AN14-V1/KSSSCISOP 03/V1

Checklist of Documents (5copies (on email and a CD or pendrive) of all documents listed below) (Non-Interventional trial require documents listed in Item no. 1 to 11 and27)

Please give page no. to all documents (start from 1,2,3..... 40 and soon.)

****Please provide version no. and date of each document* (for drug/devicetrial*)***

Protocol Title:
Principal Investigator:
Type of document: Intramural/extramural/student project/ investigator initiated/collaborative study/drug or device trial

As per **Table 3.1, Section 3.2.3** in SOP

Item No.	Mandatory Documents (*with version and date)	Yes	No	NA	Page No.
1.	Project Submission Form (AN1-V1/KSSSCISOP 03/V1)	☐	☐	☐	
2.	Study Protocol	☐	☐	☐	
3.	Case Report Form (form to enter data)	☐	☐	☐	
4.	Consent of Head of the PI's Department (AN2-V_1/KSSSCISOP 03/V1)	☐	☐	☐	
5.	Research/Department research/Doctoral/M. D Protocol committee's approval (AN3-V1/KSSSCISOP 03/V1)	☐	☐	☐	
6.	Undertaking by the PI (AN4-V1/KSSSCISOP 03/V1)	☐	☐	☐	
7.	Conflict of Interest Statement by PI (AN5-V1/KSSSCISOP 03/V1)	☐	☐	☐	

8.	CV of new investigator or investigator outside KSSSCI or of the student (AN6-V1/KSSSCISOP 03/V1)	☐	☐	☐	
9.	Participant Information document (PID) and consent forms CF) in English and Hindi (and if required in any other language) (For participants/controls/volunteers/guardian/parents) (AN7 to 10 -V1/KSSSCISOP 03/V1)	☐	☐	☐	
10.	Child Information Document and assent form in English and Hindi (and if required in any other language) (AN11-13V1/KSSSCISOP 03/V1)	☐	☐	☐	
11.	Ethics Committee clearance of other centers	☐	☐	☐	
12.	Clinical Trials Registry- India (CTRI)	☐	☐	☐	
13.	Investigator Brochure	☐	☐	☐	
14.	Advertisement/Information brochure	☐	☐	☐	
15.	Insurance policy and certificate	☐	☐	☐	
16.	DCGI approval letter	☐	☐	☐	
17.	Director General of Foreign Trade (DGFAT) approval	☐	☐	☐	
18.	Genetic Engineering Advisory Committee (GEAC) approval	☐	☐	☐	
20.	Bhabha Atomic Research Centre (BARC) approval	☐	☐	☐	
21.	Stem cell (NAC-SCRT) registration and approval	☐	☐	☐	
22.	DCGI marketing/manufacturing license for herbal formulations/nutraceutics	☐	☐	☐	
23.	Clinical Trial Agreement (CTA)	☐	☐	☐	
24.	Material Transfer Agreement (MTA)/MOU/Health Ministry Screening Committee (HMSC) approval	☐	☐	☐	
25.	IEC processing fee (applicable for sponsored trials)	☐	☐	☐	
26.	Any other Agreements/documents	☐	☐	☐	
27.	Document Receipt Form (AN15-V1/KSSSCISOP 03/V1, induplicate)	☐	☐	☐	