Inspection Checklist for Ethics Committee
CENTRAL DRUGS STANDARD CONTROL ORGANISATION

DATE OF INSPECTION:	**Address of the Ethics Committee:**		**Name and Address of the main contact person of the Ethics Committee:**	
Name of the Ethics Committee:				
Type of the Ethics Committee: ☐ **Institutional** ☐ **Independent**				
Registration No of the EC issued by CDSCO and issuance date	**S. No**	**Composition of the Ethics Committee**	**Qualification**	**Role of member**

Authorization for the Inspection:	Inspection team:
Purpose of inspection:	
List of personnel's during inspection	

Inspection Checklist for Ethics Committee

S. No	Assessment	*NDCT Rules 2019/ *GCP guidelines*	Observations
1	**Institutional policy for patient protection & EC composition**		
1.1	Does EC has principles/policy to review and accords its approval to a trial protocol to safeguard the rights, safety and well-being of all trial subjects?	*Third Schedule,(3)(3)(i)*	
1.2	Is EC an independent review committee on which Institution's board of members/directors are not included?	**Definition*	
1.3	Is EC is an multi-disciplinary/ multi sectorial committee which EC ensures an independent fair and un-biased review?	**Definition*	
1.4	Does the Institute have a list of EC members/composition of EC members with CV of all the members?	*13(2)(i)(ii)*	
1.5	Does the EC consist of at least seven members from medical, non-medical, scientific and non-scientific areas with at least,— (i) one lay person; (ii) one woman member; (iii) one legal expert; (iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian?	*7(1)*	
1.6	Does EC consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted?	*7(2)*	
1.7	Is the Chairperson of the Committee is affiliated to the Institution and not head of the same Institution to maintain the independence of the Committee?	*7 (3)*	
1.8	Is the member secretary of the Committee is affiliated to the Institution?	*7(4)*	
1.9	Does the EC functions with required quorum as per NDCT Rules 2019?	*12 (1)*	
1.10	Does the EC include specific patient group representations based on the	*7 (9)*	

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	requirement of research area such as HIV, Genetic disorder etc.?		
1.11	Does the EC invite Subject expert(s) for review? Do the subject expert(s) have voting rights	*12 (3)*	
1.12	Does the EC Inform Licensing Authority within the prescribed timeline in case of any change in the membership or the constitution of the Ethics Committee takes place ?	*12 (4)*	
1.13	Does the EC have sufficient staff (full-time or part-time) to meet its functions and responsibilities?	*7(1), (2), (3), (4) & (5)*	
1.14	Does the members of the Ethics Committee follow the provisions of rules, Good Clinical Practices Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects?	*7(6)*	
1.15	Does every member of the Ethics Committee has undergone required training and development programmes?	*7(7)*	
1.16	Does EC maintains policy regarding training for new and existing committee members along with standard operating procedures?	*Third Schedule Table1, (A)(j)*	
1.17	Does EC maintain policy to monitor or prevent the conflict of interest along with standard operating procedures? (N.B. describe the policy in brief)	*Third Schedule Table1, (A)(k)*	
1.18	Does EC has SOP to be followed by the committee in general?	*Third Schedule Table1, (A)(h)*	
1.19	Does EC has SOP to be followed by the committee for vulnerable population?	*Third Schedule Table1, (A)(i)*	
1.20	Does EC has its own SOP available with each member?	*2.4.2.3	
1.21	Does the Terms of References include a statement on Terms of Appointment of EC members with reference to the duration of the term of membership, the policy for removal, replacement and resignation procedure etc.	*2.4.2.3	

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1.22	Does EC members are made aware of their role and responsibilities as committee members? Are EC members are made aware about any change in the regulatory requirements and all national and international developments in this regard.?	*2.4.2.3	
1.23	Is the EC has been audited or inspected before? If yes, details to be provided.	*Third Schedule Table1, (A)(l)*	
2	**Submission of Application**		
2.1	Does the researcher/investigator submit appropriate application to the EC in a prescribed format along with the study protocol at least three weeks in advance?	*2.4.2.5	
2.2	Does the EC requests for clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.	*2.4.2.5 (1)	
2.3	Does the EC request recent curriculum vitae of the Investigators indicating qualification and experience?	*2.4.2.5 (2)	
2.4	Does EC requests for details regarding participant/subject recruitment procedures?	*2.4.2.5 (3)	
2.5	Does the EC requests details about inclusion and exclusion criteria for entry of participants in the study?	*2.4.2.5 (4)	
2.6	Does the EC requests for precise description of methodology of the proposed research, including intended dosages and routes of administration of drugs, planned duration of treatment and details of invasive procedures if any?	*2.4.2.5 (5)	
2.7	Does the EC request a description of plans to withdraw or withhold standard therapies in the course of research?	*2.4.2.5 (6)	
2.8	Does the EC request the plans for statistical analysis of the study?	*2.4.2.5 (7)	

