



APPLICATION FOR VIREC APPROVAL

Institutional Research & Ethics Committee, VIMSAR

[for office use only]

Virec Serial Code :

Type Of Review Recommended:

EXEMPTED / EXPEDITED / FULL

Comments & Recommendations:

Decision :

APPROVAL / REJECTION / RESUBMISSION

Signatures of Chairman & Members in Meeting: [date:

]

Segment-1: Proposal Title :

Investigators	Name, Designation & Qualifications	Address Telephone/Email ID	Signature
PI Principal Investigator			
CI Other Investigators/ Guide/Co-guide			

If out-house project proposals, please attach detailed CV of all investigators as per virec- format.



Segment-2: [scientific review]

- 1. Whether submitted to VIREC for first time ? Yes/No
If revision, original VIREC Code :
- 2. Date of VIRAB (Institutional Research Advisory Board) presentation and review : Date:
- 3. Whether approved by VIRAB ? Yes/No
- 4. Type of VIREC review recommended by VIRAB ? Exempted/ Expedited/ Full
- 5. Whether incorporated VIRAB suggestions? Yes/No

Segment-3: [drug / vaccines/ device/ herbal remedies]:

- 1. Does the study involve use of Drugs/ Devices / Vaccines / Indian Systems of Medicine/ Alternate System of Medicine/ Any other Yes/No
- 2. Is it an Investigational New Drug ? Yes/No
- 3. Is it a new route of administration /dose /formulation ? Yes/No
- 4. Is there a new indication for use ? Yes/No
- 5. Are you aware if this study/similar study is being done elsewhere ? Yes/No
If Yes, attach details ?
- 6. If yes for any of the above items whether obtained DCGI approval ? Yes/No

Segment-4: Subjects

- 1. Minimum sample size estimated : Yes/No
- 2. Duration of study proposed : Yes/No
- 3. Whether subjects from either gender be recruited? Yes/No
- 4. Type of subjects involved: Volunteers / Patients Yes/No
- 5. Is the subject selection biased? Yes/No
- 6. Involves vulnerable subjects ? Yes/No
[Tick: pregnant women/ children /elderly / fetus /illiterate /handicapped/ terminally ill/ seriously ill / mentally challenged / economically & socially backward / any other (specify)]
- 7. Involves 'special group' ? Yes/No
[Tick : captives /institutionalized/ employees/ students/nurses/ dependents/ armed forces / any other(specify)]

Segment-5:[material]

1. Whether involves Use of biological/ hazardous materials?

Yes/No

[Tick-Use of fetal tissue or abortus / Use of organs or body fluids / Use of pre-existing or stored or left over samples/ Collection for banking or future research/Use of Infectious or bio-hazardous specimens/ Use of ionising radiation or radioisotopes]

2. Provision for Proper disposal of material made available ?

Yes/No

Segment-6: [consent]

1. Whether Informed consent involved ?

Yes/No

2. Mode of informed consent involved?

Written /Audio-visual

3. Annexed in English and local language ?

Yes/No

4. Annexed Participant Information Sheet (PIS) ?

Yes/No

Segment-7: [risks]

1. The category of risk involved ?

Less than minimal /Minimal /More than minimal

[Minimal Risk implies "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."]

Segment-8: [allied review]

1. Involves genetic material

Yes/No

2. Involves stem cell material

Yes/No

3. If yes whether approved by institutional genetics and stem cell committee ?

Yes/No

[Annexure-letter of approval no...../dt.....]

Segment-9: [COI]

1. Whether involves conflict of interest (financial / nonfinancial)?

Yes/No

If Yes, specify :

Segment-10 [annexures]

1. Application For Registration of MD/MS Studentship at University (as per format 1.0)
2. FOUR HARD COPIES of Research protocol (synopsis of thesis project) [with following chapters chapter-1; Introduction-background, knowledge gap, research question/research hypothesis; Chapter-2: objectives-primary/ secondary Chapter-3-materials and methods-study period. Place of study, type of study, study design, sample size , sampling method, inclusion criteria, exclusion criteria. Tests and procedures, tools , study variables, outcome variables, data collection , compilation and analysis. Chapter-3-consent , conflict of interest, budget; Chapter-4-references ; Chapter-5- annexures- informed consent form, participant information sheet, case record proforma, questionnaires, tools, scores ,etc.]



Place:	Date:	Signature of Principal Investigator
--------	-------	-------------------------------------

Place:	Date:	Signature of Co-Guide
--------	-------	-----------------------

Place:	Date:	Signature of Co-Guide
--------	-------	-----------------------

Place:	Date:	Signature of Guide
--------	-------	--------------------

Place:	Date:	Seal & Signature of HOD
--------	-------	-------------------------

Place:	Seal & Signature of Head of Institution	
Date:	(for- out-house proposals)	

