

SOP TITLES

SOP 01/V1	Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Institutional Review Board (IRB), TMC
SOP 02/V1	Constitution of Institutional Review Board (IRB), TMC
SOP 03/V1	Management of Research Study Submissions
SOP 04a/ V1	Initial Review of Submitted Protocol
SOP 04b/ V1	Expedited Review of Submitted Protocol/Documents
SOP 04c/ V1	Exemption from the Review for Research Projects
SOP 05/V1	Agenda Preparation, Meeting Procedures and Recording of Minutes
SOP 06/V1	Review of Amended protocol/ Protocol related documents
SOP 07/V1	Continuing review of study Protocols
SOP 08/V1	Review of Protocol Deviation/Non-Compliance / Violation / Waiver
SOP 09/V1	Review of Serious Adverse Events (SAE) Reports
SOP 10/V1	Maintenance of Active Project Files, Archival / Disposal of closed files and Retrieval of documents
SOP 11/V1	Documentation of the IRB activities
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SOP 13/V1	Management of Premature Termination / Suspension /Discontinuation of the study
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