Annexure-I

Details of documents to be submitted for EC review

1. Cover letter to the Member Secretary
2. Type of review requested
3. Application form for initial review
4. The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable)
5. Case record form/questionnaire
6. Recruitment procedures: advertisement, notices (if applicable)
7. Patient instruction card, diary, etc. (if applicable)
8. Investigator's brochure (as applicable for drug/biological /device trials)
9. Details of funding agency/sponsor and fund allocation (if applicable)
10. Brief curriculum vitae of all the study researchers
11. A statement on COI, if any
12. GCP training certificate (preferably within 5 years) of investigators (clinical trials)
13. Any other research ethics/other training evidence, if applicable as per EC SOP
14. List of ongoing research studies undertaken by the principal investigator (if applicable)
15. Undertaking with signatures of investigators
16. Regulatory permissions (as applicable)
17. Relevant administrative approvals (such as HMSC approval for International trials)
18. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
19. MoU in case of studies involving collaboration with other institutions (if applicable)
20. Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)
21. Documentation of clinical trial registration (preferable)
22. Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
23. Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
24. Any additional document(s), as required by EC (such as other EC clearances for multicentric studies)
25. Protocol.

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Source: National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 of Indian Council of Medical Research (ICMR) available at https://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf assessed Jan 5, 2021.