INTERNATIONAL INSTITUTE FOR POPULATION SCIENCES

(Deemed-to-be-University)

(An Autonomous Organisation of Ministry of Health and Family Welfare, Govt. of India)

B. S. Devashi Marg (Govandi Station Road),

Deonar, Mumbai, Maharashtra 400088

https://www.iipsindia.ac.in/

Serial No of IIPS-IRB Management Office:_____

International Institute for Population Sciences -Institutional Review Board (IIPS-IRB) Application form for the review of the proposal

General instructions:

a)To be filled by the Principal Investigator (PI);
b) Please tick mark the appropriate one, mark NA if not applicable; and
c)Attach a separate sheet if required

Title of the Proposal:

……

……..……..

Name of the Applicant ……

Name of the Principal Investigator ……

Designation: ……

Department: ……

Date of submission

Type of review

Exemption from Review …… ☐ Expedited Review . ☐ Full Committee Review .. ☐

Status of Review: New ☐ Revised ☐

SECTION A: ADMINISTRATIVE INFORMATION				
Project Investigators	**Name, Qualifications and Designation**	**Department and Organization Address and contact details**	**Roles and responsibilities**	**Signature**
PI:				
Co-PI:				

SECTION A: ADMINISTRATIVE INFORMATION				
Project Investigators	**Name, Qualifications and Designation**	**Department and Organization Address and contact details**	**Roles and responsibilities**	**Signature**
Please attach a brief bio and CV for all investigators (PIs and Co-PIs) involved in the study (with subject specific publications limited to the previous 5 years).				

Funding Details

Project Duration:
Total Budget:
Share of the sponsor/s in total budget
Sponsor Information: 1. Indian a) Government ☐ i.Central ☐ ii.State ☐ iii. Institutional ☐ b) Private ☐ i.Industry ☐ ii.Development agency ☐ iii. Self-sponsored ☐
2. International Government ☐ Private ☐ UN agencies ☐ Other
3. Industry National ☐ Multinational ☐
Specify the funding agency
Contact Address of Sponsor:

SECTION B: RESEARCH RELATED INFORMATION
1. **Brief description of the study** –background, research question aim(s) & objectives, methodology describing the potential risks & benefits, monitoring and auditing, outcome measures, statistical analysis and implication of the research findings (maximum 500 words):
2. **Objectives of the study**
1. **Type of Study:**

Socio-Behavioural Science ☐ Clinical Single center ☐ Clinical Multi- centeric ☐ Epidemiological and Public health ☐ Basic science ☐ Biological sample ☐	Retrospective ☐ Prospective ☐ Quantitative ☐ Qualitative ☐ Mixed method ☐	Cross sectional ☐ Longitudebnal/cohort ☐ Case control ☐ Systematic review ☐ Baseline ☐ Endline ☐ Formative ☐

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies:

i. Does the study involve use of:

Drug ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No

d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐

4. **Are you aware if this study/similar study is being done elsewhere?**	Yes	No
If Yes, provide details		

SECTION C: PARTICIPANT RELATED INFORMATION

5. Subject selection:

i. Number of Subjects: Sampling design and Sample Size

The rationale for the selection of sample six in 100 words. In case of qualitative study describe the number and type of respondents.

ii. Duration of fieldwork :

iii. Will subjects from both sexes be recruited — Yes / No

iv. Please provide the inclusion and exclusion criteria of the selection of respondents

v. Type of subjects — Volunteers ☐ Patients ☐

vi. Vulnerable subjects — Yes ☐ No ☐

If Vulnerable subjects, Tick the appropriate boxes

Pregnant Women ☐	Children ☐	Elderly ☐
Fetus ☐	Illiterate ☐	Handicapped ☐
Terminally ill ☐	Seriously ill ☐	Mentally challenged ☐
economically & socially backward ☐		Any other (Specify) ☐

iv. Special group subjects — Yes ☐ No ☐

If yes in special subject group, tick the appropriate boxes)

