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

(本様式の作成に関する詳細な説明は、ガイダンス文書(TransCelegrate)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.

(本様式は、試験実施施設において、試験関連業務をPIが任命した者を特定するために完成させる.本様式は、試験関連業務開始前に完成させる)

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

(PIは、当院で実施されたすべてのタスクに責任を負います。そのため、PIは示されたセクションを完了しますが、PIは本様式の特定のタスクを委任されません。)

THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL.

(PIは、スタッフがその役割Roleと業務Taskに適した試験関連トレーニングがサイトの担当者によって完了したことを確認します。)

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、依頼者要件に従い本様式を常に最新の状態にする必要がある)

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

START OF STUDY DECLARATION: (to be completed at the start of the study)

\*My signature confirms/acknowledges that the information contained here is accurate and that:(ここに含まれている情報が正確であることおよび以下のことを確認し署名する)

* I will remain responsible for the overall study conduct and reported data. (私は試験全体の実施および報告されたデータに責任を負う)
* I will ensure study oversight. （試験の監督を行う）
* I will authorize the delegation of study-related tasks to each individual as listed. (リストに記載されている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. (リストに記載された業務は私から適切な訓練を受けた資格のあるものにのみ委任する)
* 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. (試験の実施を支援する全スタッフに業務に関連する情報が提供され適切な委任訓練完了前に委任された関連の業務を行っていないことを補償する)
* I will ensure that site staff receives, in a timely manner, the appropriate information and training for delegated tasks. (スタッフが委任された作業のための適切な情報入手と訓練が適時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. (スタッフや委任された試験関連の業務の変更がタイムリーに記録されるようにする)

END OF STUDY DECLARATION: I confirm that the information contained in this document is accurate and complete.　(この文書に含まれる情報が正確かつ完全であることを確認します。)

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

**SPONSOR COMMENTS (optional):**

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**CHANGE IN PI :** IN THE EVENT THAT THE PI CHANGES REFER TO THE GUIDANCE DOCUMENT.；OPTION 2(keep existing delegations and start a new log)

* Enter a statement in the comment section of the form to indicate there was a change in PI.(コメントセクションにPIに変更があった事を示す記載をします)
* The new PI will start a new DOR form by signing and dating the top section of a new page 1(新しいPIは、新しいページ1の上部に署名して日付を記入することにより、新しいDORを開始します)
* The new PI will enter a statement in the comments section of the original DOR form agreeing with the existing delegations.(新しいPIは、元のDORフォームのコメントセクションに、既存のスタッフに同意する事を記載します)
* Changes or new additions to the DOR that occur after a new PI begins will be made on the new DOR log.(新しいPIの開始後に発生するDORへの変更または新しい追加は、新しいDORログで行います)

\*Study Task Key and Example of staff（SI:Sub Investigator (分担医師), SMA：Site Management Associate(治験事務局), CRC: Study Coordinator(Study Nurse(N)/Pharmacist(P) etc.)）

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| 1. Manage IRB/EC communications & submissions (IRB提出文書管理)
 | SMA | 16. Sign off on (e)CRF visit data (CRF承認) | (PI only) |
| 1. Maintain essential documents (責任医師文書管理)
 | SMA | 17. Use IWRS/IVRS (IXRS使用) | CRC |
| 1. Receive/access safety notifications (安全性情報の管理)
 | SMA | 18. Manage IP receipt, storage, & temperature monitor (試験薬保管/温度管理) | CRC(P) |
| 1. Screen/recruit study subjects (被験者選定/リクルート)
 | SI | 19. Prepares, dispenses and/or administers IP (試験薬調剤) | SI, CRC(P) |
| 1. Obtain informed consent (同意取得)
 | SI | 20. Performs IP accountability (投薬確認) | SI. CRC |
| 1. Perform physical exam (身体検査)
 | SI | 21. Other  |  |
| 1. Obtain medical/medication history (病歴入手)
 | SI | 22. Other  |  |
| 1. Confirm eligibility criteria (inclusion/exclusion) (適格基準確認)
 | SI | 23. Other  |  |
| 1. Perform basic assessments (eg. vital signs, weight, ECG) (身体機能評価・診察)
 | SI, CRC | 24. Other  |  |
| 1. Make study related medical decisions (試験上の医学的判断)
 | SI | 25. Other  |  |
| 11. Evaluate study related test results (臨床検査判断) | SI | 26. Other  |  |
| 12. Assess AE/SAE causality (AE/SAE判断) | SI | 27. Other  |  |
| 13. Report SAEs (SAE報告) | SI | 28. Other  |  |
| 14. Collect/process/ship biological samples (検体採取/処理/送付) | SI, CRC | 29. Other  |  |
| 15. Make (e)CRF entries, corrections and queries (CRF作成) | CRC | 30. Other  |  |

Other tasks may be those that are study specific or are local regulatory requirements and have been identified by the Study Sponsor. ( Otherには、試験固有のもの、現地規制要件や依頼者規程のものを記載可能とする)

\*Normal study work in our hospital is specified. In principle, personal delegation is unnecessary. (院内各部門における通常業務は以下に明示し、原則各個人についてのDelegateは不要とする)

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| Nurse (看護師/看護部) | Biological samples collect (検体採取), measurement(vital signs, height weight, etc.) (バイタル測定, 身体測定), Patient care (患者ケア), Drug administration (投薬) |
| Pharmacist (薬剤師/薬剤部) | Since the investigational drug manager is the sub-directors of Pharmacists, investigational drug management assistants are separately designated.(治験薬管理者が副薬剤部長であるため、別途治験薬管理補助者を指名する),Prescription (薬品の調剤), Drug storage and management (薬剤保管管理) |
| Medical technologist (検査技師/検査科) | Collect/Process biological samples (検体採取, 処理), Laboratory tests (検体検査), Physiological function examination (electrocardiogram, respiratory functional examination, brain wave examination) (生理機能検査 (心電図, 呼吸機能, 脳波 等)) |
| Pathologist (検査科‐病理診断部門) | Pathological diagnosis (病理診断), Pathology specimen manufacture (病理標本作成) |
| Radiologic Technologist (放射線科) | Image inspection (X-ray, CT, MRI, scintigraphy, US, etc.) (画像検査(X線, CT, MRI, 骨シンチ, 超音波)), Radiation therapy, Diagnostic imaging (画像診断) |

\***The study collaborators specific to the project are listed only in SSDL and not in Form 2.**（課題特有の治験協力者については、書式2に記載していない）

| **Complete upon assignment of site staff** |  | **Complete when staff exit** **during 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 start date** ★ (dd/mmm/yyyy) | **End of task(s)★**(dd/mmm/yyyy) | **PI initials and date ★**(dd/mmm/yyyy) |
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★If it is indicated by an arrow (↓), it is signed by the same date and PI as in the upper row.（矢印（↓）で記載された場合、上段と同じ日付、同じPIが署名したものである。）

**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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