# 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 /Study Number** | / | **Sponsor Name** | |
| **Country** | JAPAN | **Site Name/Number** | Hokkaido University Hospital / |

**PLEASE REFER TO THE GUIDANCE DOCUMENT 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.

| Name of Principal Investigator | Principal Investigator's Signature* | Principal Investigator's Initials | Start (dd/mmm/yy) | End (dd/mmm/yy) |
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***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 appropriat 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)

**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 them 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.

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**Study Task Key:**

1. Manage IRB/EC communications & submissions（IRB提出文書管理）
2. Maintain essential documents（責任医師文書管理）
3. Receive/access safety notifications（安全性情報の管理）
4. Screen/recruit study subjects（被験者選定/リクルート）
5. Obtain informed consent（同意取得）
6. Perform physical exam（身体検査）
7. Obtain medical/medication history（病歴入手）
8. Confirm eligibility criteria (inclusion/exclusion)（適格基準確認）
9. Perform basic assessments (eg. vital signs, weight, ECG)（身体機能評価、診察）
10. Make study related medical decisions（試験上の医学的判断）
11. Evaluate study related test results（臨床検査判断）
12. Assess AE/SAE causality*（AE/SAE判断）
13. Report SAEs（SAE報告）
14. Collect/process/ship biological samples（検体採取/処理/送付）
15. Make (e)CRF entries, corrections and queries（CRF作成）
16. Sign off on (e)CRF visit data（CRF承認）
17. Use IWRS/IVRS（IXRS使用）
18. Manage IP receipt, storage, & temperature monitor(試験薬保管/温度管理)
19. Prepares, dispenses and/or administers IP（試験薬調剤）
20. Performs IP accountability（投薬確認）
21. Other * Support to obtain IC（IC補助）
22. Other *
23. Other *
24. Other *
25. Other *
26. Other *
27. Other *
28. Other *
29. Other *
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 initial and date indicate date when delegation is authorized by PI. This date should not be after “start of task(s)” date.

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| **Country** | JAPAN | **Site Name/Number** | Hokkaido University Hospital / |

| **Name** | **Signature**<br>**My signature below indicates that I accept the study task.** | **Initials** | **Study Role** | **Study Task(s)**<br>(Select from key) | **PI initials and delegation start date *** (dd/mmm/yyyy)** | **Start of task(s)**** (dd/mmm/yyyy) | **PI initials and delegation end date (dd/mmm/yyyy)** | **End of task(s)** (dd/mmm/yyyy) |
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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<br>（看護部） | ・Biological samples collect（検体採取）<br>・measurement (vital signs, height, weight, etc.)（バイタル測定、身体測定）<br>・Patient care（患者ケア）<br>・Drug administration（投薬） |
| Medical technologist<br>（検査･輸血部） | ・Collect/Process biological samples（検体採取、処理）<br>・Laboratory tests（検体検査）<br>・Physiological function examination(electrocardiogram, respiratory functional examination, brain wave examination）<br>（生理機能検査（心電図・呼吸機能・脳波　等）） |
| Pharmacist<br>（薬剤部） | ・Since the chairman of IRB and the investigational drug manager are the directors of Pharmacist, investigational drug management assistant is separatelly 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)<br>・prescription（薬の調剤）<br>・Drug storage and management（薬剤保管管理） |
| Radiologic Technologist<br>（放射線部） | ・Image inspection　(X-ray, CT scan, MRI, PET, scintigraphy, US,etc.)<br>（各種検査（X線、CT、MRI、超音波、PET、骨シンチ））<br>・Radiation therapy（放射線治療）<br>・Diagnostic imaging（画像診断） |
| Pathologist<br>（病理部） | ・Pathological diagnosis（病理診断）<br>・Pathology specimen manufacture（病理標本作製） |

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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).**

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

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



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