BIOMEDICAL RESEARCH SUBMISSION FORM

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

PART I: GENERAL INFORMATION

1. **Project Title:**……
……

2. **Type of study:** Departmental ☐ Intramural ☐ Extramural ☐

3. **Nature of study:** Single centre ☐ Multicentric (National) ☐ Multicentric (Global) ☐

4. **Funding details** Non-Funded/ Self funded ☐ Intramural grant ☐ Extramural grant ☐

Name of funding agency for Extramural grant……

Type of funding agency- Government ☐ Private ☐

5. (a) Total estimated fund requirement for intramural grant: ……

(b) Extramural funds for AIIMS Rajkot: ……

Total (if multicentric): ……

6. **Duration of the study**……

7. **Details of Investigators:**

(a) Particulars of investigators:

Name	**Designation**	**Department and Institution**	**Mobile and e-mail**	**Justification for including each investigator**
Principal Investigator				
Co-investigator(s)				

(b) List of ongoing Research projects (Intramural/Extramural/Departmental) being conducted by the applicant as Principal Investigator -

S No.	**Title**	**Type**	**Budget**	**Date of sanction**	**PDC**	**Present state of work**

PART II: TECHNICAL DETAILS OF THE PROJECT*

(** For Intramural/Departmental (Funded/ Non-Funded) Projects only;*
For Extramural projects submit technical details as per proforma of funding agency)

1. **Aim:**
2. **Objectives:**
3. **Background/ Introduction (Max 150 words):** *Provide information about the Rationale of the study supported by cited literature (2-3 references) -What is already known; What more is required to be known; Why is this study required.*
4. **Hypothesis:**
5. **Research questions:**
6. **Detailed methodology (300 words):** *Details of the procedure and methodology proposed to be used in the study. Detailed methodology with study design, basis of adequate sample size calculation, sampling frame, sampling methods, Inclusion/ Exclusion criteria**,** Independent and dependent variables, and other details specifically relevant to each study design.*
7. **Data analysis plan:**
8. **Review of relevant literature on the subject-** *with special reference to the areas in which information is lacking* **(Not to exceed 300 words)**
9. **Scope of the project-** *The relevance and expected outcome of the proposed study*
10. **References (Maximum 12)**
11. **Preliminary work (if any) you have already done in relation to the proposed study**
12. **Title(s) of paper(s) published by you in relation the subject and allied field, if any.**
13. **Timelines:**

Milestone	Targets

14. Is the facility viz. physical facilities, equipment, trained manpower etc. required for the conduct of research project available in the institute? Yes ☐ No ☐
15. Is the necessary support from various other specialties required for the conduct of the project ascertained? Yes ☐ No ☐
16. Is there an external laboratory/ outsourcing involved for investigations? Yes ☐ No ☐
(If yes; provide details and attach relevant documents etc.)
17. Do you consider the proposed number of participants will be available within the proposed period of study and will be adequate to make the study result oriented? Yes ☐ No ☐
18. Statistical consultation (*To be enclosed with every proposal*)

    Justification for the sample size chosen (Max100 words); In case of qualitative study, mention the criteria used for saturation.

(Signature of Epidemiologist/CFM specialist/ statistician Consultant with stamp)

PART III: BUDGETARY REQUIREMENT*

(* *For Intramural Funded Projects only;*
For Extramural projects submit budgetary details as per proforma of funding agency)

Details of items with quantity	**1st year**	**2nd year**	**Total**
Chemical/Reagent/Consumables (i) (ii) (iii)			
Contingencies			
Others			
Total			

Note:

1. *The budgetary requirements should be given in detail with justification of all items.*
2. *Please attach budgetary quotes from authorized vendor(s) for price justification.*
3. *The intramural funds can be utilized only for-*
   a) *Purchase of consumable: drugs, chemicals, kits, disposables etc.*
   b) *Contingency- 2.5% of total proposed budget subject to a maximum of Rs 10,000/- (Ten thousand only) can be kept as contingency fund for unforeseen expenses. The admissible contingency grant may be utilized for unpredicted expenses like on spares for apparatus, stationery (office and computer), photocopying, postage and typing of the project.*
   c) *Diagnostic tests- should preferably be carried out in the institute. Testing can be outsourced only if the facility is not available in the institute after prior approval of RRB and Executive Director.*
4. *Funds will not be utilized for-*
   a) *Purchase of any permanent items like instruments, machine, equipment, computer, books etc. which are not of consumable nature.*
   b) *All items covered under the Learning Resource Allowance (LRA) Scheme will not be allowed under this scheme.*

Signature of Principal Investigator with seal
Date

Signature of Co-Investigator(s) with seal
Date

Signature of Head of the Department with seal
Date

PART IV: INFORMATION FOR ETHICAL REVIEW

(A) RESEARCH RELATED INFORMATION

1. **Type of review requested**:

Exemption from review ☐ Expedited review ☐ Full committee review ☐

2. **Overview of research**

a) Lay summary (within 300 words)- *Summarize in the simplest possible way such that a person with no knowledge of the subject can easily understand it*

b) Type of study:

