अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, गुजरात 360006
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Institute of National Importance under PMSSY, MoHFW
Government of India www.aiimsrajkot.edu.in

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:** Funded (Intramural) ☐ Non-Funded ☐ Departmental ☐

3. **Funding details (if funded): Intramural** ☐ **Extramural** ☐

4. **Nature of study:** Single center ☐ Multicentric (National) ☐ Multicentric (Global) ☐

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	GCP certificate (Date)	Research Methodology certificate (Date)	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 -

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

PART II: TECHNICAL DETAILS OF THE PROJECT*

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

Title:

1. **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.*
2. **Hypothesis:**
3. **Research questions:**
4. **Aim:**
5. **Objectives:**
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. **Scope of the project-** *The relevance and expected outcome of the proposed study*
9. **References (Maximum 12)**
10. **Preliminary work (if any) you have already done in relation to the proposed study**
11. **Title(s) of paper(s) published by you in relation the subject and allied field, if any.**
12. **Timelines:**

Milestone	Targets

13. Is the facility viz. physical facilities, equipment, trained manpower etc. required for the conduct of research project available in the institute? Yes ☐ No ☐
14. Is the necessary support from various other specialties required for the conduct of the project ascertained? Yes ☐ No ☐
15. 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)

Signature of Principal Investigator with seal
Date

Signature of Co-Investigator(s) with seal
Date

Signature of Head of the Department with seal
Date

(D) DECLARATION (Please strike off the point if not applicable)	
1	I/We certify that the information provided in this application is complete and correct.
2	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
3	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.
4	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.
5	I/We will comply with all policies and guidelines of the institute and affiliated/ collaborating institutions where this study will be conducted.
6	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC approved protocol.
7	I/We declare that the expenditure in case of injury related to the study will be taken care of.
8	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
9	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.
10	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
11	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
12	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.
13	I/We have the following conflict of interest (PI/Co-PI): 1. ..... 2.....
14	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC approved protocol.
15	I/We declare that the expenditure in case of injury related to the study will be taken care of.
16	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 (Please submit the project proposal in the following sequence only)

S. No	Items	Yes	No	NA	Enclosure No	Remarks (If applicable)
1	Noting sheet (2 blank pages with title of the project and PI Name)	☐	☐	☐		
2	Detailed project proposal	☐	☐	☐		
3	Statistical consultation	☐	☐	☐		
4	Proforma for Budgetary requirements along with quotes from authorized vendors (for Intramural projects only)	☐	☐	☐		
5	Proforma for ethical review	☐	☐	☐		
6	Application form for clinical trial in prescribed format (if applicable)	☐	☐	☐		
7	Undertaking form for clinical trials (if applicable)	☐	☐	☐		
8	Application Form for Socio-Behavioural and Public Health Research (if applicable)	☐	☐	☐		
9	Application form for exemption from review in prescribed format (if applicable)					
10	Application form for expedited review in prescribed format (if applicable)					
11	Participant Information Sheet (PIS) in English, Gujarati and Hindi	☐	☐	☐		
12	Participant Informed Consent Form (ICF) in English, Gujarati and Hindi					
13	Waiver of consent form in prescribed format (if applicable)	☐	☐	☐		
14	Assent form for minors (12-18 years) (if applicable) in English, Gujarati and Hindi	☐	☐	☐		
15	Proforma/Questionnaire/Case Report Forms (CRF) in English, Gujarati and Hindi	☐	☐	☐		
16	Permission to use copyrighted Proforma/ Questionnaire	☐	☐	☐		
17	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
18	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
19	EC clearance of other centers*	☐	☐	☐		
20	Agreement between collaborating partners*	☐	☐	☐		
21	MTA between collaborating partners*	☐	☐	☐		
22	Permission from governing authorities - CTRI/ DCGI/BARC etc (as applicable)	☐	☐	☐		
23	Any other relevant information/ Document related to study	☐	☐	☐		
24	Brief CV of all Investigators in prescribed format	☐	☐	☐		
25	Good Clinical Practice (GCP) training of all investigators in last 3 years	☐	☐	☐		
26	Certificates for Research Methodology training of all investigators	☐	☐	☐		
27	Soft copy of the complete project proposal (in Word format) sent on researchcell@aiimsrajkot.edu.in	☐	☐	☐		
28	Blinded (without investigator details) soft copy of the complete project proposal (in Word format) sent on researchcell@aiimsrajkot.edu.in	☐	☐	☐		

* *For Multicentric projects*