



APPLICATION FOR VIREC APPROVAL



Part-1-Application Profile

1.Principal Investigator	<p>To, The Member Secretary, VIREC; Sir/Madam; 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.</p> <p>Annexures: <input type="checkbox"/> Project proposal <input type="checkbox"/> Signature page <input type="checkbox"/> ICF(English) <input type="checkbox"/> ICF (Odia/local language) <input type="checkbox"/> PIS(English) <input type="checkbox"/> PIS (Odia/local language) <input type="checkbox"/> Others (as applicable) <input type="checkbox"/> CV of PI if from other institution</p> <p>Principal Investigator _____/Dt. _____ Name & Designation (capital letter):</p>				
2.Proposal Title (in title case)					
3.Proposal Category	<table border="0"> <tr> <td><input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Others _____</td> <td><input type="checkbox"/> Thesis proposal <input type="checkbox"/> Non-thesis proposal</td> </tr> <tr> <td><input type="checkbox"/> Institutional(VIMSAR) <input type="checkbox"/> Outside institution</td> <td><input type="checkbox"/> Initial proposal <input type="checkbox"/> Revised proposal</td> </tr> </table>	<input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Others _____	<input type="checkbox"/> Thesis proposal <input type="checkbox"/> Non-thesis proposal	<input type="checkbox"/> Institutional(VIMSAR) <input type="checkbox"/> Outside institution	<input type="checkbox"/> Initial proposal <input type="checkbox"/> Revised proposal
<input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Others _____	<input type="checkbox"/> Thesis proposal <input type="checkbox"/> Non-thesis proposal				
<input type="checkbox"/> Institutional(VIMSAR) <input type="checkbox"/> Outside institution	<input type="checkbox"/> Initial proposal <input type="checkbox"/> Revised proposal				

Part-2: For-Office-Use-Only

a. Code	<input type="checkbox"/> Date of Receipt of Application _____ <input type="checkbox"/> VIREC Serial Code _____		
b. Submission Checklist	<input type="checkbox"/> Project proposal <input type="checkbox"/> Signature page <input type="checkbox"/> ICF(English) <input type="checkbox"/> ICF (Odia/local language)	<input type="checkbox"/> PIS (English) <input type="checkbox"/> PIS (Odia/local language) <input type="checkbox"/> Others__	OA-sign./dt.
c. Category	<input type="checkbox"/> Initial proposal <input type="checkbox"/> Revised proposal <input type="checkbox"/> Thesis <input type="checkbox"/> Non-thesis	<input type="checkbox"/> Institutional <input type="checkbox"/> Faculty	<input type="checkbox"/> Outside institution <input type="checkbox"/> Student <input type="checkbox"/> Others
d. Subcommittee Assignment			VMS sign. /Dt.
e. Subcommittee Report:	Recommendation/Dt. _____; <input type="checkbox"/> INCOMPLETE <input type="checkbox"/> EXEMPTED <input type="checkbox"/> EXPEDITED <input type="checkbox"/> FULL Comment:		Sign/dt:
f. Full Committee Review:	Decision/Dt _____; <input type="checkbox"/> APPROVED <input type="checkbox"/> REJECTED <input type="checkbox"/> RESUBMISSION Comment:		VMS sign/dt.
g. Communications	<input type="checkbox"/> No _____/Dt _____:Subject: _____ <hr/> <input type="checkbox"/> No _____/Dt _____:Subject: _____ <hr/> <input type="checkbox"/> No _____/Dt _____:Subject: : _____ <hr/> <input type="checkbox"/> No _____/Dt _____:Subject: : _____ <hr/>		

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:

- | | | | | |
|---|--|--|---|--|
| <input type="checkbox"/> Observational | <input type="checkbox"/> Interventional | <input type="checkbox"/> Cross sectional descriptive | <input type="checkbox"/> Cross-sectional-analytical | |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Quantitative | <input type="checkbox"/> Mixed method | <input type="checkbox"/> Case control | <input type="checkbox"/> Cohort |
| <input type="checkbox"/> Basic Sciences | <input type="checkbox"/> Clinical | <input type="checkbox"/> Epidemiological | <input type="checkbox"/> Systematic Review | <input type="checkbox"/> Meta analysis |
| <input type="checkbox"/> Prospective | <input type="checkbox"/> Retrospective | <input type="checkbox"/> Any others (Specify) | | |
| <input type="checkbox"/> Animal study | <input type="checkbox"/> Stem cell study | | | |

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 below 18yrs/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:		<p><i>I shall comply with all research responsibilities and VIREC decisions.</i></p> <p><i>Full Signature; date; seal</i></p>
2.Co-PI(Guide)		<p><i>I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.</i></p> <p><i>I will provide continuous supervision as the guide. (for PG Thesis Protocol)</i></p> <p><i>Full Signature; date; seal</i></p>
3.Co-PI		<p><i>I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.</i></p> <p><i>Full Signature; date; seal</i></p>
4.Co-PI		<p><i>I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.</i></p> <p><i>Full Signature; date; seal</i></p>
5.Co-PI		<p><i>I will ensure that the research is conducted in adherence to ethical and institutional standards with academic and scientific integrity.</i></p> <p><i>Full Signature; date; seal</i></p>
6.Head-of- Department		<p><i>The proposal is original and genuine, has been approved through departmental scientific review and is recommended for VIREC review.</i></p> <p><i>Full Signature; date; seal</i></p>
7.Head of Institution (if from other institution)		<p><i>The proposal is original and genuine, has been approved through departmental scientific review and is forwarded for VIREC review.</i></p> <p><i>Full Signature; date; seal</i></p>