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2.9	Does EC request procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and vernacular languages.?	*2.4.2.5 (8)	
2.10	Does EC request details regarding safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research?	*2.4.2.5 (9)	
2.11	Does EC request details regarding research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage?	*2.4.2.5 (10)	
2.12	Does EC requests for details regarding proposed compensation and reimbursement of incidental expenses?	*2.4.2.5 (11)	
2.13	Does EC request details regarding Storage and maintenance of all data collected during the study/research ?	*2.4.2.5 (12)	
2.14	Does EC request plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants?	*2.4.2.5 (13)	
2.15	Does the EC request for a statement on probable ethical issues and steps taken to tackle the same ?	*2.4.2.5 (14)	
2.16	Does EC requests for all other relevant documents related to the study protocol including regulatory clearances?	*2.4.2.5 (15)	
2.17	Does EC requests for agreement to comply with national and international GCP protocols for clinical study/research?	*2.4.2.5 (16)	
2.18	Does the EC requests for details of Funding agency / Sponsors and fund allocation for the proposed work?	*2.4.2.5 (17)	
2.19	Does the EC requests for statement on conflict of interest, if any ?	*2.4.2.5 (18)	
2.20	Does the EC requests for relevant administrative approvals (such as HMSC approval for International trials, if applicable)?	*2.4.2.5 (19)	
2.21	Does the EC request for Indemnity policy, clearly indicating the conditions of	*2.4.2.5 (20)	

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	coverage, date of commencement and date of expiry of coverage of risk (if applicable) ?		
2.22	Does the EC request for Insurance policy for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)?	*2.4.2.5 (21)	
3	**Decision Making/Review Process**		
3.1	Does the EC is able to provide complete and adequate review of the research proposals submitted to them?	*2.4.2.6	
3.2	Does EC meet periodically at frequent intervals to review new proposals, evaluate annual progress of ongoing ones and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate?	*2.4.2.6	
3.2	Does the EC has the procedure whereby the decision is taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps? Does the Member Secretary communicate the decision in writing?	*2.4.2.6 (a)	
3.3	Does the EC has set procedure whereby a member voluntarily withdraw from the EC while making a decision on an application which evokes a conflict of interest, which is indicated in writing to the chairperson prior to the review and is recorded so in the minutes?	*2.4.2.6 (b)	
3.4	Does EC has set procedure whereby if one of the members has her/his own proposal for review, then the member does not participate when the project is discussed?	*2.4.2.6 (c)	
3.2	Does the EC document clearly defined reasons supporting any negative decision?	*2.4.2.6 (d)	
3.3	Does the EC has reverse its positive decision on a study in the event of	*2.4.2.6 (e)	

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	receiving information that may adversely affect the benefit/risk ratio? Is there any Procedure set?		
3.4	Does the EC has ordered discontinuation of a study/research if the goals of the study/research have already been achieved midway or unequivocal results are obtained? Is there any Procedure set?	*2.4.2.6 (f)	
3.5	Does the EC has recorded the reasons for termination along with the summary of results in case of premature termination of study conducted till date?	*2.4.2.6 (g)	
3.6	Does the following are reviewed by EC? i. any amendment to the protocol form the originally approved protocol with proper justification; ii. serious and unexpected adverse events and remedial steps taken to tackle them; iii. any new information that may influence the conduct of the study	*2.4.2.6 (h)	
3.7	Does EC has set procedure to invite the applicant/investigator to present the protocol or offer clarifications in the meeting if necessary?	*2.4.2.6 (i)	
3.5	Does EC has set procedure to invite participant/subject experts to offer their views which shall not be part in the decision-making process? (However, the opinion must be recorded.)	*2.4.2.6 (j)	
3.6	Does EC has set procedure for minuting of meetings? Does all the minutes of meetings are approved and signed by the Chairperson?	*2.4.2.6 (k)	
3.7	Does the EC ensure that members with conflicts of interest are not part of the decision making?	*7 (10)*	
3.8	Does EC has maintained all the record of its proceedings?	*Third Schedule 3(3)(iii)*	

