30.06.2009

CLINICAL RESEARCH ORGANISATION - REGISTRATION

The proposed draft rules for Registration of Clinical Research Organisation are being published for the information of all persons likely to be affected thereby for comments, if any. These guidelines have been approved by DTAB for placing it on website for information of the public and comments.

Any Person interest in making any objection or suggestion on the proposed draft rules may do so in writing for consideration of the CDSCO within a period of 45 days from the date of its uploading through post to the Drugs Control General (India), CDSCO, FDA Bhavan, Kotla Road, New Delhi – 110002.

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PROPOSED AMENDMENTS TO THE DRUGS & COSMETICS RULES, 1945 FOR REGISTRATION OF CLINICAL RESEARCH ORGANISATION

Rule 122 DAB. – Registration of clinical research organisation for conducting clinical trials.

(1) The clinical research organisation, contracted in writing by the sponsor to carry out any or all obligations transferred to it by the sponsor, shall perform such functions only, if it is duly registered, under the rules, by the Licensing Authority defined in Clause (b) of Rule 21.

(2) An application for registration of clinical research organisation shall be made to the said authority accompanied by the information as required under Schedule Y-1.

(3) If the licensing authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules have been complied with and the conditions of registration will be observed, he may grant registration subject to the conditions stated there in.

(4) A registration, unless it is sooner suspended or cancelled, shall be valid for a period of five years from the date of issue.

(5) If the licensing authority is not satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and the conditions which must be satisfied before the registration can be granted.

(6) If the clinical research organisation fails to comply with any of the conditions of registration, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel it for such period as deemed fit.

(7) The clinical research organisation, whose license has been suspended or cancelled by the licensing authority, may within ninety days of the receipt of the copy of the order by him prefer an appeal to the Central Government and the Central Government may after giving an opportunity of being heard, confirm, reverse or modify such order.

Explanation **–** For the purpose of this part a clinical research organisation is an individual or a company or an organisation contracted by the sponsor or a part of the company sponsoring clinical trial, that takes the responsibility under a legal contract for the management, documentation, co-ordination and one or more trial related duties or functions assigned to it.

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Schedule Y-1

(See Rules 122 DA, 122 DAA, 122 DAB)

Requirements and Guidelines for registration of clinical research organisations

1. Scope

These guidelines cover all organisations, individuals, institutions and companies that takes the responsibility of the initiation or management or co-ordination of a clinical trial. It does not include clinical trial sites. An individual who both initiates and actually conducts , alone or with other associates, a clinical investigation and under whose immediate directions the test article is administered or dispensed or used involving a subject would be exempt.

These guidelines are not stand alone guidelines and are not in derogation of any other rules or guidelines applicable to the clinical trials e.g. Schedule Y of the rules, Indian GCP guidelines and Ethical Guidelines for Bio-Medical Research on human subjects by ICMR or any other similar guidelines applicable to the clinical trial.

2. Criteria for Registration

(i) The Clinical Research Organisation shall be under the charge of a person who is responsible for the overall activities of the organisation. He shall be thoroughly familiar with the investigational product(s), the protocol, written informed consent forms or other information provided to the subjects, the standard operative procedures by the sponsors, GCP guidelines and other rules applicable to the conduct of clinical trials.

(ii) The organisation shall have adequate resources, qualified and trained staff for oversight of clinical trials. The staff members are required to be trained regularly to update their skills.

(iii) The trial related duties and functions transferred to and assumed by the Clinical Research Organisation shall be specified in writing and properly quantified.

(iv) The organisation shall ensure that the trials are adequately monitored and the trial related responsibilities transferred to it, partially or fully, by the sponsor are discharged effectively and efficiently.

(v) The organisation shall implement quality assurance and quality control as per standard operative procedures designed for the purpose. Such SOPs shall be well documented.

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(vi) The organisation should check the accuracy and completeness of the data/documents and other related records and ensure that the investigator(s) have maintained the essential documents required for the conduct of the trial.

(vii) The organisation shall ensure that the investigator(s) received all documents and trial related supplies needed to conduct the trial properly.

(viii) The organisation shall have education programmes to help its investigators to carry out the research studies as per guidelines applicable to such trials. Training will include protocol adherence, seeking a free and fair informed consent and responding to concerns of research participants during the study.

3. Record Keeping

All records (written documents, electronic, magnetic or optical records, scans, etc.) such as protocols, approvals from the CDSCO & ethics committee, investigator(s) particulars, consent forms, monitor reports, audit certificates, relevant letters, reference ranges, completed and the final reports, shall be maintained. All documentation and communication are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures.

4. Information required for registration

(i) Name and address of the organisation to be registered along with its telephone no., fax no., e-mail address.

(ii) Name and address of the proprietors/partners/directors.

(iii) Status of the organisation as legal entity.

(iv) A brief profile of the specific activities/services undertaken by the organisation including facilities, resources and infrastructure.

(v) An organogram of the organisation including brief CVs of key personal.

(vi) List of SOPs with salient highlights about specific areas to be scrutinised.

(vii) Copy of the contract between the sponsor and the organisation.

(viii) An undertaking to declare that

(a) We shall comply with the conditions imposed on the registration certificate along with the adherence to other guidelines like GCP guidelines and provisions of the Drugs and Cosmetics rules, 1945.

(b) We shall comply with such further requirements, if any, as may be specified by the Government of India, under the Act and the rules, made thereunder.

(c) We shall allow the licensing authority and/or any person authorised by him in that behalf to enter and inspect the premises and to examine the process/procedure and documents in respect of any clinical trial conducted by us for which the registration certificate has been made.

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