

ANNEXURE-1**CHECKLIST FOR SUBMISSION OF APPLICATIONS FOR REGISTRATION OF ETHICS COMMITTEE**

S.No	Documents required to be submitted	Status		Page No.
		Y	N	
1.	Application for registration in accordance with the requirements as specified in Appendix VIII of Schedule Y			
2.	a) Name of the Ethics Committee			
	b) Address of the office of the Ethics Committee.			
3.	Authority under which the EC has been constituted			
4.	Name, address, qualification, organizational title, telephone number, fax number, e-mail, mailing address and brief profile of the Chairman			
5.	Names, qualifications, organizational title, telephone number, fax number, e-mail and mailing address of the members of the Ethics Committee. The information shall also include member's specialty (primary, scientific or non-scientific), member's affiliation with institutions and patient group representation, if any.			
6.	Membership requirements of the EC			
7.	The terms of reference of the committee			
8.	Documents, if any, proving that the members of the committee are conversant with the provisions of clinical trials as per the provisions of D&C Rules and CDSCO-GCP Guidelines for clinical trials in India.			
9.	Conditions of appointment and the quorum required.			
10.	Procedure for resignation, replacement or removal of members.			
11.	Details of the supporting staff.			
12.	In the case of Ethics Committee existing before 08.02.2013, following should be submitted-			
	a) Types of clinical research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological, retrospective, herbals etc.).			
	b) Documents reviewed for every clinical trial protocol including Informed Consent documents.			
	c) Information in respect of number of meetings of the committee and documentation of the minutes of meetings of these committees concerning clinical trials.			
	d) Information regarding review of SAE reported during the conduct of the trial.			
13.	The SOP to be followed by the committee in general.			
14.	SOP to be followed by the committee for vulnerable population			
15.	Policy regarding training for new and existing committee members along with standard operating procedures.			
16.	Policy to monitor or prevent the conflict of interest along with SOP			
17.	If the committee has been audited or inspected before, give details.			
18.	Undertaking by the committee			