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**Annexure – 03/SOP-06/V3**

**Application Form for Initial Review by SMVMCH – Ethics Committee**

SMVMCH-EC Ref. No. (for office use) :

General Instructions:

1. Tick one or more as applicable. Mark NA if not applicable
2. Attach
3. additional sheets if required
4. May select more than one option

**SECTION A – BASIC INFORMATION**

1. ADMINISTRATIVE DETAILS
2. Name of Principal Investigator:
3. Department/Division:
4. Date of submission:
5. Type of review requested :

(*Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review)*

Exemption from review Expedited review Full committee review

1. Title of the study:
2. Details of Investigators:

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Designation and  Qualification | Department and  Institution | Address for communication  (E-mail ID & Mobile No) |
| Principal Investigator/Guide | | | |
|  |  |  |  |
| Co-investigator/student/fellow | | | |
|  |  |  |  |

1. Number of studies where applicant is a:
2. Principal Investigator at time of submission
3. Co Principal Investigator at time of submission
4. Duration of the study:
5. FUNDING DETAILS AND BUDGET
6. Total estimated budget for site :
7. Self-funding Institutional funding Funding agency *(Specify)*

**SECTION B - RESEARCH RELATED INFORMATION**

1. OVERVIEW OF RESEARCH
2. Lay summary (*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it)* (within 300 words):
3. Type of study:

Basic Sciences Clinical Cross Sectional

Retrospective Epidemiological/ Public Health Case Control

Prospective Socio-behavioural Cohort

Qualitative Biological samples Systematic Review

Quantitative Mixed Method Any others *(Specify)*

1. METHODOLOGY
   1. Sample size/ number of participants *(as applicable)*

……………………………....................…………………………...……………………………........…............... …………………………………… ………………………………….…......…......................... ……

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation .

1. Is there an external laboratory/outsourcing involved for investigations? Yes No NA

(*If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU)*

**SECTION C: PARTICIPANT RELATED INFORMATION**

1. RECRUITMENT AND RESEARCH PARTICIPANTS
2. Type of participants in the study:

Healthy volunteer Patient Vulnerable persons/ Special groups

Others (Specify)…………………………………………………

Who will do the recruitment?

Participant recruitment methods used:

Posters/ TV/Radio ads/ Patients / Family/ Friends Telephone

leaflets/Letters Social media/ visiting hospitals

Institution website

Others *(Specify)…………………………………………………………………………..*

1. (i) Will there be vulnerable persons / special groups involved ? Yes No NA

(ii) If yes, type of vulnerable persons / special groups

Children under 18 yrs Pregnant or lactating women

Differently abled (Mental/Physical) Employees/Students/Nurses/Staff

Elderly Institutionalized

Economically and socially disadvantaged Refugees/Migrants/Homeless

Terminally ill (stigmatized or rare diseases)

Any other *(Specify)*:………………………………………………………………………

(iii) Provide justification for inclusion/exclusion

(iv) Are there any additional safeguards to protect research participants?

1. Is there any reimbursement to the participants? Yes No

If yes, Monetary Non-monetary

1. Are there any incentives to the participants? Yes No

If yes, Monetary Non-monetary

1. Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution? Yes No

If yes, Monetary Non-monetary

1. BENEFITS AND RISKS

(i) Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes No

If yes, categorize the level of risk:

(*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1)*

Less than Minimal risk Minimal risk

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

(ii) Describe the risk management strategy:

1. What are the potential benefits from the study? Yes No If yes, Direct Indirect

For the participant

For the society/community

For improvement in science

Please describe how the benefits justify the risks

1. Are adverse events expected in the study? Yes No NA

*(The term adverse events in this regard encompass both serious and non-serious adverse events)*

Are reporting procedures and management strategies described in the study? Yes No

If Yes, Specify

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1. INFORMED CONSENT
2. Consent planned for :

Waiver of consent Informed Witnessed consent

Consent from LAR For children<7 yrs Verbal assent from Written assent from

(If so, specify from whom) parental/LAR minor (7-12 yrs) along minor (13-18 yrs) along

consent with parental consent with parental consent

Audio-Video (AV) consent (required for regulatory clinical trials involving vulnerable population) Other

If waiver of consent requested for, then specify the reason (tick the box)

1. Research on publicly available information/ Documents/ Records/ Works/ Performances/ Reviews/ Quality assurance studies/ Archival materials or third- party interviews
2. Research on anonymised biological samples from deceased individuals/ Left over samples after clinical investigation/ Cell lines or cell free derivatives like viral isolates/ DNA or RNA from recognized institutions or qualified investigators/ Samples or data from repositories or registries etc.
3. Emergency situations - Epidemic/ Outbreak
4. Who will obtain the informed witnessed consent?

PI

CO PI

1. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English Local language Other  *(Specify)*………………………........

List the languages in which translations were done……………………………………...

If translation has not been done, please justify…………………………………………….

1. Provide details of consent requirements for previously stored samples if used in the study?(*Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 54 in Section 5.8)*
2. Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language Data/ Sample sharing Compensation for study related injury

Risks and discomforts Need to recontact Statement that consent is voluntary

Alternatives to participation Confidentiality Commercialization/ Benefit sharing

Right to withdraw Storage of samples Statement that study involves research

Benefits Return of research results Use of photographs/ Identifying data

Purpose and procedure Payment for participation Sponsor contact information

Others(Specify)

1. PAYMENT/COMPENSATION
   1. Who will bear the costs related to participation and procedures? (*Enclose undertaking from PI confirming the same)*

PI Institution Sponsor Other agencies (specify)

1. Is there a provision for free treatment of research related injuries? Yes No

If yes, then who will provide the treatment?

1. Is there a provision for compensation of research related SAE? If yes, specify. Yes No

Sponsor Institutional corpus fund Project grant Insurance

1. Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes No
2. STORAGE AND CONFIDENTIALITY
3. Identifying Information: Study Involves samples/data *(specify)*:

Anonymous/Unidentified Anonymized: Reversibly coded

Irreversibly coded Identifiable

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

1. Who will be maintaining the data pertaining to the study?
2. Where will the data be analyzed and by whom? (*For example, a data entry room, a protected computer etc)*
3. For how long will the data be stored?
4. Do you propose to use stored samples/data in future studies? Yes No Maybe

If yes, explain how you might use stored material/data in the future?

**SECTION D: OTHER ISSUES**

1. PUBLICATION, BENEFIT SHARING AND IPR ISSUES
2. Will the results of the study be reported and disseminated? If yes, specify. Yes No
3. Will you inform participants about the results of the study? Yes No
4. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes No NA
5. Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes No
6. Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details

Yes No

1. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes No

SECTION E: DECLARATION AND CHECKLIST

1. DECLARATION (Please tick as applicable)

I/We certify that the information provided in this application is complete and correct.

I/We confirm that all investigators have approved the submitted version of proposal/related documents.

I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guide-lines.

I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.

I/We will comply with all policies and guidelines of the institute and affiliated/ collaborating institutions where this study will be conducted.

I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.

I/We declare that the expenditure in case of injury related to the study will be taken care of.

I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.

I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.

I/We confirm that we will maintain accurate and complete records of all aspects of the study.

I/We will protect the privacy of participants and assure confidentiality of data and biological samples.

I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.

I/We have the following conflict of interest (PI/Co-PI):

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Name & Signature of PI with date

Name & Signature of Co-PI with date Name & Signature of Co-PI with date