DELEGATION OF DUTIES LOG

CLINICAL TRIAL CARE
PARKVILLE CANCER CLINICAL TRIALS UNIT

Protocol Number:		**Sponsor Name:**	
Principal Investigator Name:		**Site Number:**	
Primary Site Name:		**Teletrial (TT) Satellite Site Name:**	

Principal Investigator (PI) Declaration:

I confirm the tasks listed below will only be delegated to appropriately trained, skilled and qualified staff. I have overall responsibility and oversight of clinical trial conduct and reported data. All associates, colleagues, and employees assisting in the conduct of the clinical trial are informed about their obligations, and have not performed any clinical trial tasks prior to appropriate delegation and completion of appropriate training. By signing, I confirm the start and end date fields represent the start and end date of delegation of tasks as part of the clinical trial.

Name	PI Signature	Initials	PI Tasks	Start (dd/mmm/yyyy)	End (dd/mmm/yyyy)
			1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 13, 14		

Task Key:

1. eCRF Sign-off (PI/Acting PI task only)
2. Informed consent medical discussion
3. Obtain informed consent
4. Determine clinical trial participant eligibility
5. Obtain medical history
6. Perform physical exam
7. Make clinical trial related medical decisions
8. Evaluate clinical trial related test results (including disease/response assessment)
9. Assess, assign causality and sign-off of AEs/SAEs
10. Receive and assess safety information i.e. dear investigator letter
11. IP preparation, dispensation, accountability, receipt, storage and destruction
12. Delegate pharmacy staff to pharmacy delegation log
13. IP administration oversight
14. Use IWRS/IVRS
15. Informed consent RN/SC discussion
16. Sample processing
17. Sample shipping
18. Make entries/corrections in eCRFs
19. Perform clinical trial procedures, as relevant to role (i.e. vital signs, ECGs, diary/QoL oversight)
20. Maintain essential documents
21. Medical imaging upload
22. Other: _____
23. Other: _____
24. Other: _____
25. Other: _____
26. Other: _____

Role Key:

API	Acting Principal Investigator	CTA	Clinical Trials Assistant	LS	PCCTU Laboratory Staff	LSI	TT Local Site Investigator	PH	Pharmacist
RN	Research Nurse	SC	Study Coordinator	SI	Sub-Investigator		Other: _____		Other: _____

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Name	Role (P.1)	Signature	Initials	Task(s) (See Key on P.1)	Start (dd/mmm/yyyy)	PI Signature	End (dd/mmm/yyyy)	PI Signature
						Date: _____		Date: _____
						Date: _____		Date: _____
						Date: _____		Date: _____
						Date: _____		Date: _____
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						Date: _____		Date: _____
						Date: _____		Date: _____
						Date: _____		Date: _____
						Date: _____		Date: _____

Principal Investigator End of Study Declaration

I hereby confirm that the above information is accurate and complete, and that I authorised the delegation of clinical trial related tasks to each individual as listed above. By signing the below declaration, I confirm that all staff involvement has ceased as indicated by end date.

Principal Investigator Signature: _____ **Date:** _____

The original Site Signature and Delegation Log will be kept at site for the duration of the clinical trial and archived with the Investigator Site Files at the completion of the study. A certified copy will be presented to the sponsor upon request.