# APPLICATION FOR VIREC APPROVAL

**Part-1-Application Profile**

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|---|---|
| 1.**Principal Investigator** | To,<br>**The Member Secretary, VIREC;**<br>Sir/Madam;<br>I am herewith submitting my application for favour of issue of necessary approval for the enclosed research project proposal from Institutional Ethics Committee on Biomedical Health Research for Observational Studies at VSS Institute of Medical Sciences & Research.<br><br>**Annexures:** ☐ Project proposal ☐ Signature page ☐ ICF(English) ☐ ICF (Odia/local language) ☐ PIS(English) ☐ PIS (Odia/local language) ☐ Others (as applicable) ☐ CV of PI if from other institution<br><br>**Principal Investigator_____/Dt._____**<br>Name & Designation (capital letter): |
| 2.**Proposal Title** (in title case) | |
| 3.**Proposal Category** | ☐Faculty ☐Student ☐Others_____ ☐Thesis proposal ☐Non-thesis proposal<br>☐Institutional(VIMSAR) ☐Outside institution ☐Initial proposal ☐Revised proposal |

**Part-2: For-Office-Use-Only**

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|---|---|---|---|
| a. **Code** | ☐ Date of Receipt of Application _____ ☐ VIREC Serial Code _____ | | |
| b. **Submission Checklist** | ☐ Project proposal<br>☐ Signature page<br>☐ ICF(English)<br>☐ ICF (Odia/local language) | ☐ PIS (English)<br>☐ PIS (Odia/local language)<br>☐ Others__ | OA-sign./dt. |
| c. **Category** | ☐ Initial proposal ☐ Revised proposal ☐ Thesis ☐ Non-thesis | ☐ Institutional ☐ Faculty | ☐Outside institution ☐Student ☐ Others |
| d. **Subcommittee Assignment** | | | VMS sign. /Dt. |
| e. **Subcommittee Report:** | Recommendation/Dt._____;<br>☐ **INCOMPLETE** ☐ **EXEMPTED** ☐ **EXPEDITED** ☐ **FULL**<br>Comment: | | Sign/dt: |
| f. **Full Committee Review:** | Decision/Dt_____;<br>☐ **APPROVED** ☐ **REJECTED** ☐ **RESUBMISSION**<br>Comment: | | VMS sign/dt. |
| g. **Communications** | ☐No_____/Dt_____:Subject:_____<br>_____ | | |
| | ☐No_____/Dt_____:Subject: _____<br>_____ | | |
| | ☐No_____/Dt_____:Subject: :_____<br>_____ | | |
| | ☐No_____/Dt_____:Subject: :_____ | | |

**Part-3:Scientific Profile**

4.**Research Training of PI:**

- ☐ None
- ☐ Institutional Workshop on Basic Research Methodology; dates: _____
- ☐ Workshop on GCP/GLP; dates_____
- ☐ NMC prescribed BCBR course; dates_____
- ☐ Others if any_____;dates_____

5.**Research Experience of PI:**

- ☐ No of Publications in Indexed journals;_____
- ☐ No of Research projects with grant as PI/Co-PI;_____
- ☐ Current ongoing Research Projects as PI/Co-PI;_____

6.**Scientific Review of Proposal:**

- ☐ None
- ☐ Departmental; dates _____
- ☐ Institutional; dates _____

7. **Type of study:**

- ☐ Observational ☐ Interventional
- ☐ Qualitative ☐ Quantitative ☐ Mixed method
- ☐ Basic Sciences ☐ Clinical ☐ Epidemiological
- ☐ Prospective ☐ Retrospective
- ☐ Animal study ☐ Stem cell study
- ☐ Cross sectional descriptive ☐ Cross-sectional-analytical
- ☐ Case control ☐ Cohort
- ☐ Systematic Review ☐ Meta analysis
- ☐ Any others (Specify)

8.**Proposal characteristics:**

- ☐ No of study centers: ☐ Single center ☐ Multiple centers(detail)_____
- ☐ Place of study: _____
- ☐ Periodof study: Duration; _____ Years_____ Months; From dt. _____to dt. _____
- ☐ Studentship tenure (if PG/UG/Research Scholar): From dt. _____to dt. _____

**Part-4: Participants**

9.**Minimum Estimated Sample size**: Total _____Control Group_____ Study group_____

10.**Sampling technique** ☐ Convenient ☐ Simple random ☐ Systemic random ☐ Cluster ☐ Stratified ☐ Snowball ☐ Purposive ☐ Judgement ☐ Others(specify) _____

11.**Type of participants:**

☐ Healthy volunteers ☐ Hospital attending patients' families/relatives/friend

☐ Patients ☐ Community member ☐ Others(specify)_____

12.**Vulnerable group /Special population**:

- ☐ None ☐ Children below 18yrs ☐ Pregnant ☐ Lactating mother ☐ Captive/prisoners
- ☐ With Cognitive impairment ☐ Elderly ☐ Tribal ☐ Institutionalized
- ☐ Students/Employees/Nurses/Staff ☐ Terminally ill ☐ Refugee-migrant-homeless
- ☐ Socio-economically disadvantaged ☐ Any other(specify)_____

13.**Justification for inclusion/exclusion** of vulnerable /special group:

14.**Subject Recruitment methods**: (specify)_____

_____

15. **Who shall recruit participants**: ☐ PI ☐ Co-PI ☐ Others(specify)_____

16. **Provision of reimbursement/incentives/compensation to the participants**?

