

Site Signature and Delegation of Responsibilities Log

Study Sponsor:		Principal Investigator:	
Protocol Study Number:		Site Name:	Kurashiki Central Hospital
Country:	Japan	Study Site Number:	

<p>PLEASE REFER TO THE <u>GUIDANCE DOCUMENT</u> FOR DETAILED INSTRUCTIONS ON THE COMPLETION OF THIS FORM. <small>(本様式の作成に関する詳細な説明はガイダンス文書 (TransCelerate) を参照する)</small> 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. <small>(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)</small> 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. <small>(PIは、当院で実施されたすべてのタスクに責任を負うため、PIは指定された項目を記入するがPIは本様式の特定のタスクを委任されぬ)</small></p>	<p>THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL. <small>(PIは、サイト担当者がその役割と業務に適切なトレーニングが修了したことを確認する)</small></p> <p>THE STUDY SITE IS REQUIRED TO MAINTAIN AN UP TO DATE VERSION OF THIS FORM IN ACCORDANCE WITH SPONSOR REQUIREMENTS. <small>(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)</small></p>
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START OF STUDY DECLARATION:

Name of Principal Investigator	Principal Investigator's Signature*	Principal Investigator's Initials	Date (dd/mmm/yyyy)
	(日本語)		
	(英語)		

<p>*My signature confirms/acknowledges that the information contained here is accurate and that: * (署名により、ここに記載された情報が正確であることを確認・承認し、以下の事項を認める)</p> <ul style="list-style-type: none"> ● I will remain responsible for the overall study conduct and reported data. (私は研究全体の実施と報告データについて責任を負う) ● 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. (全ての関係者に責務を周知し、適切な委任と役割に応じた研修が完了するまでは、治験関連業務を実施させない) ● 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. (スタッフの変更や委任された試験関連の業務の変更が適時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. (本書に記載された情報は正確かつ完全であることを確認する)

Name of Principal Investigator:	Signature:	Date:
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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する)
- 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を開始する)
- 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ログで行う)

STUDY TASKS:

1. Determine eligibility criteria (inclusion/exclusion) (適格性基準確認)	17. Manage SI receipt/storage/temperature monitor (治験薬受領 / 保管 / 温度管理)
2. Perform Physical Exam (身体検査)	18. Prepare / Dispense Study Intervention (SI) (治験薬の調剤 / 交付)
3. Make study-related medical decisions (試験上の医学的判断)	19. Perform SI accountability (治験薬の管理)
4. Evaluate study related test results (試験関連の検査結果の評価)	20. IP (SI) destruction/return (治験薬の破棄/返却)
5. Assess AE/SAE causality (AE/SAE 評価)	21. Administer SI (治験薬の投与)
6. Assess Safety notifications (安全性情報の評価)	22. Obtain/Conduct Informed Consent (同意説明の実施と取得)
7. Sign off on (e)CRF visit data (CRF の承認)	23. Support for Informed Consent (同意説明の補助)
8. Unblind/Unmask (盲検解除)	24. Report SAEs (SAE の報告)
9. Discuss medical content of Informed Consent (同意説明の医学的な内容の説明)	25. Administer (e)PROs ((e)PRO 実施)
10. Manage IRB/EC communications & submissions (IRB / EC 提出文書管理)	26. Imaging data submission / System query response (画像提出/システムクエリ対応)
11. Maintain essential documents (必須文書の管理)	27. Collecting data necessary for clinical trials (治験に必要なデータの収集)
12. Collect/process biological samples (検体収集 / 処理)	28. Other
13. Ship biological samples (検体送付)	29. Other
14. Make (e)CRF entries, corrections and queries (CRF の作成)	30. Other
15. Recruit study subjects (被験者の選定)	31. Other
16. Use IWRS/IVRS/IRT (IXRS の使用)	32. Other

*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)
Medical technologist (検査技師/臨床検査技術部)	Collect/Process biological samples (検体採取, 処理), Laboratory tests (検体検査), Pathology specimen manufacture (病理標本作成) Physiological function examination (electrocardiogram, respiratory functional examination, brain wave examination,US) (生理機能検査 (心電図, 呼吸機能, 脳波, 超音波等))
Pathologist (病理医 - 病理診断科)	Pathological diagnosis (病理診断),
Radiologic Technologist (放射線技師/放射線技術部)	Image inspection (X-ray, CT, MRI, scintigraphy, etc.) (画像検査(X線, CT, MRI, 骨シンチ))
Pharmacist(薬剤部)	Prescription (薬品の調剤),Drug storage and management (薬剤保管管理)

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 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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