Application Form for Expedited Review

Surat Municipal Institute of Medical Education and Research (SMIMER)

Opp. Bombay Market, Umarwada, Surat - 395 010. (Gujarat - India).

Ph: (0261) 2368040 to 43; Fax: (0261) 2343241

Title of study: .....

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Principal Investigator (Name, Designation and Affiliation): .....

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1. Choose reasons why expedited review from EC is requested[12] ?
   i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   ix. Any other (please specify) .....

   .....
2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons[13] ? Yes ☐ No ☐

   If Yes give details: .....

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Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*
[13] *For details, refer to application for initial review, Section-C, 5(b)*
* *In case this is first submission, leave it blank*

CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	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						
12	Copy of the detailed protocol[11]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	Tribal Board	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28		☐	☐	☐		
29		☐	☐	☐		