☐ None ☐ Yes; Details _____

**Part-5:Benefit-Risk**

17. **Potential benefits from the study**? (detail in the proposal body)

□ Direct medical or health benefit to participant □ Indirect benefit (e.g., health awarenesses.)

□ Contribution to scientific knowledge □Community or public health benefit

□ Other (specify): _____

18. **Potential risks with the study**? (detail in the proposal body)

□Physical harm or discomfort □Psychological distress □Breach of confidentiality/privacy

□ Social stigma or discrimination □Economic burden (e.g., travel, time) □Legal implications (e.g., disclosures)

□ Other (specify): _____

19.**Category of Potential Risk:**

□ **Less than Minimal** (probability of harm or discomfort anticipated in the research is nil or not expected.)

□ **Not more than Minimal** (probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests/treatment where occurrence of serious harm or an adverse event is unlikely)

□ **Low Risk** (increment in probability of harm or discomfort is only a little more than the minimal risk threshold as in routine research on children and adolescents, persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. ;use of personal identifiable data in research; social risks, psychological harm, and discomfort;)

□ **High Risk**(probability of harm or discomfort anticipated in the research is invasive and greater than minimal
risk as in any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.)

**Part-6:Informed Consent Process**

20.**Whether requesting consent waiver**: □ No / □ Yes; Detail;

21.**Type of Informed Consent**: □ Written Consent (above-18yrs) □ Written Assent (12-18yrs)

□ Verbal assent (7-12yrs) □LAR (Legally Authorized Representative) for participant below18yrs/incapacitated;

22.**Mode of consent**; □ Written □ Audio-visual □ Verbal

23.**Language** for communication, PIS & ICF: □ English□ Odia□ Hindi□ Others_____□ In participant's language

24.**Who shall gather consent**: □ PI □ Co-PI □ Trained assistant

25.**Measures of confidentiality & privacy**:

□ Anonymous/Unidentified □ Identifiable □ Anonymized-Reversibly coded □ Anonymized-Irreversibly coded

□data storage through encryption, password protection, access logs

26.**Scope of future use of data and result**: □ Yes □ No

**Part-7:Funds-Sponsorship-Conflict of Interest**

27.**Estimated Budget**: □ Amount(rupees)-

28.**Funding source**: □ Personal □ Participant □ Sponsor

29.**Sponsorship details**: □ None □ Yes (detail like amount, source, contract, etc.) _____

_____

30. **Conflict of interest** □ None □Yes(detail)_____

**Part-8: Undertaking:**

1. I certify that the information provided in this application is complete and correct.
2. I confirm that I will initiate the study only after necessary regulatory and ethical approval.
3. I will not implement any deviation from the approved protocol without prior written approval from VIREC.
4. I confirm that all the investigators have approved this protocol and are committed towards their research responsibilities;
5. I will personally ensure the conduct of the study and ensure strict compliance of all ethical standards throughout.
6. I will maintain accurate and complete records of all study-related data in accordance with Good Clinical Practice and Good Laboratory Practice guidelines.
7. I will protect the privacy of participants and assure confidentiality of data and biological samples.
8. I confirm to submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report including any additional report asked for to the Ethics Committee.
9. I undertake to abide by any order issued in the context of any of my research misconduct related to this proposal.

**PI (full signature) _____Place_____/Date_____**

| Part-9: Signatures | | |
|---|---|---|
| **Authority** | **Name-Designation-Department-Institutional Address-Phone-Email-id;** | **Signature** |
| 1.**Principal-Investigator:** | | *I shall comply with all research responsibilities and VIREC decisions.*<br><br>*Full Signature; date; seal* |
| 2.**Co-PI(Guide)** | | *I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.*<br>*I will provide continuous supervision as the guide. (for PG Thesis Protocol)*<br><br>*Full Signature; date; seal* |
| 3.**Co-PI** | | *I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.*<br><br>*Full Signature; date; seal* |
| 4.**Co-PI** | | *I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.*<br><br>*Full Signature; date; seal* |
| 5.**Co-PI** | | *I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.*<br><br>*Full Signature; date; seal* |
| 6.**Head-of-Department** | | *The proposal is original and genuine, has been approved through departmental scientific review and is recommended for VIREC review.*<br><br>*Full Signature; date; seal* |
| 7.**Head of Institution (if from other institution)** | | *The proposal is original and genuine, has been approved through departmental scientific review and is forwarded for VIREC review.*<br><br>*Full Signature; date; seal* |