



Maratha Vidya Prasarak Samaj's
**Dr. Vasantrao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

Institutional Ethics Committee
Application Form for Initial Review

General Instructions: a) Tick one or more options as applicable. Mark NA if not applicable
 b) Attach additional sheets if required

PG Student Dissertation Research PG Student non dissertation Research UG Student Research
 Faculty Research Clinical Trial Research from other institute

SECTION A-BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization:

(b) Name of Ethics Committee:

(c) Name of Principal Investigator:

(d) Department/Division: (e) Date of submission:

(f) Type of review requested:

Exemption from review Expedited review Full committee review

(g) Title of the study:

.....

.....

Acronym/ Short title, (If any):

(h) Protocol number (If any): Version number:

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication (Mobile No & Email ID)
Principal Investigator			
Co-investigator			



Maratha Vidya Prasarak Samaj's
**Dr. Vasantrao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

(b) Type of study:

- | | | | | | |
|----------------|--------------------------|-----------------------------------|--------------------------|-------------------|--------------------------|
| Basic Sciences | <input type="checkbox"/> | Clinical | <input type="checkbox"/> | Cross Sectional | <input type="checkbox"/> |
| Retrospective | <input type="checkbox"/> | Epidemiological/
Public Health | <input type="checkbox"/> | Case Control | <input type="checkbox"/> |
| Prospective | <input type="checkbox"/> | Socio-behavioral | <input type="checkbox"/> | Cohort | <input type="checkbox"/> |
| Qualitative | <input type="checkbox"/> | Biological samples/ data | <input type="checkbox"/> | Systematic Review | <input type="checkbox"/> |
| Quantitative | <input type="checkbox"/> | Any others(<i>Specify</i>) | <input type="checkbox"/> | | |
| Mixed Method | <input type="checkbox"/> | | | | |

4. **METHODOLOGY**

(a) Sample size/ number of participants (*as applicable*)

At site..... In India..... Globally

Control group..... Study group

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

.....

.....

.....

.....

Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.

(b) Is there an external laboratory/outsourcing involved for investigations? Yes No NA

(c) How was the scientific quality of the study assessed?

Independent external review Review by sponsor/Funder

Review within PI's institution (Department review for PG student) No review

Date of review:

Comments in review meeting, if any (100 words)

.....

.....

.....

.....



Maratha Vidya Prasarak Samaj's
**Dr. Vasantrao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers Patients Vulnerable persons/ Special groups

Others (Specify).....

Who will do the recruitment?

Participant recruitment methods used:

Posters/Leaflets/Letters TV/Radio ads/Social Media/Institution Website

Patient/Family/Friends/Visiting Hospitals Telephone Others

Specify

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

ii. If yes, type of vulnerable persons / special groups

Children under 18yrs 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?

.....

(c) Is there any reimbursement to the participants? Yes No

If yes, Monetary Non-monetary Provide details

.....



Maratha Vidya Prasarak Samaj's
**Dr. Vasantrao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

(d) Are there any incentives to the participants? Yes No

If yes, Monetary Non-monetary *Provide details*

.....

(e) Are there any participant recruitment fees/incentives for the study provided to the PI/Institution? Yes No

If yes, Monetary Non-monetary *Provide details*

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/risk to participants?

Yes No

If yes, categorize the level of risk* :

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:

.....

*

Sr.No	Type of Risk	Examples
1.	Less than minimal risk	Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
2.	Minimal risk	Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc
3.	Minor increase over minimal risk or Low risk	Routine research on children and adolescents; research on persons incapable of giving consent, 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
4.	More than minimal risk or High risk	Research involving 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.



Maratha Vidya Prasarak Samaj's
**Dr. Vasantrao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

- (b) What are the potential benefits from the study?
- | | Yes | No | If yes, | Direct | Indirect |
|----------------------------|--------------------------|--------------------------|---------|--------------------------|--------------------------|
| For the participant | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| For the society/ community | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| For improvement in science | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
- Please describe how the benefits justify the risks.....
-
-

(c) Are adverse events expected in the study? Yes No NA

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

If Yes, Specify.....

.....

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes ,please specify reasons and skip to item no.8

Yes No

.....

.....

(b) Version number and date of Participant Information Sheet (PIS):

Version number and date of Informed Consent Form (ICF) :.....

(c) Type of consent planned for:

Signed consent Verbal/Oral consent Witnessed consent Audio-Video(AV)

Consent from LAR For children <7yrs Verbal assent from Written assent from
 (If so,specify from parental/ LAR minor (7-12 yrs) along minor (13-18 yrs)
 whom) consent with parental consent along with parental consent

Other (specify)

(d) Who will obtain the informed consent?