Basic Science ☐	Clinical ☐	Cross sectional ☐
Retrospective ☐	Epidemiological/ ☐	Case control ☐
Prospective ☐	Public-Health	Cohort ☐
Qualitative ☐	Socio-behavioural ☐	Systemic review ☐
Quantitative ☐	Biological samples ☐	
Mixed method ☐	Any other (specify) ☐	

3. **Methodology**- *Describe in the simplest possible way such that a layman with no knowledge of the subject can easily understand it*

(B) PARTICIPANT RELATED INFORMATION

4. **Recruitment and research participants:**

a) Types of participants in the study

Healthy volunteers ☐ Patients ☐ Vulnerable patients/ Special groups ☐

Others ☐ *(specify)*……..

b) Will there be vulnerable persons/ special groups involved: Yes ☐ No ☐ NA ☐

If yes, type of vulnerable persons/ special group involved

Children under 18 years ☐	Pregnant or lactating women. ☐
Differently abled (Mental/Physical) ☐	Employees/Students/Nurses/ Staff ☐
Elderly ☐	Economically & socially disadvantaged ☐
Refugees/Migrants/Homeless ☐	Terminally Ill (stigmatized or rare disease) ☐
Any other *(Specify):* ☐	……

c) Is any of the clinician involved directly in clinical care of vulnerable population included as PI or Co-I, if not justify……

……

d) Are there any incentives to the participant? Yes ☐ No ☐ NA ☐

If yes; Provide details……

……

5. **Benefits and Risks:**

a) Are there any anticipated physical/social/psychological discomforts/ risk to participants?
Yes ☐ No ☐

b) 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 ☐

c) What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

6. **Informed Consent:**

a) Type of consent planned for:

i) Written Informed consent ☐

ii) Waiver of consent ☐

iii) Consent from LAR ☐

iv) For children <7 yrs parental/LAR consent ☐

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

vi) Written Assent from Minor (13-18 yrs) along with parental consent ☐

vii) Other *(specify)* …….. ☐

b) Participant Information Sheet (PIS) and Informed Consent Form (ICF):

English ☐ Hindi ☐ Gujarati ☐

c) Are you seeking waiver of consent: Yes ☐ No ☐

If yes, what are the reasons…….

……

7. **Storage and Confidentiality:**

a) Identifying information: Study involves samples/data *(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) How long the data will be stored? ……..

d) Whether provisions for maintaining confidentially and privacy of the participants have been addressed?.....

e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

(C) OTHER ISSUES

8. **PUBLICATION, BENEFIT SHARING AND IPR ISSUES:**

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

b) Will you inform participants about the results of the study? Yes ☐ No ☐

c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? Yes ☐ No ☐ NA ☐
If yes describe in brief (Max 50 words)……
……

d) Will the results of the study be reported and disseminated? Yes ☐ No ☐ NA ☐

e) Is there is any commercial value or a plan to patent/IPR issues. Yes ☐ No ☐ NA ☐
If yes, Please provide details……
……

f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? Yes ☐ No ☐
If yes, Please provide details……
……

(D) DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/ collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. ..... 2.....
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We certify that the information provided in this application is complete and correct.

Signature of Principal Investigator with seal

Signature of Co-Investigator(s) with seal and date

(F) CHECKLIST						
S. No	**Items**	**Yes**	**No**	**NA**	**Enclosure No**	**Remarks (If applicable)**
Administrative requirements						
1	Cover letter	☐	☐	☐		
2	Noting sheet (2 blank pages with title of the project and PI Name)					
3	Title page and acknowledgement	☐	☐	☐		
4	Brief CV of all Investigators in prescribed format	☐	☐	☐		
5	Good Clinical Practice (GCP) training of all investigators in last 3 years	☐	☐	☐		
6	Certificates for Research Methodology training of all investigators	☐	☐	☐		
7	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
8	EC clearance of other centers*	☐	☐	☐		
9	Agreement between collaborating partners*	☐	☐	☐		
10	MTA between collaborating partners*	☐	☐	☐		
11	Evidence of external laboratory credentials in case of an externally outsourced laboratory study; QA/QC certification etc.	☐	☐	☐		
12	Soft copy in single file (pdf and word) sent on researchcellaiimsrajkot@gmail.com	☐	☐	☐		
Proposal related						
13	Copy of the detailed protocol	☐	☐	☐		
14	Statistical consultation	☐	☐	☐		
15	Budgetary quotes from authorized vendors	☐	☐	☐		
16	Application for exemption from review in prescribed format	☐	☐	☐		
17	Application for expedited review in prescribed format	☐	☐	☐		
18	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF) (English and translated)	☐	☐	☐		
19	Waiver of consent form in prescribed format	☐	☐	☐		
20	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
21	Proforma/Questionnaire / Case Report Forms (CRF) (English and translated)	☐	☐	☐		
22	Permission to use copyrighted Proforma/ Questionnaire	☐	☐	☐		
23	Application Form for Socio-Behavioural and Public Health Research	☐	☐	☐		
24	Application for Clinical Trial in prescribed format	☐	☐	☐		
25	Application for Socio-Behavioural and Public Health Research	☐	☐	☐		
26	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
27	Permission from governing authorities - CTRI/ DCGI/BARC etc (as applicable)	☐	☐	☐		
28	Any other relevant information/ Document related to study	☐	☐	☐		

* *For Multicentric projects*