Captives ☐	Institutionalized ☐	Employees ☐
Students ☐	Nurses/Dependent ☐	Armed ☐
Any Other ☐	Staff	Forces

6. Privacy and confidentiality i. Study involves - Direct Identifiers ☐ Indirect Identifiers/coded ☐ Completely anonymised/ delinked ☐			
ii. Confidential handling of data by staff	Yes	No	NA
7. Use of biological/ hazardous materials i. Use of fetal tissue or abortus	Yes	No	NA
ii. Use of organs or body fluids	Yes	No	NA
iii. Use of recombinant/gene therapy	Yes	No	NA
If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes	No	NA
iv. Use of pre-existing/stored/left over samples	Yes	No	NA
v. Collection for banking/future research	Yes	No	NA
vi. Use of ionising radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No	NA
vii. Use of Infectious/biohazardous specimens	Yes	No	NA
viii. Proper disposal of material	Yes	No	NA
ix. Will any sample collected from the patients be sent abroad?	Yes	No	NA
If Yes, justify with details of collaborators:			
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?		Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. ☐
If so, reasons…

Informed Consent

Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes ☐ No ☐

Type of consent planned

*Written/Signed ☐ Oral/Verbal ☐ Audio-visual

In case of a minor children

Verbal assent from o minor (7-12 yrs)along with parental consent

Written assent from o minor (13-18 yrs) along with parental consent

List of languages in which translation is done

Details of number of consent or/assent to be obtained in the study

i.: Tick the included elements in the Consent form

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

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

8. Payment/Compensation

Will you provide any form of payment/compensation to the participants as a result of their participation?	Yes	No

Ye yes, please give details of the payment/compensation		
9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits:		
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No
In case if risks are involved, mention the risks and risk addressing mechanism: Risk Risk addressal mechanism		
ii.Is there a potetial benefit ? a) to the subject ☐ No benefit ☐ Direct benefit ☐ Indirect benefit ☐ b) to the society ☐ No benefit ☐ Direct benefit ☐ Indirect benefit ☐ c) for improvement in knowledge ☐ No benefit ☐ Direct benefit ☐ Indirect benefit ☐		
Mention the benefits:		
Storage And Confidentiality		
a) Identifying Information: Study Involves samples/data. If Yes, Specify Yes ☐ No ☐ NA ☐ 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		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to: Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long? ☐ ☐	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No

14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No

SECTION E: CHECK LIST AND DECLARATION			
Cover letter	**Yes**	**No**	**NA**
Copy of filled-in and duly signed IRB Form (4 copies)	**Yes**	**No**	**NA**
Project proposal – 4 Copies	**Yes**	**No**	**NA**
Short bio of the invigilators	**Yes**	**No**	**NA**
Curriculum Vitae of Investigators in prescribed format	**Yes**	**No**	**NA**
In case of collaborative research, attach the MOU with the collaborating organization	**Yes**	**No**	**NA**
Format of review type	**Yes**	**No**	**NA**
Participant information sheet-cum-Informed Consent form, (if multiple respondents, consent should be taken from each respondent)	**Yes**	**No**	**NA**
Informed Assent form (If applicable)	**Yes**	**No**	**NA**
Investigator self-declaration form	**Yes**	**No**	**NA**
Questionnaire and/or Copy of clinical trial protocol and/or interview guidelines	**Yes**	**No**	**NA**
Investigator's brochure for recruiting subjects	**Yes**	**No**	**NA**
Copy of advertisements/Information brochures	**Yes**	**No**	**NA**
Institutional Animal Ethics Committee clearance	**Yes**	**No**	**NA**
Any other specify	**Yes**	**No**	**NA**

CPCSEA clearance, if any	**Yes**	**No**	**NA**
HMSC/DCGI/DBT/BARC clearance if obtained	**Yes**	**No**	**NA**
Survey Protocol on COVID-related Measures	**Yes**	**No**	**NA**

Date: Principal Investigator
Place: