了の宣言: I confirm that the information contained in this document is accurate and complete. 私はこの文書の内容が正確かつ完全であることを確認する．

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

**CHANGE IN PRINCIPAL INVESTIGATOR INSTRUCTIONS 治験責任医師変更手順**: The Principal Investigator will record the end date above. Before starting trial operations, the new PI must complete a new log using the form on this page. The new PI records the change in PI. If existing delegations are to be maintained, the new PI also confirms their agreement to the tasks previously delegated by the former PI. Both the original log and the new log should be retained at the site. If there are additional procedures, refer to the guidance document (TransCelerate). 治験責任医師が終了日を上記に記録する．試験業務を開始する前に新しい治験責任医師がこのページのフォームを用いて新しいログを作成する．新しい治験責任医師は治験責任医師の変更があったことを記録する．既存の委任を維持する場合，新しい治験責任医師は前任の治験責任医師によって委任されたタスクに同意したことを記録する．元のログと新しいログの両方がサイトで保管される．追加の手順がある場合，ガイダンス文書(TransCelerate)を参照する．

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| 1. Determine eligibility criteria (inclusion/exclusion)   適格(選択/除外)基準の確定 | 14. Manage IRB/EC communications & submissions  　　 IRBへの提出/提出文書の管理 | 27. Obtain/Conduct Informed Consent  　　同意説明/同意取得 |
| 1. Perform Physical Exam   身体検査の実行 | 15. Maintain essential documents  　　必須文書の保管管理 | 28. Support conduct of Informed Consent  　　同意説明の補助 |
| 1. Make study-related medical decisions   試験上の医学的な決定 | 16. Collect/process biological samples / examination data  　　生体試料/検査データの採取/処理 | 29. Obtain medical/medication history  　　病歴/薬歴の収集 |
| 1. Evaluate study related test results   試験上の臨床検査結果の評価 | 17. Ship biological samples / Medical test data  　　生体試料/検査データの送付 | 30. Report SAEs  SAE報告 |
| 1. Assess AE/SAE causality   AE/SAEの因果関係の判断 | 18. Management of Inspection material  　　検査資材管理 | 31. Other |
| 1. Assess Safety notifications   安全性情報の評価 | 19. Make (e)CRF entries， corrections and queries  　　 CRFの入力/記入，修正，クエリ対応 | 32. Other |
| 1. Sign off on (e)CRF visit data   CRFのVisitデータの承認 | 20. Recruit study subjects  　　被験者のリクルート | 33. Other |
| 1. Unblind/Unmask   盲検解除 | 21. Use IWRS/IVRS/IRT  　　 IWRS/IVRS/IRTの使用 | 34. Other |
| 1. Discuss medical content of Informed Consent   同意説明文書の医学的情報についての説明 | 22. Manage Study Intervention receipt/ storage/ temperature monitor  　　治験薬の受領/保管/温度管理の管理 |  |
| 1. Other | 23. Prepare Study Intervention  　　治験薬の準備(調剤・調製を含む) |  |
| 1. Other | 24. Dispense Study Intervention  　　治験薬の交付 |  |
| 1. Other | 25. Perform Study Intervention accountability  　　治験薬管理 |  |
| 1. Other | 26. Administer Study Intervention  　　治験薬投与 |  |

**STUDY TASKS:**

Any study specific tasks or local regulatory requirements identified by the study sponsor should be listed under 'Other'.　治験依頼者が特定した試験特有の業務や地域規制要件の業務はOtherに記載する．

The following outlines the routine duties performed by our staff. When these duties are conducted in this clinical trial, they will be performed under the oversight of the principal investigator as part of their routine practice. In principle, delegation of these duties to each individual involved is unnecessary. However, if delegation is required, it will be assigned to a representative following consultation.

以下に当院のスタッフの通常業務を示す．この治験でこれらの業務を実施する場合，治験責任医師の監督の下，通常の業務として行う．原則，これらの業務に関与する各個人への委任は不要とする．委任が必須の場合，協議の上で代表者に委任する．

