Parkinson's Progression Markers Initiative

PPMI Operations Manual-Summary of Changes

Version 10.0_24Feb2026

Section #	Section Title	Description of Change
Throughout	Where Applicable	Updated language from Delegation of Responsibilities to Delegation of Authority.
1.0	Study Personnel	• Added statement that after initial site selection, any primary site investigator changes must be approved by the Steering Committee. • Clarified the process for completing the Delegation of Authorities Form within Florence. Noted that each site must have a minimum of one imaging lead for SPECT and one for MRI on the DOA log
4.0	Imaging	• Updated terminology from "SPECT Imaging Trial Operations Manual (TOM)" to "SPECT Imaging Procedure Manual." • Added United Kingdom and Canada to Ordering DaTscan
5.0	Source Documentation	• Updated 72 hours to 3 business days • Under Assessment and Supply Ordering updated IU Screening Core to IU Biorepository.
9.0	Essential Documents	• Updated terminology from "Site XXX" to "Site ###" throughout section. • Clarified that team members refer to the most current version of the Florence Start Guide for PPMI Site Use. • Updating naming convention for DOA logs • Updated language so it is clear there is one DOA log per site not per individual • Clarified the process of creating/maintaining DOA logs
9.0	Essential Documents – Training	• Added information about filing training documents in Florence • Under CTSDMC EDC removed statement about training videos and a site training log may be found in the Study Materials section of the EDC, as well as removed a training certificate will be emailed to both the user and the SMC and be filed in Florence.

Section #	Section Title	Description of Change
		• Updated language around Florence and EDC training. • Added statement that some clinic roles do not require protocol training • Human Subject Research Training was updated to Good Clinical Practice (GCP) an Human Subject Research (HSR) Training. Clarified that all site staff working directly with humans must complete this training. • Updated file naming convention of GCP/HSR
9.0	Essential Documents – eTMF	Removed reference to IND Project Management Core
9.0	Essential Documents – Personnel-Specific Documents	• Added columns for roles Data Entry, CRC/CTU, and Lab Manager. • Updated process on how staff contact form is added to the folder (PDF vs printout) • Updated DOA steps
9.0	Essential Documents – Participant Transfer Process	• Table indicating Other added that SMC and INDD Finance will notify Greenphire Support to request a transfer.
Appendix A	List of Exclusionary Medications	Updated formatting
Appendix F	Greenphire ClinCard	Added comment about Suvoda acquiring Greenphire.
Appendix H	Screening and Baseline Visit Guidance	Updated version and date of this document