SYSTEM FOR THE PRE-SCREENING OF THE APPLICATIONS FOR REGISTRATION OF ETHICS COMMITTEE

Regulations for conducting clinical trials in the country are prescribed under Rule 122DA, 122DAA, 122DAB, 122DAC, 122DD,122E and Schedule Y to the Drugs & Cosmetics Rules, 1945.

The Drugs & Cosmetics Rules have been amended vide **GSR no. 72 (E)** dated 08-02-2013 inserting a Rule 122DD, in Schedule 'Y' along with other amendments. The amendment specifies the detail procedures for the registration of Ethics Committee.

As per Rule 122DD, No Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with DCG(I). An application for registration of Ethics Committee shall be made to the DCG(I) in accordance with the requirements as specified in the Appendix VIII of Schedule Y.

In order to streamline the submission of application for registration of Ethics Committee and their examination as per Rule 122DD, it has been decided to introduce a system of preliminary scrutiny of such applications at the time of their receipt, to determine their acceptability for examination by CDSCO.

The preliminary scrutiny of the applications will be done by CDSCO officer(s) based on laid down checklist which is attached herewith. During the preliminary examination, the CDSCO officer(s) will scrutinize the application to ensure that it contains all the required administrative as well as technical information in proper manner as per the checklist. If the applications are not submitted in accordance with the format and the checklist, it will not be accepted by CDSCO for further examination.

Once an application is accepted, the information in the application will be reviewed by CDSCO as per the specified procedures.

I. The Ethics Committee is requested to prepare the application for submission to CDSCO as per appendix-VIII of Schedule-Y of D&C Rules and the **checklist alongwith undertaking by the committee as per the format enclosed.**

II. The application must be submitted with indexing and page number. Without indexing or page number, no application will be accepted.

III. Clear and unequivocal information should be provided in the application.

IV. Text and tables should be prepared using margins that allow the document to be printed clearly without losing any information and the left-hand margin should be sufficiently large so that information is not obscured by the method of binding. The documents printed on both sides of a page, can be submitted provided, however, one should take care that the information is not obscured when the page is placed in a binder.

V. While submitting reply to a query, the applicant should always enclose with the reply, a copy of query letter issued by CDSCO.

VI. All items mentioned in the checklist may not be applicable. The items not relevant to a particular application should be marked with "Not Applicable (NA)".

This system of preliminary scrutiny to determine the acceptability of the application for registration of ethics committee will come into effect from **25.02.2013**

CHECKLIST FOR SUBMISSION OF APPLICATIONS FOR REGISTRATION OF ETHICS COMMITTEE

#	Documents required to be submitted	Status		Page No.
		Yes	No	
1.	Application for registration in accordance with the requirements as specified in Appendix VIII of Schedule Y			
2.	Name of the Ethics Committee			
3.	Authority under which the Ethics Committee has been constituted			
4.	Membership requirements of the Ethics Committee			
5.	The terms of reference of the committee			
6.	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 Good Clinical Practice Guidelines for clinical trials in India.			
7.	Conditions of appointment and the quorum required.			
8.	Procedure for resignation, replacement or removal of members.			
9.	Address of the office of the Ethics Committee.			
10.	Name, address, qualification, organizational title, telephone number, fax number, e-mail, mailing address and brief profile of the Chairman.			
11.	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.			
12.	Details of the supporting staff.			
13.	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 serious adverse events reported during the conduct of the trial.			
14.	The standard operating procedures to be followed by the committee in general.			
15.	Standard operating procedures to be followed by the committee for vulnerable population.			
16.	Policy regarding training for new and existing committee members along with standard operating procedures.			
17.	Policy to monitor or prevent the conflict of interest along with standard operating procedures.			
18.	If the committee has been audited or inspected before, give details.			
19.	Undertaking by the committee as per the format Annexed.			

ANNEXURE

UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairman

2. Name and address of the office of Ethics Committee

3. Names, address, qualifications & designation of the other members of the Ethics Committee.

4. Commitments:
   (i) The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well- being of the trial subjects.

   (ii) In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Committee shall analyse and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.

   (iii) The Committee shall allow inspectors or officials authorised by the Central Drugs Standard Control Organisation to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.

   (iv) We agree to maintain adequate and accurate records after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

(Signature of the Chairman) **(Signature of the Member secretary)**

Date: