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***Annexure 2: AX 02/SOP 06/V3***

**Checklist for proposal submission to the Ethics Committee**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **S. No** | **Items** | **Yes** | **No** | **NA** | **Page No** | **EC Remarks****(If applicable)** |
| ADMINISTRATIVE REQUIREMENTS |
| 1. | Cover letter |  |  |  |  |  |
| 2. | Application form for initial review by SMVMCH-EC |  |  |  |  |  |
| 3. | Additional information to be provided with application form for clinical trials |  |  |  |  |  |
| 4. | Additional information to be provided with application form for human genetics testing research |  |  |  |  |  |
| 5. | Additional information to be provided with application form for socio-behavioral and public health research |  |  |  |  |  |
| 6. | Request for exempt from review / expedited review |  |  |  |  |  |
| 7. | Brief CV of all Investigators\* |  |  |  |  |  |
| 8. | Good Clinical Practice (GCP) training of investigators\*  |  |  |  |  |  |
| 9. | Research Committee comments and response template |  |  |  |  |  |
| 10. | Research Committee approval letter |  |  |  |  |  |
| 11. | Declaration from guide for PG thesis & UG studies |  |  |  |  |  |
| 12. | EC clearance of other centers\*\* |  |  |  |  |  |
| 13. | Agreement between collaborating partners\*\* |  |  |  |  |  |
| 14. | MTA between collaborating partners\*\* |  |  |  |  |  |
| 15. | Insurance policy/certificate |  |  |  |  |  |
| 16. | Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification |  |  |  |  |  |
| 17. | Copy of contract or agreement signed with the sponsor or donor agency |  |  |  |  |  |
| 18. | Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol |  |  |  |  |  |
| PROPOSAL RELATED |
| 19. | Copy of the detailed protocol as per EC template |  |  |  |  |  |
| 20. | Investigators Brochure (If applicable for drug/biologicals/device trials) |  |  |  |  |  |
| 21. | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/Guides for Focused Group Discussions (FGDs) (English and translated)  |  |  |  |  |  |
| 22. | Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated) |  |  |  |  |  |
| 23. | Assent form for minors (12-18 years) (English and Translated) |  |  |  |  |  |
| 24. | Advertisement/material to recruit participants (fliers, posters etc) |  |  |  |  |  |

*\* Incase of Clinical trial \*\*For multicentric research.*

*MTA-Material transfer agreement;*

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| --- |
| PERMISSION FROM GOVERNING AUTHORITIES |
|  | **Other permissions** | **Required** | **Not****required** | **Received** | **Applied****dd/mm/yy** | **EC Remarks** |
| 25. | CTRI |  |  |  |  |  |
| 26. | DCGI |  |  |  |  |  |
| 27. | Others (Specify) |  |  |  |  |  |
| ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY |
|  | **Item** | **YES** | **NO** | **NA** | **Enclosure no.** | **EC remarks** |
| 28. |  |  |  |  |  |  |
| 29. |  |  |  |  |  |  |

*CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India*

**For SMVMCH – EC Office use only**

**Risk categorization**

Less than Minimal risk Minimal risk

Minor increase over minimal risk or low risk More than minimal risk or high risk

**Type of review:**

1. Exempt review 2. Expedited review 3. Full board review

**Primary reviewer:**

 Signature of Signature of

Member Secretary / Asst. Member Secretary Chairman