

<b>Study Sponsor:</b>		<b>Principal Investigator:</b>	
<b>Protocol Study Number:</b>		<b>Study Site Number:</b>	
<b>Country:</b>			

**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 (TransCelerate)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、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、当院で実施された全ての業務に責任

を負う。そのため、PI は示されたセクションを完了しますが本様式の特定の業務を委任されません。)

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のトレーニングを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. (実施施設は、依頼者要件に従い本様式を最新の状態にする必要がある。)

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。)

**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	Date (dd/mmm/yyyy)

\*My signature confirms/acknowledges that the information contained here is accurate and that (私の署名は、ここに含まれる情報が正確であること、および次のことを確認/承認するものである。):

- I will remain responsible for the overall study conduct and reported data. (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. (確実に試験を監督する。)
- 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.** (試験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、適切なトレーニング完了前に委任された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業務のための適切な情報入手とトレーニング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.

<b>Name of Principal Investigator:</b>	<b>Signature:</b>	<b>Date:</b>
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## STUDY TASKS:

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。)

<i>Medically Qualified/Trained/Licensed Staff (分担医師)</i>	<i>Pharmacist (薬剤師), Medically Qualified/Trained/Licensed Staff (分担医師)</i>	<i>Trained/Qualified Staff (トレーニングを受けたスタッフ)</i>
1. Obtain/Conduct Informed Consent (同意取得)	14. Manage SI receipt/storage/temperature monitor (試験薬の受領、保管、温度管理)	18. Support for Informed Consent (同意補助説明)
2. Discuss medical content of Informed Consent (IC に伴う医学的内容の説明・協議)	15. Prepare Study Intervention (SI) (試験薬の準備)	19. Recruit study subjects (被験者のリクルート)
3. Determine eligibility criteria (inclusion/exclusion) (適格性確認)	16. Dispense Study Intervention (SI) (試験薬の払い出し)	20. Obtain medical/medication history (既往歴/合併症、併用薬の確認)
4. Perform Physical Exam (身体検査、診察)	17. Perform Study Intervention (SI) accountability (試験薬管理表の記録)	21. Collect/process biological samples (検体の採取/処理)
5. Make study-related medical decisions (試験に関連した医学的判断)		22. Ship biological samples (検体の発送)
6. Evaluate study related test results (試験に関連した検査結果の評価)		23. Use IWRS/IVRS/IRT (IWRS/IVRS/IRT の使用)
7. Assess AE/SAE causality (有害事象/SAE の因果関係評価)		24. Make (e)CRF entries, corrections and queries (EDC 入力/修正/クエリ回答)
8. Assess Safety notifications (安全性情報の評価)		25. Submission and query resolution of study data (imaging, Lab data, ECG, PRO etc.) (データの提供 とクエリ対応 (画像、検査データ、ECG、PRO など))
9. Unblind/Unmask (盲検解除)		26. Report SAEs (SAE 報告)
10. Sign off on (e)CRF visit data (症例報告書への署名)		27. Manage IRB/EC communications & submissions (IRB 提出文書の管理)
11. Other		28. Maintain essential documents (必須文書/責任医師文書の管理)
12. Other		29. Administer Study Intervention (SI) (試験薬の投与)
13. Other		30. Other
		31. Other
		32. Other

Nurse (看護師/看護部)	Collect biological samples (検体採取), Measurement of vital signs, height weight, etc. (バイタル測定, 身体測定など), Administer medicine (薬の投与), Physiological function examination (electrocardiogram, etc.) (生理機能検査 (心電図など))
Medical technologist (検査技師/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, 超音波など))
Pathologist (病理部)	Pathological diagnosis (病理診断), Pathology specimen manufacture (病理標本作成)
Radiologic Technologist (放射線部)	Image inspection (X-ray, CT, MRI, scintigraphy, etc.) (画像検査 (X線, CT, MRI, 骨シンチなど)), Radiotherapy (放射線治療), Diagnostic imaging (画像診断)
Pharmacist (except delegated) (薬剤師/薬剤部)	Manage medicine * receipt/storage/temperature monitor (薬剤の受領、保管、温度管理), Prepare/Dispense medicine * (薬剤の準備/払い出し), Perform medicine * accountability (管理表の記録)  * exclude medicine provided by sponsor (Study Intervention, Pre-medication, Other concomitant medication, etc.) (依頼者提供品以外の薬剤 (試験薬、前投薬、その他の併用薬など))

Complete upon assignment of site staff (スタッフの任命後に完了する)						Complete when staff exit during the study (試験途中で業務を終了した場合)	
Name	Signature My signature below indicates that I accept the study task. (私の署名は試験業務を受諾することを意味する。)	Initials	Study Role (役割)	Study Task(s) (Select from key) (試験業務)	PI initials and date (dd/mmm/yyyy)	End of task(s) (dd/mmm/yyyy)	PI initials and date (dd/mmm/yyyy)
治験 花子 Hanako Chiken	治験 花子 <i>Hanako Chiken</i>	HC	Study Coordinator	18-26	TC 31/MAY/2017	30/JUN /2018	TC 30/JUN/2018
			Sub Investigator	1-8, 19-21, 26, 29			
			Study Coordinator	18-26			
			Study Coordinator/ pharmacist	14-26			
			pharmacist	14-17			

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


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)

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


Complete upon assignment of site staff						Complete when staff exit during the study	
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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*
