



SUGHRA SHAFI MEDICAL COMPLEX

(A Teaching Hospital)

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PHC Regular License No. 2014600223

ISO Certified: 9001: 2015

List of Standard Operating Procedures (SOPs) of Clinical Trial Site

Sr. #	Title	Document No
01	SOP on Informed Consent taking Process	SSMS-CTS-SOP-01
02	SOP for AE/SAE/SUSAR/Safety Reporting	SSMS-CTS-SOP-02
03	SOP for Reporting to the Institutional Review Board (IRB)/ Sponsor /Regulatory Bodies	SSMS-CTS-SOP-03
04	SOP of the Management/Handling/Storage of IMP	SSMS-CTS-SOP-04
05	SOP of Inventory and Calibration Maintenance	SSMS-CTS-SOP-05
06	SOP of Responsibilities of PI	SSMS-CTS-SOP-06
07	SOP of Record Keeping and Documentation (Retention, Storage and Destruction of record)	SSMS-CTS-SOP-07
08	SOP of Data Handling (prevent unauthorized access to record)	SSMS-CTS-SOP-08
09	SOP for Cold Chain Maintenance	SSMS-CTS-SOP-09
10	SOP of Temperature Monitoring	SSMS-CTS-SOP-10
11	SOP of Disposal, Return & Destruction of IMP	SSMS-CTS-SOP-11
12	SOP of Incinerator	SSMS-CTS-SOP-12
13	SOP of Randomization process	SSMS-CTS-SOP-13
14	SOP for Electronic Data Archiving (Controlled Access to Archived data)	SSMS-CTS-SOP-14
15	SOP to Prevent Disclosure of the Sponsor's Proprietary Information	SSMS-CTS-SOP-15
16	SOP for Equipment Calibration	SSMS-CTS-SOP-16
17	SOP for CAPA	SSMS-CTS-SOP-17
18	SOP for Deviation Management	SSMS-CTS-SOP-18
19	SOP for Clinical Trial Governance	SSMS-CTS-SOP-19
20	SOP for Emergency Management & Response	SSMS-CTS-SOP-20
21	SOP for Clinical Trial Protocol Management	SSMS-CTS-SOP-21
22	SOP for Staff Training & Competency Management	SSMS-CTS-SOP-22
23	SOP for Temperature Excursion management	SSMS-CTS-SOP-23
24	SOP for Audit Trail Process	SSMS-CTS-SOP-24
25	SOP for Monitoring Visit Handling	SSMS-CTS-SOP-25
26	SOP for Subject Recruitment	SSMS-CTS-SOP-26
27	SOP for Vendor Qualification	SSMS-CTS-SOP-27
28	SOP for Sample Handling, Collection, Transportation, Storage & Disposal	SSMS-CTS-SOP-28
29	SOP for Risk Assessment	SSMS-CTS-SOP-29

A Project of SAHARA For Life Trust

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