Study Site Duty Delegation Log

PLEASE REFER TO THE GUIDANCE DOCUMENT FOR DETAILED INSTRUCTIONS ON THE COMPLETION OF THIS FORM.

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 PRINCIPAL INVESTIGATOR MUST ENSURE PERSONNEL DO NOT START DELEGATED STUDY-RELATED TASKS UNTIL CONFIRMING THAT THEY HAVE COMPLETED STUDY RELATED TRAINING APPROPRIATE TO THE ROLE AND TASK.

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

My signature below 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 site staff receives, in a timely manner, the appropriate information and training for delegated tasks.
- 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 any and all changes in staff or delegated study-related task will be recorded in a timely manner.

Name of Principal Investigator	Principal Investigator's Signature	Principal Investigator's Initials	Start (dd/mmm/yy)	End (dd/mmm/yy)
JERZY BIAŁECKI	Jerzy Białecki	JB	11.06.21	

CHANGE IN PI INSTRUCTIONS: 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. Please see the guidance document for additional instructions

Study Site Duty Delegation Log

Protocol ID:	H-34	**Principal Investigator:**	Dr Jerzy Białecki
Protocol short title:	Delta Revision CUP	**Study site ID:**	01
Study site name:	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	**Country:**	Poland

Full Name	Signature	Initials	Study Role	Task(s) (Use Task Codes Below)	Dates of Work on Study (DD-MMM-YYYY)	Investigator Initials & Date (DD-MMM-YYYY)
JULIA MACIAS		JM	si	1-17 11.06.2021 r.	Start: 11.June.21	Start: J.B 11.June.21
					End:	End:
PAWEŁ BARTOSZ		PB	Si	1-17	Start: 11.June.21	Start: J.B 11.June.21
					End:	End:
					Start:	Start:
					End:	End:
					Start:	Start:
					End:	End:
					Start:	Start:

Study Role Key:
Sub-Investigator Nurse Radiologist Study Coordinator Data Manager Other: _____ Other: _____ Other: _____ Other: _____

Study Task Key:
Study personnel, whose signatures and initials appear above, are authorized to perform the following study tasks indicated by the codes below as authorized by the Principal Investigator.

1. Manage IRB/EC communications & submissions
2. Maintain essential documents/Investigator Site File
3. Receive/access safety notifications
4. Obtain informed consent
5. Perform physical exam
6. Obtain medical/medication history
7. Confirm eligibility criteria (inclusion/exclusion)
8. Evaluate study related test results
9. Make study related medical decisions
10. Assess the radiological data and reports (CT-scan, X-ray, MRI, etc.)
11. Performs the implant of the device
12. Assess AE/SAE causality
13. Report SAEs
14. Make (e)CRF entries, corrections and queries
15. Sign off on (e)CRF visit data
16. Perform study related test (eg. collects Patient Reported Outcomes)
17. Perform basic assessments (eg. vital signs, weight)
18. Manage device receipt, storage, & accountability
19. Collect/process/ship biological sample
20. Other * _____
21. Other * _____
22. Other * _____
23. Other * _____
24. Other * _____