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3.9	Does EC review the following documents? (a) Trial protocol and protocol amendments, (b) Patient information sheet and informed consent form (including updates, if any) in English or vernacular language. (c) Investigator's brochure and Proposed methods for patient accrual including advertisements etc. to be used for the purpose. (d) Principal investigator's current Curriculum Vitae. (e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation. (f) Investigator's agreement with the sponsor. (g) Investigator's undertaking as per (Table 4) of Third schedule of NDCT Rule 2019.	*Third Schedule Table 1,B.*	
3.10	Does the EC exercise particular care to protect the rights, safety and well-being of all vulnerable subjects participating in the study, e.g., members of a group with hierarchical structure (e.g. prisoners armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or other incapable of personally giving consent?	*Third Schedule 3(3)(ii)*	

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3.11	Does the EC reviews ongoing trials at appropriate intervals, for which they have reviewed the protocol? Does EC reviews on the basis of the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or visiting the study sites?	*Third Schedule 3(3)(iii)*	
3.12	Does EC visit study sites?	*Third Schedule 3(3)(iii)*	
3.13	Does the EC has revoked its approval accorded to a trial protocol with the record of reasons for doing so and has communicated such a decision to the Investigator as well as to the Central Licensing Authority?	*Third Schedule 3(3)(v)*	
3.14	Does the EC review every research proposal on human participants?	*2.4.2.4	
3.15	Does EC ensure that a scientific evaluation has been completed before ethical review is taken up? The Committee should evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality, and justice issues.	*2.4.2.4	
3.15	Does all the ethical review are done through formal meetings or if any decisions are made through circulation of proposal?	*2.4.2.4	
4	**Serious Adverse Event**		
4.1	Does EC received all the reports of serious adverse event occurred during clinical trial to a subject of clinical trial within the stipulated time?	*25(x)*	
4.2	Does EC analyse the relevant documents pertaining to SAE?	*11(iv)*	
4.3	Does the EC forward the SAE due analysis report along with its opinion on the financial compensation, if any, determined in accordance with the formula specified in the Seventh	*42(2) (iii)& (3)(ii)*	

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	Schedule of NDCT Rules 2019 to Licensing Authority within the stipulated time?		
5	**Record keeping**		
5.1	Does the EC has maintained data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial?	*13(1)*	
5.2	Does the EC has maintained the following records for a period of five years after completion of every clinical trial or bioavailability study or bioequivalence study, namely:— (i) the constitution and composition of the Ethics Committee; (ii) the curriculum vitae of all members of the Ethics Committee; (iii) standard operating procedures followed by the Ethics Committee; (iv) national and international guidelines followed by the Ethics Committee; (v) copies of the protocol, data collection formats, case report forms, investigators brochures; etc., submitted for review; (vi) all correspondence with committee members and investigators regarding application, decision and follow up; (vii) agenda of all Ethics Committee meetings and minutes of all Ethics Committee meetings with signature of the Chairperson; (viii) copies of decisions communicated to applicants;	*13(2)*	

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	(ix) records relating to any order issued for premature termination of study with a summary of the reasons thereof; (x) final report of the study including microfilms, compact disks or video recordings; (xi) recommendation given by Ethics Committee for determination of compensation; (xii) records relating to the serious adverse event, medical management of trial subjects and compensation paid.		
6	Finance		
6.1	Does EC review all financial aspects of conducting and reporting a study and budget made out?	*2.3.1.12(a)	
6.2	Does EC review information about the sources of economic support (e.g. foundations, private or public funds, sponsor / manufacturer)? Does EC review how the expenditures is distributed e.g. payment to participants, refunding expenses of the participants, payments for special tests, technical assistance, purchase of apparatus, possible fee to or reimbursement of the members of the research team, payment of the investigator / institution etc.)?	*2.3.1.12(b)	
6.3	Does EC review the financial arrangement between the sponsor, the individual researcher(s)/manufacturer involved, institution and the investigator(s) in case such information is not stated explicitly?	*2.3.1.12(c)	

The following observations were noted at M/s---------- by the inspection team:

Remarks and Recommendations:

Signature of inspection team