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| Doctor  ( 医師 ) | Inspection instructions( 検査指示 ), General drug administration instructions( 一般薬投与指示 ), Rest level indication( 安静度指示 ), Biological sample collection( 検体採取 ), Measurement (vital signs, height, weight, etc.) ( バイタルや身体測定 ), Physiological function examination( 生理機能検査 ), Drug administration( 投薬 ), Diagnostic imaging( 画像診断 ), Medical examination / diagnosis( 診察/診断 ) |
| Radiologist  ( 放射線医 ) | Image inspection( 画像検査 ), Radiation therapy( 放射線治療 ), Diagnostic imaging( 画像診断 ) |
| Pathologist  ( 病理医 ) | Pathological diagnosis( 病理診断 ), Pathology specimen preparation( 病理標本作成 ) |
| Pharmacist  ( 薬剤師 ) | Prepare/Dispense drugs( 薬剤の準備( 調剤・調製を含む )/交付 ), Drug storage and management( 薬剤保管管理 ) |
| Nurse  ( 看護師 ) | Biological sample collection( 検体採取 ), Measurement ( vital signs,height,weight,etc.) ( バイタルや身体測定 ), Drug administration( 投薬 ), Assisting in medical care( 診療補助 ), Care during the medical procedures( 医療行為におけるケア ), Patient care( 患者ケア ) |
| Medical technologist  ( 臨床検査技師 ) | Collect/Process biological samples( 検体採取/処理 ), Laboratory testing( 検体検査 ), Physiological function examination( 生理機能検査 ), Inspection material management / sending( 検体資材管理/送付 ), Pathology specimen preparation ( 病理標本作成 ) |
| Radiologic Technologist  ( 診療放射線技師 ) | Image inspection( 画像検査 ), Radiation therapy( 放射線治療 ) |
| clinical engineering technologist  ( 臨床工学技士 ) | Biological sample collection( 検体採取 ), Prepare/Dispense devices( 医療機器の準備/交付 ), device storage and management( 医療機器保管管理 ) |

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| Clinical Trial Office  (治験事務局) | Manage IRB/EC communications & submissions( IRB提出/提出文書管理), Maintain essential documents( 必須文書管理 ) |

The duties of the Clinical Trial Office are defined in our institution's SOPs,and the following tasks performed by Clinical Trial Office Personnel are standard in clinical trials, so delegation is unnecessary. If delegation becomes necessary, it will be assigned to a representative after consultation.当院のSOPで治験事務局の業務を規定しており、治験事務局担当者が実施する以下の業務は治験における標準業務である。そのため、委任は不要とする。委任が必要な場合，協議の上で代表者に委任される。

| Complete upon assignment of site staff | | | | |  | Complete when staff exitduring the study | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Signature**  My signature below indicates that I accept the study task. | **Initials** | Study Role | **Study Task(s)** (Select from key) | **PI initials and date** (dd/mmm/yyyy) | **End of task(s)**  (dd/mmm/yyyy) | PI initials anddate (dd/mmm/yyyy) |
| Example:  Kenishi　Tohoku | (日本語) 東北　研一 | K・T | Sub-investigator | 1,2,3,4,5,9,16,19,20,24,26,27,29,30 | DMG 31/MAY/2017 | 30/JUN/2018 | DMG 31/MAY/2017 |
| (英語) Kenishi　Tohoku |
|  | (日本語) |  | Sub-investigator | 1,2,3,4,5,9,16,19,20,24,26,27,29,30 |  |  |  |
| (英語) |
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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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| Complete upon assignment of site staff | | | | |  | Complete when staff exitduring the study | |
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| **Name** | **Signature**  My signature below indicates that I accept the study task. | **Initials** | Study Role | **Study Task(s)** (Select from key) | **PI initials and date** (dd/mmm/yyyy) | **End of task(s)**  (dd/mmm/yyyy) | PI initials anddate (dd/mmm/yyyy) |
|  | (日本語) |  | Study Coordinator | 14,15,16,17,18,19,20,21,28,  29,30 |  |  |  |
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| **Name** | **Signature**  My signature below indicates that I accept the study task. | **Initials** | Study Role | **Study Task(s)** (Select from key) | **PI initials and date** (dd/mmm/yyyy) | **End of task(s)**  (dd/mmm/yyyy) | PI initials anddate (dd/mmm/yyyy) |
|  | (日本語) |  | Pharmacist | 21,22,23,24,25 |  |  |  |
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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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| Complete upon assignment of site staff | | | | |  | Complete when staff exitduring the study | |
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| **Name** | **Signature**  My signature below indicates that I accept the study task. | **Initials** | Study Role | **Study Task(s)** (Select from key) | **PI initials and date** (dd/mmm/yyyy) | **End of task(s)**  (dd/mmm/yyyy) | PI initials anddate (dd/mmm/yyyy) |
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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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