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The Central Drugs Standard Control Organisation(CDSCO) under Directorate General of Health Services,Ministry of Health & Family Welfare,Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices,four sub zonal offices,thirteen Port offices and seven laboratories spread across the country. The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well being of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera. All clinical research needs approval from an Ethics Committee (EC). In India, trials/studies can be divided into two broad categories depending on whether a permission to conduct the trial is required from the Central Licensing Authority of India (CLA) i.e. the Drugs Controller General of India (DCGI), Central Drug Standard Control Organization (CDSCO): Regulatory clinical trials: Trials that require regulatory approval from CDSCO Biomedical and Health Research (including Academic clinical trials): Trials that do not require regulatory approval from CDSCO The rules/requirements governing the approving EC are different and the table below provides further information ECs reviewing clinical trial applications that require a regulatory approval from CDSCO Applicable Rules from the New Drugs and Clinical Trial Rules, 2019 – Chapter III (pages 150 – 153) Rule 6: Requirement of the EC Rule 7: Constitution of EC for clinical trial Rule 8: Registration of EC relating to clinical trial, Bioavailability (BA) and Bioequivalence (BE) study Rule 9: Validity period of registration of EC for clinical trial Rule 10: Renewal of registration of EC for clinical trial Rule 11: Functions of EC Rule 12: Proceedings of EC for clinical trial Rule 13: Maintenance of records by EC for clinical trial Rule 14: Suspension or cancellation of registration of EC for clinical trial Registration with CDSCO Via Form CT-01 (Eighth Schedule – page 236) Documents as per Table 1 of the Third Schedule (page 212) Application via SUGAM portal (more information is available on CDSCO's webpage for EC). Renewal of registration with CDSCO Via Form CT-01 (Eighth Schedule – page 236) Documents as per Table 1 of the Third Schedule (page 212) Ninety days prior to the date of expiry of the registration Grant of registration Via Form CT-02 (Eighth Schedule – page 236) Proposed timeline for processing an application for registration – 45 working days from the date of receipt of application. Validity of registration – for 5 years, unless cancelled or suspended by the CDSCO. Any change in membership or the constitution of a registered EC must be intimated in writing to the CDSCO within 30 working days. If an application is rejected by the CDSCO, there are provisions to appeal the decision within 60 working days after the intimation of rejection. If a clinical trial site or BA/BE centre does not have its own EC A trial at such a site or centre may be initiated by: o Obtaining approval from the EC of another trial site OR an Independent EC for clinical trial (constituted in accordance to Rule 7 of the New Drugs and Clinical Trial Rules, 2019). o The approving EC will be responsible for the study at the site or centre o The EC and the trial site or BA/BE centre must be located in the same city or within 50 kilometres of each other. ECs reviewing applications that do not require a regulatory approval from CDSCO (including academic clinical trials, biomedical and health research) Applicable Rules from the New Drugs and Clinical Trial Rules, 2019 – Chapter IV (pages 153 – 155) this has come into force 180 days after the publication of these rules (i.e. 12th September 2019 onwards) o Rule 15: EC for biomedical and health research o Rule 16: Constitution of EC for biomedical and health research o Rule 17: Registration of EC related to biomedical and health research o Rule 18: Suspension or cancellation of registration of EC for biomedical and health research ICMR National Ethical Guidelines (section 4.3 onwards – page 27) provide detailed guidance on constitution, terms of reference for EC members, registration and accreditation. Registration with the authority designated by the Ministry of Health and Family Welfare, Department of Health Research (DHR) o Via Form CT-01 (Eighth Schedule – page 236) o Documents as per Table 1 of the Third Schedule (page 212) o Validity: two years (provisional registration) o Application via Naitik portal (more information is available on DHR's webpage for EC). Renewal of registration with CDSCO o Via Form CT-01 (Eighth Schedule – page 236) o Documents as per Table 1 of the Third Schedule (page 212) o Ninety days prior to the date of expiry of the registration Grant of registration o Provisional registration: granted on receipt of application for registration of EC. This is valid for two years. o Grant of final registration via Form CT-03 (Eighth Schedule – page 236) Designated Ethics Committee (DEC) o For multicentric biomedical and health research (or low risk), studies the participating sites may utilize the services of a DEC. o DEC is the EC of a participating site, which has been identified as a designated EC for the purpose of a primary review, when all sites are using a common protocol. This is not applicable for clinical trials seeking a regulatory approval from the CDSCO. Composition of the Ethics Committee Rules 7 and 16 (Chapter III and IV, respectively) of the New Drugs and Clinical Trial Rules, 2019 and the ICMR National