・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う。そのため、PIは示されたセクションを完了するが、本様式の特定のタスクを委任されない)

・THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL. (PIはスタッフが役割とTaskに適したトレーニングが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、依頼者要件に従い本様式を常に最新の状態にする必要がある)

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

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

\*My signature confirms/acknowledges that the information contained here is accurate and that(私の署名は記載された情報が正確であること、及び以下の事項を確認／承認するものである):

* I will remain responsible for the overall study conduct and reported data. (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 .(試験を監督する）
* 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)
* 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者にのみ委任する）
* 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. (本試験の実施に協力する全てのスタッフが、その義務について知らされていることを確認し、適切な委任を受け、本試験に適した訓練を終了するまでは、委任された試験関連業務を行わないようにする)
* 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業務に関する適切な情報と訓練を適時に受けられるようにする)
* 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.

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

**CHANGE IN PI :** 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に変更があった旨を記す)
* **The new PI will start a new DOR\* form by signing and dating the top section of a new page 1.**(新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を開始する)
* **The new PI will enter a statement in the comments section of the original DOR form agreeing with the existing delegations.** (新PIは元のDOR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する)
* **Changes or new additions to the DOR that occur after a new PI begins will be made on the new DOR log.** (新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で行う)

\*Site Signature and Delegation of Responsibilities Log

|  |  |  |
| --- | --- | --- |
| **Medically Qualified/Trained/Licensed Staff** | **Trained/Qualified Staff** | **Trained/Qualified Staff Continued** |
| 1. Determine eligibility criteria (inclusion/exclusion)   適格性基準の判定 | 9. Manage IRB/EC communications & submissions  IRB提出文書管理 | 22. Report SAEs  　　SAE報告 |
| 1. Perform Physical Exam   身体検査 | 10. Maintain essential documents  　　責任医師文書管理 | 23. Other |
| 1. Make study-related medical decisions   試験上の医学的判断 | 11. Collect/process biological samples  　　検体採取・処理 | 24. Other |
| 1. Evaluate study related test results   臨床検査結果の判断 | 12. Ship biological samples  　　検体発送 | 25. Other |
| 1. Assess AE/SAE causality   AE/SAEの評価 | 13. Make (e)CRF entries, corrections and queries  　　CRF作成 | 26. Other |
| 1. Assess Safety notifications   安全に関する通知の評価 | 14. Recruit study subjects  　　被験者リクルート |  |
| 1. Sign off on (e)CRF visit data   CRF承認 | 15. Use IWRS/IVRS/IRT  　　IWRS/IVRS/IRTの使用 |  |
| 1. Unblind/Unmask   非盲検 | 16. Manage SI receipt/storage/temperature monitor  　　治験薬の受領/保管/温度管理 |  |
|  | 17. Prepare, dispense Study Intervention (SI)  　　治験薬の準備、調剤 |  |
|  | 18. Perform SI accountability  　　治験薬の出納管理 |  |
|  | 19. Administer SI  　　治験薬の投与 |  |
|  | 20. Obtain/Conduct Informed Consent  　　同意取得 |  |
|  | 21. Obtain medical/medication history  　　病歴の入手 |  |

**STUDY TASKS:**

| 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 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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| 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 and date (dd/mmm/yyyy) |
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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 | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 and date (dd/mmm/yyyy) |
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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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\*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)

|  |  |
| --- | --- |
| Nurse  (看護部) | ・Biological samples collect(検体採取)  ・measurement(vital signs, height, weight, etc.)(バイタルサイン測定、身体測定等)  ・Patient care(患者ケア)  ・Drug administration(薬剤の投与) |
| Medical technologist  (臨床検査科) | ・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, etc)(生理機能検査 (心電図、 呼吸機能、脳波等)) |
| Pathologist  (病理診断科) | ・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、超音波等))  ・Radiation therapy(放射線療法)  ・Diagnostic imaging(画像診断) |
| Pharmacist  (薬剤部） | ・Dispensing of drug(薬剤の調剤）  ・Drug storage and management (薬剤の保管、管理)  ・Record of drug inventory log (薬剤の出納記録) |