Re-Registration of Ethics Committee

Amendments to Drugs and Cosmetics Rules were published vide G.S.R. dated 08.02.2013 specifying the requirements and guidelines for registration of Ethics Committee and re-registration under Rule 122DD to the Drugs and Cosmetics Rules 1945.

CDSCO has since registered several Ethics Committees.

The registration of Ethics Committees is valid for a period of three years. The re-registration applications need to be made within 3 months before the expiry of registration. Registration remains deemed continued unless otherwise orders are passed or until the registration is Suspended or Cancelled.

Accordingly applicants shall apply to CDSCO for re-registration as per check list annexed.

If there is no change in address, composition etc. only such undertaking along with details of performance of Ethics Committee with respect to its review and monitoring function needs to be provided.

Procedure is kept quite simple to facilitate re-registration. Check-list along with simple covering letter and necessary documents shall be submitted.

It is requested to submit documents with pagination (Page Numbering), in clear and legible language, ensuring sufficient margins space for easy handling, evaluation, storage and retrieval.

CHECKLIST FOR SUBMISSION OF APPLICATIONS FOR RE-REGISTRATION OF ETHICS COMMITTEE

Sr. No.	Documents required to be submitted	Submission Status		Page No
		Yes	No.	
1.	**Application for Re-registration of the Ethics Committee**			
2.	**Name of the Ethics Committee**			
3.	**Address of the Ethics Committee**			
4.	**Authority under which the Ethics Committee has been constituted for re-registration of the Ethics committee.** (Submit authority letter from appropriate authority of the institute)			
5.	**Documents providing evidence that all members of the committee are conversant with the provisions of clinical trials as per the provisions of D & C Rules and GCP Guidelines. You may submit training record or certificate.**			
6.	**In case of clinical trials of new drugs to be approved by Ethics Committee and Licencing Authority under Drugs and Cosmetics Rules, 1945 , for safeguarding the safety , well-being and rights of the trial participants , whether the Ethics Committee , while approving protocol and subsequent monitoring of clinical trials , examine and ensures :-** a) the appropriateness of investigator including his/her qualification and experience for conduct of Clinical Trial-? b) the appropriateness of Clinical Trial site for conduct of clinical trial including the facilities available. c) that the effective compensation mechanism is provided? d) that the due analysis/ causality Assessment of serious adverse event's (SAE's) and payment of compensation and medical management is done? e) that the informed consent is designed and administered properly as per rules? f) that the monitoring of Ethics Committees own conduct, functioning and records is done to fulfil the objective and responsibilities of Ethics Committee and also to ensure timely disposal of cases?			
7.	**Detailed report of functioning of the Ethics Committee** a) Titles of Clinical Trial protocols reviewed under Drugs and Cosmetics Rules along with brief summary (Protocol title: whether part of global trial, NCE/non-NCE trial). b) Details of SAE reviewed as per & under Drugs & Cosmetics Rules {along with protocol no , protocol title, SAE (death/other than death), result of review (related/non-related), further action with respect to compensation/medical management , if any}. c) List of trial sites and investigators approved for conduct of trials.			
8.	**Information regarding any changes in composition/ members of the Ethics Committee, if any.**			
9.	**Information regarding any change in location/address of the Ethics Committee. If yes, provide the date of change in address, other than the already approved address.**			
10.	**If the committee has been audited or inspected by any regulatory authorities, give details**			
11.	**Methods used by Ethics Committee for monitoring the clinical trials, with brief description.**			
12.	**Undertaking by the committee as per the format Annexed.**			

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.***

Sr. No.	Name	Qualification with Specialization	Current Organization	Telephonenumber,fax number,e-mail I.D. andmailingaddress	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
					Chairman	
					Member Secretary	
					Basic Medical Scientist	
					Clinician	
					Legal Expert	
					Social Scientist	
					Lay Person	

* Indicate if there is any change in address & com position of the Ethics Committee.

* If yes, provide the complete details i.e. new address and date of change & qualification, experience, and training of the new members as per the requirement of Drugs & Cosmetics Rules.

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: **Date:**