Ethical Guidelines contain detailed guidance on the composition of an Ethics Committee. The qualifications, roles, responsibilities, training, development and affiliation of the members of the committee, should be as per the details provided in both these documents. To streamline applications requiring review by an EC, ICMR in collaboration with THSTI has released a set of common forms and checklists to facilitate the review process. The forms available are: Application for Initial Review, Application for Expedited Review, Application for Exemption from Review, Application for Continuing Review or Annual Report Format, Application/Notification form for Amendments, Protocol Violation or Deviation Reporting Form (reporting by case), Serious Adverse Reporting format (Biomedical Health Research), Premature Termination or Suspension or Discontinuation Report Format, Application form for Clinical trials, Serious Adverse Event Reporting Format for Clinical Trials, Application Form for Human Genetics Testing Research, Application Form for Socio-Behavioural and Public Health Research, Format for Study Completion or Final Report Format, Format for Curriculum Vitae for Investigators. The Common Forms for Ethics Review are accessible from here. These forms may be downloaded, adapted and/or customised for use by ECs of institutions. Since the primary focus of the Clinical Trials toolkit is clinical trials that require a regulatory approval from CDSCO, the sections that follow describe the composition, roles and responsibilities, etc. of ECs reviewing such trials. Ethics Committee for Clinical Trials, Bioavailability and Bioequivalence Study The EC should be multi-disciplinary and have at least seven members. The Institute or organisation should appoint a Chairperson (from outside the institution) and a Member Secretary who is affiliated with the institution. Members of the committee should comprise of medical, non-medical, scientific, non-scientific experts; to reflect different viewpoints. The committee shall include, at least: One lay person A woman member One legal expert An independent member from any other field, such as a social scientist, or representative of non-governmental voluntary agency or philosopher or ethicist or theologian. One member whose primary area of interest or specialization is non-scientific. At-least 50 percent of the members should not be affiliated with the institute or the organization forming the EC. In addition to the above, members representing medical scientists and clinicians in the EC, shall possess at least post-graduate qualification in their respective fields, adequate knowledge and experience in their respective field and shall be aware of their roles and responsibilities as EC members Based on the protocol being reviewed, subject matter experts may be invited to offer their views and recommendations. Examples of such research areas include HIV/AIDS, specific patient groups, genetic disorders, etc. Members who are independent of the trial and the sponsor should provide opinions or vote during the EC deliberations. Clause B of Table 1 of the Third Schedule (page 212) of the New Drugs and Clinical Trial Rules, 2019 provides the format of approval by the Ethics Committee. All the members shall sign a declaration to the effect that there is no conflict of interest with respect to the protocol reviewed by them. In case there is conflict of interest, the members shall voluntarily withdraw from the EC meeting No clinical trial protocol or BA/BE study or related documents will be reviewed unless the following five members are present: Medical scientist (preferably a pharmacologist) Clinician Legal expert Social scientist / representative of a non-governmental voluntary agency / philosopher / ethicist / theologian / similar person. Lay person Roles and Responsibilities of an EC The EC is responsible for a full committee review of clinical trials and BA/BE studies. Since clinical trials and BA/BE studies present more than minimal risk, they are not eligible for an exemption from review or an expedited review. Please refer to Table 2.1 (page 6) for categories of risk and Table 4.2 (page 36) for details on types of review in the ICMR National Ethical Guidelines. The format for according an approval to a clinical trial application by an EC is provided in Clause B of Table 1 of the Third Schedule (page 212) in the New Drugs and Clinical Trial Rules, 2019. The EC is also responsible for an ongoing review of the clinical trials for which it has accorded an approval. These reviews may be based on: Periodic study progress reports that are submitted by the investigator Monitoring and internal audit reports submitted by the sponsor By visiting the trial/study sites site or BA/BE centre. The EC also plays an important role with respect to Serious Adverse Event (SAE) reporting and assessment during a trial or BA/BE study. The EC of the site (where the SAE has occurred) is required to submit a report of its analysis, to CDSCO. The applicable Rules are provided in Chapter VI (page 161) of the New Drugs and Clinical Trial Rules, 2019. An EC can stop/suspend a trial or study and withdraw permission in case any compromise with rights, safety, and well-being of study participants is noted and inform the same to both the CDSCO and the head of institution, where the trial is being conducted. The EC is also required to provide reasons for rejecting an application