

Site Signature and Delegation Of Responsibilities Log



北海道大学病院
臨床研究開発センター

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|--------------------------------------|-------|---------------------|------------------------------|
| Protocol Number/ Study Number | / | Sponsor Name | |
| Country | JAPAN | Site Name | Hokkaido University Hospital |
| Site Number | | | |

- THIS FORM IS TO BE COMPLETED FOR SITE PERSONNEL INVOLVED IN THE STUDY TO WHOM THE INVESTIGATOR HAS DELEGATED SIGNIFICANT STUDY-RELATED DUTIES. (このフォームはInvestigatorが重要な試験関連の任務を委任した研究に関与しているサイトスタッフのために記入されるものである)
- THE FORM IS TO BE COMPLETED PRIOR TO CONDUCTING STUDY RELATED TASKS. (このフォームは試験関連のTaskを行う前に完成させるものである)
- 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. (PIは研究施設で行われるすべてのTaskに対して責任があるため、特定のTaskをデリゲートされないが、全てのTaskを完全に示す)
- THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL. (PIはサイトスタッフが役割とTaskにふさわしいトレーニングを完了したことを確認する)
- 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. (PIはスタッフが役割やTaskにあった試験関連のトレーニングを完了するまでDelegateされた試験関連のTaskを開始していないことを確認しなければならない)

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/yy) | End (dd/mmm/yy) |
|--------------------------------|-------------------------------------|-----------------------------------|-------------------|-----------------|
| | (日本語) | | | |
| | (英語) | | | |

*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をもって承認します)

- I will remain responsible for the overall study conduct and reported data. (私は研究全体の実施および報告されたデータに責任を負います)
- I will ensure study oversight. (研究の監督を行う)
- 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します)
- 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. (研究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研究関連の業務を行っ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. (スタッフが委任された作業のための適切な情報と訓練を適時に受け取るようにする)
- 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研究関連の業務の変更がタイムリーに記録されるようにします)
- I consent that my personal information that is the site staff is used for the study appropriately. (私はサイトスタッフである私の個人情報が試験のために適切に使用されることを承諾します。)

END OF STUDY DECLARATION (試験終了宣言) : I confirm that the information contained in this document is accurate and complete. (私はこの文書に含まれる情報が正確で完全であることを承認する)

| | | |
|-------------------------------------|-------------------|--------------|
| Principal Investigator name: | Signature: | Date: |
|-------------------------------------|-------------------|--------------|

CHANGE IN PI INSTRUCTIONS (PI変更時の指示): 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 them commencing any study tasks. Both the original and the new log will be held by the site. (PI変更時は終了日を記載し、新PIは全てのTask開始前に新しいログを完成させ、サイトで保管します。)

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Study Tasks Key:

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|---|---|---|
| 1. Manage IRB/EC communications & submissions (IRB提出文書管理) | 11. Evaluate study related test results (臨床検査判断) | 21. Other * Conduct Informed consent (同意説明補助) |
| 2. Maintain essential documents (責任医師文書管理) | 12. Assess AE/SAE causality* (AE/SAE判断) | 22. Other * |
| 3. Receive/access safety notifications (安全性情報の管理) | 13. Report SAEs (SAE報告) | 23. Other * |
| 4. Screen/recruit study subjects (被験者選定/リクルート) | 14. Collect/process/ship biological samples (検体採取/処理/送付) | 24. Other * |
| 5. Obtain informed consent(同意取得) | 15. Make (e)CRF entries, corrections and queries (CRF作成) | 25. Other * |
| 6. Perform physical exam (身体検査) | 16. Sign off on (e)CRF visit data (CRF承認) | 26. Other * |
| 7. Obtain medical/medication history (病歴入手) | 17. Use IWRS/IVRS/IRT (IXRS使用) | 27. Other * |
| 8. Confirm eligibility criteria (inclusion/exclusion) (適格基準確認) | 18. Manage IP receipt, storage, & temperature monitor(試験薬保管/温度管理) | 28. Other * |
| 9. Perform basic assessments (eg. vital signs, weight, ECG) (身体機能評価、診察) | 19. Prepares, dispenses and/or administers IP (試験薬調剤) | 29. Other * |
| 10. Make study related medical decisions (試験上の医学的判断) | 20. Performs IP accountability (投薬確認) | 30. Other * |

(* Other tasks may be those that are study specific or are local regulatory requirements and have been identified by the Study Sponsor.
(その他のタスクは試験特有またはローカルで調整が必要である可能性があり、Study Sponsorにより認定されたものである)

(***) PI initial and date indicate date when delegation is authorized by PI. This date should not be after "start of task(s)" date.
(PIイニシャルと日付は、PIが委任を承認した日付とする。この日付は、Taskの開始日より後の日付であってはならない)

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| Name | Signature <i>My signature below indicates that I accept the study task.</i> | Initials | Study Role | Study Task(s) (Select from key) | PI initials and delegation start date *** (dd/mmm/yyyy) | PI initials and delegation end date (dd/mmm/yyyy) |
|------|--|----------|------------|------------------------------------|--|--|
| | (日本語) | | | | | |
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SAMPLE

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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)

| | Study Task(s) |
|-----------------------------------|--|
| Nurse (看護部) | <ul style="list-style-type: none"> • Care in the medical treatment (療養上の世話) • Assist in medical care (診療の補助) <ul style="list-style-type: none"> • Biological samples collect (検体採取) • Measurement (vital signs, height, weight, etc.) (バイタル測定、身体測定) • Drug administration (投薬) |
| Medical technologist (検査・輸血部) | <ul style="list-style-type: none"> • 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, US, etc.) (各種検査 (心電図・呼吸機能・脳波・超音波 等)) |
| Pharmacist (薬剤部) | <ul style="list-style-type: none"> • Since the chairman of IRB and the investigational drug manager are the directors of Pharmacist, investigational drug management assistant is separately designated. (治験審査委員会委員長及び治験薬管理者が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 (薬の調剤) • Drug storage and management (薬剤保管管理) |
| Radiologic Technologist (放射線部) | <ul style="list-style-type: none"> • Image inspection (X-ray, CT scan, MRI, PET, scintigraphy, US, etc.) (各種検査 (X線、CT、MRI、PET、骨シンチ、超音波、等)) • Radiation therapy (放射線治療) • Diagnostic imaging (画像診断) |
| Pathologist (病理部) | <ul style="list-style-type: none"> • Pathological diagnosis (病理診断) • Pathology specimen manufacture (病理標本作製) |