PI/Co-I Nurse/Counselor Research Staff Other (Specify).....

Any tools to be used.....

(e) 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.....



Maratha Vidya Prasarak Samaj's
**Dr. Vasant Rao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada Nagar, Adgaon, Nashik, Maharashtra - 422 003

(f) Provide details of consent requirements for previously stored samples if used in the study

.....

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

- | | | | | | |
|-------------------------------|--------------------------|----------------------------|--------------------------|--|--------------------------|
| Simple language | <input type="checkbox"/> | Data/Sample sharing | <input type="checkbox"/> | Compensation for study related injury | <input type="checkbox"/> |
| Risks and discomforts | <input type="checkbox"/> | Need to re contact | <input type="checkbox"/> | Statement that consent is Voluntary | <input type="checkbox"/> |
| Alternatives to participation | <input type="checkbox"/> | Confidentiality | <input type="checkbox"/> | Commercialization/Benefit sharing | <input type="checkbox"/> |
| Right to withdraw | <input type="checkbox"/> | Storage of samples | <input type="checkbox"/> | Statement that study involves research | <input type="checkbox"/> |
| Benefits | <input type="checkbox"/> | Return of research results | <input type="checkbox"/> | Use of photographs/ Identifying data | <input type="checkbox"/> |
| Purpose and procedure | <input type="checkbox"/> | Payment for participation | <input type="checkbox"/> | Contact information of PI and Member Secretary of EC | <input type="checkbox"/> |
| Others (Specify) | | | | | |

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures?

PI Institution Sponsor Other agencies
 (specify)

(b) Is there a provision for free treatment of research related injuries? Yes No N/A

If yes, then who will provide the treatment?.....

Is there a provision for compensation of research related SAE? Yes No N/A

If yes, specify.

Sponsor Institutional/Corpus fund Project grant Insurance

(c) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? Yes No N/A

If yes, specify.

.....

(d) Is there a provision for ancillary care for unrelated illness during the study period ?

Yes No N/A If yes, please specify.



Maratha Vidya Prasarak Samaj's
**Dr. Vasantrao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

9. STORAGE AND CONFIDENTIALITY

a. Identifying Information: Study Involves samples/data. Yes No NA

If Yes, 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.).....

(b) Who will be maintaining the data pertaining to the study?.....

(c) Where will the data be analyzed and by whom?

(d) For how long will the data be stored?

(e) 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

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

a. Will the results of the study be reported and disseminated? If yes, specify. Yes No NA

.....

b. Will you inform participants about the results of the study? Yes No NA

c. 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

.....

d. Is there any plan for post research benefit sharing with participants? If yes, specify

Yes No NA

.....

e. Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details

Yes No NA

.....

f. 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

.....



Maratha Vidya Prasarak Samaj's
**Dr. Vasant Rao Pawar Medical College,
Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

Name of PI:	
Signature:	dd mm yy
Name of Co-PI:	
Signature:	dd mm yy
Name of Guide:	
Signature:	dd yy
Name of HOD:	
Signature:	dd mm yy



Maratha Vidya Prasarak Samaj's
**Dr. Vasantrao Pawar Medical College,
Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Brief CV of all Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.	Department MOM of reviewing Synopsis (PG Research/ PG dissertation only)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5.	Basic Course in Biomedical Research (BCBR) Certification (For PG Students & Teachers Synopsis)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6.	EC Review Fee paid receipt (For PG Dissertation Synopsis)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7.	EC clearance of other centers*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8.	Agreement between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9.	MTA between collaborating partners*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10.	Insurance policy/certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
12.	Copy of contract or agreement signed with the sponsor or donor agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13.	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
PROPOSAL RELATED						
14.	Copy of the detailed protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
15.	Investigators Brochure(If applicable for drug/	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		



Maratha Vidya Prasarak Samaj's
**Dr. Vasant Rao Pawar Medical College,
 Hospital & Research Centre**



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

	biological/ device trials)					
16	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
17	Assent form for minors (12-18 years) (English and Translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
18	Proforma /Questionnaire/Case Report Forms(CRF) /Interview guides/ Guides for Focused Group Discussions (FGDs)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
19	Advertisement/material to recruit participants (fliers, posters etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
20	CTRI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
21	DCGI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
22	HMSC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
23	NAC-SCRT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
24	ICSCR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
25	RCGM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
26	GEAC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
27	BARC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
28	Tribal Board	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
29	Others (Specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

* For multicentre research. MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC-Health Ministry's Screening Committee; NAC-SCRT – National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research ;RCGM-Review Committee on Genetic Manipulation ;GEAC-Genetic Engineering Approval Committee ;BARC-Bhabha Atomic Research Centre