or for requesting for changes in protocol, in writing. These should also be provided to the CDSCO. The EC is required to maintain all records, data, documents, etc. related to its functioning and review of the trial or BA/BE study for a minimum period of five years, after the completion of the trial or study. There are provisions in the New Drugs and Clinical Trial Rules, 2019 to issue show cause and suspend permission of EC by CDSCO in case of major regulatory non-compliances. There are also provisions to appeal to the Central Government within 60 working days in case of such regulatory action by CDSCO. CDSCO designated officials (inspectors) might conduct inspection visits to an EC office, with or without prior notice. These inspection visits are generally conducted to ensure compliance with applicable Rules, GCP, etc. Optional Accreditation of an Ethics Committee Accreditation of an Ethics Committee is recommended (optional at present). It is advisable that the EC makes an effort to seek recognition or accreditation or certification from a national or international body. In India, accreditation of an EC is done by Quality Council of India (QCI), National Accreditation Board for Hospitals and Healthcare Providers (NABH). Information about NABH's accreditation of the ethics committees can be accessed here. Some other optional accreditation bodies are: Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) Association for the Accreditation of Human Research Protection Programmes (AAHRPP). Investigators engaging in a clinical trial or BA/BE study, are required to submit the following set of documents to an EC for review: In accordance with the ICMR National Ethical Guidelines the following documents need to be submitted for an EC review for a clinical trial or study application: Cover letter to the Member Secretary Application form for initial review Correct versions of informed consent document in English + local language. Translation and back translation certificates (if applicable) A copy of the Case record form (CRF) / Questionnaire Recruitment procedures, for example: via advertisements, etc. Participant instruction cards, diary, etc. (if applicable) Investigators Brochure (as applicable) Details of the funding agency / sponsor / fund allocation (if applicable) Brief Curriculum Vitae of the Principal Investigator (PI) and Co-PI A statement on Conflict of Interest (if any) by the PI and Co-PI Documentation of clinical trial registration (with CTRI for details please refer to the section on Clinical Trial Registration of this toolkit). Insurance policy for the participants indicating the commencement and expiration dates and risk coverage. This should be a national policy, applicable in India. Undertaking (signed) by the Investigators GCP training certificates for PI and Co-PI (preferably within the last 5 years of trial initiation) Any other research ethics / other training evidence List of ongoing research studies undertaken by the Principal Investigator, including clinical trials and BA/BE studies Regulatory permissions (as applicable) Relevant administrative approvals (example: HMSC Approval for an international trial) Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable) MoU in case of studies involving collaboration with other institutions (if applicable) Clinical Trial Agreement between the sponsors, investigator and the Head of the institution (if applicable) Indemnity Policy indicating dates of commencement and expiration, and conditions of coverage Any additional documents as required by the EC (example: other EC clearances for multicentric studies Protocol *Once an approval has been granted by the EC, the CDSCO must be informed within 15 working days of the grant of the approval. Protocol Amendments As per the New Drugs and Clinical Trial Rules, 2019, all protocol amendments need to be notified and approved by the CDSCO along with an approval from the EC (that has granted the approval for the study). No deviations or changes from the approved protocol can be implemented without the prior written approval of the EC and the CDSCO in case of a regulatory clinical trial or EC for an academic clinical trial. Exceptions to this are circumstances when there is an urgent requirement to eliminate immediate hazards to the trial participant(s) or when the changes involve only the logistic or administrative aspect of the trial. These changes should be notified to the CDSCO and the EC, within 30 days. References and further reading National Ethical Guidelines for Biomedical and Health Research involving Human Participants, Indian Council of Medical Research, 2017, available online (last accessed on 26.02.2019). New Drugs and Clinical Trial Rules, 2019, G.S.R. 227(E), Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, available online (last accessed on 01.04.2019). Good Clinical Practices for Clinical Research in India, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, 2001, available online (last accessed on 26.02.2019). Handbook on National Ethical Guidelines for Biomedical and Health Research involving Human Participants, Indian Council of Medical Research, 2018, available online (last accessed on 13.05.2019). Please refer to the following sections of the toolkit for further information on types of trials, SAE reporting timelines and Archiving: Trial Planning Safety Management Plan Archiving

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