

**AN15-V1/KSSSCISOP 03/V1****IEC Document Receipt Form (to be submitted in duplicate)**

<b>Type of Submission:</b>	<input type="radio"/> <b>New</b> <input type="radio"/> <b>Revised</b>
<b>Protocol Title:</b>	
<b>Principal Investigator:</b>	
<b>Type of document:</b> Intramural project/extramural/student project/investigator initiated/collaborative study/drug or device trial	

**Checklist to assess the projects before they are submitted to IEC for review**

<b>Item No.</b>	<b>Mandatory Documents (*with version and date)</b>	<b>Yes</b>	<b>No</b>	<b>NA</b>	<b>Page No.</b>
1.	Project Submission Form (AN1-V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2.	Study Protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.	Case Report Form (form to enter data)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.	Consent of Head of the PI's Department (AN2-V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.	Research/Department research/Doctoral/M. D Protocol committee's approval (AN3-V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.	Undertaking by the PI (AN4-V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7.	Conflict of Interest Statement by PI (AN5-V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.	CV of investigator outside KSSSCI or of the student (AN6-V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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) (AN7to 10 -V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10.	Child Information Document and assent form in English and Hindi (and if required in any other language)  (AN11-13V1/KSSSCISOP 03/V1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11.	Ethics Committee clearance of other centers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12.	Clinical Trials Registry- India (CTRI)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13.	Investigator Brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14.	Advertisement/Information brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15.	Insurance policy and certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16.	DCGI approval letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17.	Director General of Foreign Trade (DGFAT) approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18.	Genetic Engineering Advisory Committee (GEAC) approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20.	Bhabha Atomic Research Centre (BARC) approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21.	Stem cell (NAC-SCRT) registration and approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22.	DCGI marketing/manufacturing license for herbal formulations/nutraceuticals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23.	Clinical Trial Agreement (CTA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24.	Material Transfer Agreement (MTA)/MOU/Health Ministry Screening Committee (HMSC) approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25.	IEC processing fee (applicable for sponsored trials)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
26.	Any other Agreements/documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

27.	Document Receipt Form (AN15-V1/KSSSCISOP 03/V1, in duplicate)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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**Note:** Please provide version no. and date of each document (for drug/device trial)

<p><b>Documents submitted:</b></p> <p>( ) Complete</p> <p>( ) Incomplete; will submit on.....</p>
<p><b>Comments:</b></p>   
<p><b>Receiver Name, Sign &amp; Date:</b> _____</p> <p><b>(IEC Secretariat)</b></p>   <p><b>Project submitted by Name &amp; sign:</b> _____</p> <p><b>(Project or study team member)</b></p>