INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES
(Deemed University)
Govandi Station Road, Deonar Mumbai

SUMMARY SHEET TO BE <u>TYPED</u> BY RESEARCH SCHOLAR FOR THE ETHICAL CLEARANCE

Students are required to complete the following summary sheet and submit it to the Convener of Student Research Ethics Committee. Ethics Committee will examine methodological, technical and ethical soundness of the proposal.

1. PhD / M.Phil.:	
2. Full Name of Research Scholar:	
3. Academic & professional qualification:	
4. Thesis/Dissertation Title:	
5. Personal Particulars	
a. Current Address:	
b. Permanent Address:	
c. Email:	
d. Mobile Number:	
6. Guide	
a. Name:	
b. Contact Details:	
c. Department:	
7. Advisory Committee Member	**Advisory Committee Member**
a. Name:	**a. Name:**
b. Department:	**b. Department:**

8. **Abstract of the proposal: (***include at least 3 references to recent literature)*
Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (maximum 500 words)

9. Research objectives:

The objectives of the research are:

10. Research Design:

Population; sample & sampling technique; inclusion or exclusion criteria (if applicable); withdrawal or discontinuation criteria (if applicable) Research design, activity timeline, research instrument (self/adapted/existing); data collection process; data analysis method; ethical concerns with reference to respondents, institution as person, researcher, specific to study field. Procedures followed to protect participants from physical and or emotional harm (if applicable)

11. Measurable (expected) Indicators:

12. How should this study be characterized? (please tick all appropriate boxes.)

a.	Personal and social information collected directly from participants	Yes	No
b.	Participants to undergo physical health examination	Yes	No
c.	Participants to undergo psychometric testing	Yes	No
d.	Identifiable information to be collected about people from available records (e.g. medical records, staff records, student records, etc.)	Yes	No
e.	Participants to undergo biomarker testing / Anthropometric measurement	Yes	No

If yes, which tests will be covered and rational:

Equipments:

Protocols:

f.	Are you aware if this study/similar study is being done elsewhere or done by other student?	Yes	No

If Yes, write details

13. Description of the risks/benefits posed by the proposed study which research participants may/will suffer/get as well as the level of risk/benefit *(please consider any discomfort, pain/physical or psychological problems/side-effects, persecution, stigmatization or negative labeling)*

Benefit:

Risk:

How will you address the risk?:

a. Are the risks reasonable compared to the anticipated benefits to subject/community/country?	Yes	No
b. Are there physical / social / psychological risk / discomforts?	Yes	No
☐ If Yes**, Minimal** or no risk		
☐ More than minimum risk		
☐ High risk		

14. Type of Study: ☐ Behavioral ☐ Epidemiological ☐ Basic Sciences

Clinical: ☐ Single center ☐ Multicenter

15. Status of Review: ☐ New ☐ Revised

15.a. If Revised date of First Submission (dd/mm/yy):

15.b. If Revised, no of revisions till now: ☐☐

16. Any external funding to execute field work ☐ **Yes** ☐ **No**

17. Sample selection:

a. Sample Size :		
b. Duration of data collection :		
c. Will respondents from both sexes be recruited:	Yes	No
If Yes, sample size	☐ Male	☐ Female
d. Inclusion / exclusion criteria given:	Yes	No
e. Type of subjects:	Volunteers	Patients

f. Vulnerable subjects Yes No

(Tick the appropriate boxes)

☐ Pregnant women	☐ Children	☐ Elderly
☐ Fetus	☐ Illiterate	☐ Handicapped
☐ Terminally ill	☐ Seriously ill	☐ Mentally challenged
☐ Economically & socially backward	☐ Any other	

g. Special group subjects Yes No

(Tick the appropriate boxes)

☐ Captives	☐ Institutionalized	☐ Employees
☐ Students	☐ Nurses/dependent staff	☐ Armed forces
☐ any other		

h. Age group : ☐

18. Privacy and confidentiality

a. during data collection, study involves
- ☐ Direct Identifiers
- ☐ Indirect Identifiers/coded

b. during data entry/analysis, study involves
- ☐ Completely anonymized/ delinked
- ☐ Partially anonymized identifiers

c. Confidential handling of data	Yes	No
19. Use of biological/ hazardous materials	Yes	No

20. Consent :
- ☐ Written
- ☐ Oral
- ☐ Audio-visual

a. Consent form : (tick the included elements)

☐ Understandable language	☐ Alternatives to participation
☐ Statement that study involves research	☐ Contact information
☐ Confidentiality of records	☐ Statement that consent is voluntary
☐ Purpose and procedures	☐ Right to withdraw
☐ Risks & Discomforts	☐ Consent for future use of biological material
☐ Benefits	☐ Benefits if any on future commercialization e.g. Genetic basis for drug development
☐ Compensation for participation	☐ Compensation for study related injury

*If written consent is not obtained, give reasons:

b. Who will obtain consent ? ☐ Researcher ☐ Any other		
21. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
22. Is there any compensation for participation?	Yes	No
If Yes, ☐ Monetary ☐ In kind Specify amount and type:		
23. Is there compensation for injury?	Yes	No
If Yes, what compensation:		
24. Do you have conflict of interest? (financial/nonfinancial)	Yes	No
If Yes, specify:		

25. Interviews will be conducted by the researcher or hired investigators?(Tick appropriate)	**Researcher** ☐	**Investigator** ☐	**Both** ☐
a.If both what proportion of sample will be interviewed by investigator?	☐☐ **%**		
b.If investigator/both, how training will be imparted to the investigators?			

26. If questionnaire/sets of questions/scales are adapted from other sources, the source should be adequately and clearly acknowledged in the application form as well as proposal/ synopsis and thesis. **Yes** ☐ **No** ☐

Declaration: Yes, I will acknowledge the sources in Synopsis and Thesis ☐

Sources:

1

2

3

4

5

27. Checklist for enclosure (please prepare three sets consisting filled-in application and following enclosures)

☐ Filled in application – 3 Copies

☐ Proposal – 3 Copies

☐ Informed Consent forms (3 copies)

☐ Investigator's brochure for recruiting subjects (3 copies)

☐ Copy of clinical trial protocol and/or questionnaire

☐ Rapporteur's report

Declaration: The information provided in this form is accurate.

Signature of Student:

NB: Please ensure that the applicant has completed the attached check sheet and that the form is forwarded to ethics committee for further attention.

Signature of Guide:

Date:

For Official Use: Observation by the Student Research Ethics Committee:

Thesis/dissertation Title:

Does this proposal fulfill standard Ethical Protocols?

☐ **Yes**

☐ **No, it should be referred back to the candidate**

Comments to be given to the applicant

This proposal has been reviewed. The Student Research Ethics Committee is satisfied/not satisfied.

Place: **Signature of President**
Student Research Ethics Committee

Date: