



Site Signature and Delegation Of Responsibilities Log

Protocol Number		Sponsor Name		Study Number 治験整理番号	
Country/Site Name	JAPAN/ Hokkaido University Hospital	Clinical Department 診療科		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参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はサイトスタッフで役割と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 (yyyy/mm/dd)	End (yyyy/mm/dd)
	(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:

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:

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

(*) 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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Print Name	Signature My signature below indicates that I accept the study task.	Initials	Study Role	Study Task(s) (Select from key)	PI initials and delegation start date *** (yyyy/mm/dd)	PI initials and delegation end date (yyyy/mm/dd)
	(日本語) _____			_____	_____	
	(英語) _____			_____	_____	
	(日本語) _____					
	(英語) _____					
	(日本語) _____					
	(英語) _____					
	(日本語) _____					
	(英語) _____					

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)

Clinical Department	Study Task(s)	Clinical Department	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) 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) Disease guidance (患者指導) 	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) Treasurer record (出納記録) 	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) 	Doctor (医師)	<ul style="list-style-type: none"> Inspection instructions (検査指示) Instructions of general drug administration (一般薬投薬指示) Indication of rest level (安静度指示)
CRC assistant	<ul style="list-style-type: none"> Inspection material management / sending (検体資材管理/送付) Make documents / management (書類作成/管理) 		