Site Signature and Delegation of Responsibilities Log

Kawasaki Medical School Hospital

Study Sponsor:		**Principal Investigator:**	
Country/Site Name:	Japan/Kawasaki Medical School Hospital	**Study Site Number:**	
Protocol Study Number:			

PLEASE REFER TO THE GUIDANCE DOCUMENT FOR DETAILED INSTRUCTIONS ON THE COMPLETION OF THIS FORM.
(本様式の作成に関する詳細な説明は、ガイダンス文書(TransCelegrate)を参照する)
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業務に責任を負う
そのため、PIは示されたセクションを完了するが、PIは本様式の特定の業務を委任されない)
THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL.
(PIは、スタッフがその役割と業務に適した試験関連トレーニングがサイトの担当者によって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 Date (dd/mmm/yyyy)	End Date (dd/mmm/yyyy)
	(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する)

- **I will remain responsible for the overall study conduct and reported data.** (私は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.** (試験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.** (スタッフや委任された試験関連の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. (この文書に含まれる情報が正確かつ完全であることを確認する)

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

SPONSOR COMMENTS (optional):

CHANGE IN PI : IN THE EVENT THAT THE PI CHANGES REFER TO THE GUIDANCE DOCUMENT. (PIが変更された場合は、ガイダンス文書を参照する)；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 SSDL 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SSDLを開始する)
- The new PI will enter a statement in the comments section of the original SSDL form agreeing with the existing delegations.(新しいPIは、元のSSDL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 SSDL that occur after a new PI begins will be made on the new SSDL log.(新しいPIの開始後に発生するSSDLへの変更または新しい追加は、新しいSSDLログで行う)

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STUDY TASKS: (SI:Sub Investigator (分担医師), SMA：Site Management Associate(治験事務局), CRC: Study Coordinator(Pharmacist(P) etc.))

Medically Qualified/Trained/Licensed Staff		*Trained/Qualified Staff*		*Trained/Qualified Staff Continued*	
1. Determine eligibility criteria (inclusion/exclusion) (適格性基準確認)	SI	14. Manage IRB/EC communications & submissions (IRB 提出文書管理)	SMA	27. Obtain medical/medication history (薬歴/病歴の入手)	SI
2. Perform Physical Exam (身体所見の実施)	SI	15. Maintain essential documents (責任医師文書管理)	SMA	28. Report SAEs (SAE の報告)	SI
3. Make study-related medical decisions (試験上の医学的判断)	SI	16. Collect/process biological samples (検体採取/処理)	SI,CRC	29. Other*	
4. Evaluate study related test results (臨床検査結果の判断)	SI	17. Ship biological samples (検体送付)	SI,CRC	30. Other*	
5. Assess AE/SAE causality (AE/SAE 評価)	SI	18. Make (e)CRF entries, corrections and queries (CRF 作成)	CRC	31. Other*	
6. Assess Safety notifications (安全性情報の評価)	(PI only)	19. Recruit study subjects (被験者募集)	SI,CRC	32. Other*	
7. Sign off on (e)CRF visit data (CRF 承認)	(PI only)	20. Use IWRS/IVRS/IRT (IXRS 使用)	CRC,(P)		
8. Unblind/Unmask (盲検解除)	SI	21. Manage SI receipt/storage/temperature monitor (試験薬受領/保管/温度管理)	(P)		
9. Discuss medical content of Informed Consent (同意説明の医学的な内容の説明)	SI	22. Prepare/ dispense Study Intervention (SI) (試験薬の調剤/交付)	SI,CRC,(P)		
10. Other*		23. Perform SI accountability(試験薬の管理)	SI,CRC,(P)		
11. Other*		24. Administer SI (試験薬投与)	SI		
12. Other*		25. Obtain/Conduct Informed Consent (同意説明の実施と取得)	SI		
13. Other*		26. Support obtain informed consent (同意説明の補助)	CRC		

***Other tasks may be those that are study specific or are local regulatory requirements and have been identified by the Study Sponsor.**

(Other には、試験固有のもの、現地規制要件や依頼者規程のものを記載可能とする)

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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.) (バイタル測定, 身体測定), Patient care (患者ケア), Drug administration (投薬),Care in the medical treatment(療養上の世話), Assist in medical care(診療の補助), Disease guidance(患者指導)
Pharmacist(薬剤部)	Prescription (薬品の調剤),Drug storage and management (薬剤保管管理)
Medical technologist (中央検査部)	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.) (生理機能検査(心電図,呼吸機能, 脳波,超音波,等))
Pathologist (病院病理部)	Pathological diagnosis (病理診断), Pathology specimen manufacture (病理標本作成)
Radiologic Technologist (中央放射線部)	Image inspection (X-ray, CT, MRI, scintigraphy ,PET,etc.) (画像検査(X 線, CT, MRI,骨シンチ,PET,等)), Diagnostic imaging(画像診断),Radiation therapy(放射線治療)
Doctor (医師)	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	Inspection material management / sending(検体資材管理/送付), Make documents / management(書類作成/管理)

****The study collaborators specific to the project are listed only in SSDL and not in Form 2.** (試験特有の治験協力者については、書式2に記載していない)
***** If delegation is required, only the person responsible for each department is listed on the SSDL.** (Delegate が必要な場合は、各部署の責任者のみを記載する)

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Country/Site Name:	Japan/Kawasaki Medical School Hospital	**Study Site Number:**	
Protocol Study Number:			

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 start date** (dd/mmm/yyyy)	**End of task(s)** (dd/mmm/yyyy)	**PI initials and date** (dd/mmm/yyyy)
[ ]	(日本語) (英語)		[ ]	[ ]	[ ]		
[ ]	(日本語) (英語)		[ ]	[ ]	[ ]		
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[ ]	(日本語) (英語)		[ ]	[ ]	[ ]		

INVESTIGATOR SITE COMMENTS (optional): *(all Comments must be signed and dated)*

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