

LIST OF SOP

SOP No.	SOP Title
	I. GENERAL
A	Administrative and legislation
I-A1	SOP creation
I-A2	SOP training and education
I-A3	CTU staff education
I-A4	QA/QC
I-A5	Managed documents
I-A6	Clinical trials legislation
I-A7	Clinical trials document keeping and storage
B	Clinical Research Project Management
I-B2	CTU Personal management
I-B3	Project manager
I-B4	Start-up coordinator
I-B5	Study coordinator
I-B6	Data manager
I-B7	Clinical trials financing and payments
	II. MMCI as clinical trial site
C	Start-up phase
II-C1	Clinical trials feasibility
II-C2	Clinical trials start-up
D	Clinical trial management
II-D1	Communication and education
II-D2	Site initiation visit
II-D3	Monitoring visit
II-D4	Screening
II-D5	Randomization
II-D6	Blinding and unblinding in clinical trial
II-D7	Investigational product
II-D8	Clinical trials out-patient unit
II-D9	Clinical trials and GreyFox - Hospital Informational System
II-D10	Protocol deviations
II-D11	Delegation of activities and PI oversight
E	Patients
II-E1	Patient enrollment
II-E2	Informed Consent Process
II-E3	Treatment phase in clinical trials
II-E4	Subject compensations
II-E5	Adverse and Serious Adverse Events
II-E6	Biological samples
II-E7	ECG
F	Data management
II-F1	Clinical trials essential documents
II-F2	Data management and eCRF
II-F4	Clinical trial Note in GreyFox
II-F5	Source documentation
II-F6	Equipment and laboratory certification and quality control
II-F7	Evaluation of laboratory AE and SAE
G	Clinical trials close-out
II-G1	Clinical trials close-out and archiving
	III. MMCI as clinical trial sponsor
H	Essential documents
H1	Clinical trials essential documents
H2	Protocol
H3	Protocol amendment
H4	Investigator Brochure
H5	Informed Consent Form
H6	Contract
I	Clinical trials management
I1	Regulatory and Clinical trial approval
I2	IMP
I3	Pharmacovigilance
I4	Protocol deviations
I5	Reporting
I6	Final/Closing Report on Clinical Trial
I7	Archiving
J	Phase I Trials Management
J1	Organization and management of Phase I Clinical Trials
J2	Equipment of Phase I Znit
J3	Safety of Study Subjects in Phase I Clinical trials