

Delegation Log



Study Sponsor:	<i>insert sponsor's name</i>	Qualified Investigator:	<i>insert QI's name</i>
Study Name:	<i>insert study name</i>		
Primary Site	<i>insert healthcare institution name</i>	Country:	<i>insert country</i>
Protocol Study Number:	<i>insert number</i>	Study Site Number:	<i>insert number</i>

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 QUALIFIED INVESTIGATOR IS RESPONSIBLE FOR ALL TASKS CONDUCTED AT THE STUDY SITE. THE QI COMPLETES THE SECTIONS INDICATED BUT THE QI IS NOT DELEGATED SPECIFIC TASKS IN THE TASK SECTION OF THE LOG.

THE QUALIFIED INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL.

THE STUDY SITE IS REQUIRED TO MAINTAIN AN UP TO DATE VERSION OF THIS FORM IN ACCORDANCE WITH SPONSOR REQUIREMENTS.

START OF STUDY DECLARATION: (to be completed at the start of the study)

Name of Qualified Investigator	Qualified Investigator's Signature*	Qualified Investigator's Initials	Date (dd/mmm/yyyy)

*My signature confirms/acknowledges that the information contained here is accurate and that:

- I will remain responsible for the overall study conduct and reported data.
- I will ensure study oversight.
- I will authorize the delegation of study-related tasks to each individual as listed.
- The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
- 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.
- I will ensure that site staff receives, in a timely manner, the appropriate information and training for delegated tasks.
- I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.

END OF STUDY DECLARATION: I confirm that the information contained in this document is accurate and complete.

Name of Qualified Investigator:	Signature:	Date:
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SPONSOR COMMENTS (optional):

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Medically Qualified/Trained/Licensed Staff	Trained/Qualified Staff	Trained/Qualified Staff Continued
1. Determine eligibility criteria (inclusion/exclusion)	14. Manage IRB/EC communications & submissions	28. Report SAEs
2. Perform Physical Exam	15. Maintain essential documents	29. Other
3. Make study-related medical decisions	16. Collect/process biological samples	30. Other
4. Evaluate study related test results	17. Ship biological samples	31. Other
5. Assess AE/SAE causality	18. Make (e)CRF entries, corrections and queries	32. Other
6. Assess Safety notifications	19. Recruit study subjects	
7. Sign off on (e)CRF visit data	20. Use IWRS/IVRS/IRT	
8. Unblind/Unmask	21. Manage SI receipt/storage/temperature monitor	
9. Discuss medical content of Informed Consent	22. Prepare/Dispense Study Intervention (SI)	
10. Other	23. Perform SI accountability	
11. Other	24. Administer SI	
12. Other	25. Obtain/Conduct Informed Consent	
13. Other	26. Obtain medical/medication history	
	27. Perform study activities	

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Complete upon assignment of site staff					Complete when staff exit during the study		
Name	Signature <small>My signature below indicates that I accept the study task.</small>	Initials	Study Role	Study Task(s) <small>(Select from key)</small>	QI initials and date <small>(dd/mmm/yyyy)</small>	End of task(s) <small>(dd/mmm/yyyy)</small>	QI initials and date <small>(dd/mmm/yyyy)</small>
Example: <i>Katarina Koordinator</i>	<i>Katarina Koordinator</i>	<i>KMK</i>	Study Coordinator	17, 18, 20	<i>QI</i> <i>31/MAY/2017</i>	30/JUN/2018	<i>QI</i> <i>30/JUN/2018</i>

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

Delegation Log - insert satellite site name

Study Sponsor:	<i>insert sponsor's name</i>	Qualified Investigator:	<i>insert QI's name</i>
Protocol Study Number:	<i>insert number</i>	Primary Site Name:	<i>insert healthcare institution name</i>
Study Name:	<i>insert study name</i>		
Satellite Site Name:	<i>insert healthcare institution name</i>	Satellite Site ID:	<i>insert satellite site identifier</i>

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)	QI initials and date (dd/mmm/yyyy)	End of task(s) (dd/mmm/yyyy)	QI initials and date (dd/mmm/yyyy)

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

Delegation Log - insert satellite site name

Study Sponsor:	<i>insert sponsor's name</i>	Qualified Investigator:	<i>insert QI's name</i>
Protocol Study Number:	<i>insert number</i>	Primary Site Name:	<i>insert healthcare institution name</i>
Study Name:	<i>insert study name</i>		
Satellite Site Name:	<i>insert healthcare institution name</i>	Satellite Site ID:	<i>insert satellite site identifier</i>

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)	QI initials and date (dd/mmm/yyyy)	End of task(s) (dd/mmm/yyyy)	QI initials and date (dd/mmm/yyyy)

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