**BIOMEDICAL RESEARCH SUBMISSION FORM FOR**

**INSTITUTIONAL REVIEW AND INSTITUTIONAL ETHICS COMMITTEE**

***General Instructions: a) Tick one or more as applicable. Mark NA if not applicable***

 ***b) Attach additional sheets wherever required***

1. **TITLE OF STUDY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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1. **DETAILS OF PRINCIPAL INVESTIGATOR/ STUDENT/ FELLOW:**
2. **Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. **Department/Division:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. **Designation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. **Date of Submission:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. **No of ongoing studies:**

Non-Funded- Institutional  Non-Funded- Multicentre  Funded 

1. **List of participating investigators/ guides and co-guides:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Designation | Department and Institution | Mobile and e-mail | Justification for including each investigator/ co-guide |
| Principal Investigator/Student/Fellow |
|  |  |  |  |  |
| Co-investigator/Guide/Co-Guide |
|  |  |  |  |  |
|  |  |  |  |  |
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|  |  |  |  |  |

1. **RESEARCH RELATED DETAILS:**
2. **Overview of research Methodology**

 Basic Sciences 

 Clinical 

 Cross Sectional 

 Retrospective 

 Epidemiological/ 

 Public Health

 Case Control 

 Prospective 

Sociobehavioural 

Cohort 

Qualitative 

 Systematic Review 

Quantitative  Biological samples/Data 

Any others (Specify) 

1. **Nature of Study:**
2. Faculty Driven  Student Driven  Specify details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Single Centre  Multicentric (National)  Multicentric (Global) 
4. **Duration of study:**
5. **Funding details and budget:**
6. Type of study:

Non-funded  Intramural/ Institutional  Extramural 

1. In case of funded study, fill the following details:
2. Specify type of funding agency:

 Government  Private  AIIMS, Jodhpur 

1. Name of funding agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Estimated budget in INR:
	1. Extramural fund (Sanctioned for AIIMS Jodhpur): \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Total (if multicentric): \_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. Student/ Intramural fund (Funding sought): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
1. **Summary of proposed study in 300 words including PICOT, research question, aims and objectives, inclusion exclusion criteria and expected outcomes:**
2. **Novelty Statement:**
3. **Sample size/ No. of Participants (as applicable)**
4. At site: \_\_\_\_\_\_\_\_\_ India: \_\_\_\_\_\_\_\_\_\_\_ Globally: \_\_\_\_\_\_
5. Control group: \_\_\_\_\_\_\_\_\_\_\_\_ Study Group: \_\_\_\_\_\_\_\_\_\_\_\_\_
6. Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation
7. **Is there an external laboratory/ outsourcing involved for investigations?**

(If yes; provide details and attach relevant documents/MTA/ MoU etc.)

1. **Future Implications:**
2. **PARTICIPANT RELATED INFORMATION:**
3. **Type of participants in the study:**

 Healthy volunteer  Patient 

 Vulnerable person/ Special groups  Others (Specify) 

1. **If vulnerable person /special group:**

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 diseases) 

Any other (Specify): 

1. **Is any of the clinician involved directly in clinical care of vulnerable population included as PI or CoI, if not justify**
2. **Are there any incentives to the participant?**

 Yes  No 

If yes; Provide details:

1. **BENEFITS AND RISKS:**
2. **Are there any anticipated physical/social/psychological discomforts/ risk to participants?**

 **Yes  No **

1. **If yes, categorize the level of risk2:**

 Less than Minimal risk  Minimal risk 

 Minor increase over minimal risk or Low Risk  More than Minimal Risk or High Risk 

1. **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    

1. **INFORMED CONSENT:**
2. **Type of consent planned for:**
3. Written Informed consent 
4. Audio-Video (A/V) consent 
5. Consent from LAR 
6. For children<7 yrs parental/LAR consent 
7. Verbal assent from minor (7-12 yrs) along with parental consent 
8. Written Assent from Minor (13-18 yrs) along with parental consent 
9. Other (specify) 
10. **Participant Information Sheet (PIS) and Informed Consent Form (ICF):**

English  Hindi  Others (specify) 

1. **STORAGE AND CONFIDENTIALITY:**
2. **Who will be maintaining the data pertaining to the study? How long the data will be stored?**
3. **Whether provisions for maintaining confidentially and privacy of the participants have been addressed?**

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

1. **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 

1. **Will the results of the study be reported and disseminated?**

 Yes  No  NA 

1. **Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details**

 Yes  No  NA 

* + 1. **DO YOU HAVE ANY ADDITIONAL INFORMATION TO ADD IN SUPPORT OF THE APPLICATION, WHICH IS NOT INCLUDED ELSEWHERE IN THE FORM? IF YES, PROVIDE THE DETAILS.**

 Yes  No 

**TECHNICAL DETAILS OF PROJECT**

**Introduction:**

**Rationale of the study supported by cited literature:**

**Hypothesis:**

**Research questions:**

**Aims and Objectives:**

**Detailed methodology:**

**Inclusion criteria:**

**Exclusion criteria:**

**Data analysis plan:**

**Review of literature:**

**The relevance and expected outcome of the proposed study:**

**References:**

**Details of funding sought:**

**Timelines:**

**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 including responsible.

 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 EC approved protocol.

 I/We declare that the expenditure in case of injury related to the study will be taken care of, if applicable

 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 safety and confidentiality of study 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)

 I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI/ Student: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_

Name of Co-I/ Guide: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_

Name of Co-I/ Co-guide: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_

Name of Co-I/ Co-guide: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_

Name of HOD: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| **CHECKLIST** |
| **S.No** | **Items** | **Yes** | **No** | **NA** | **Enclosure No.** | **EC Remarks(If applicable)** |
| **ADMINISTRATIVE REQUIREMENTS** |
|  | Cover letter  |  |  |  |  |  |
|  | Brief CV of all Investigators |  |  |  |  |  |
|  | EC clearance of other centers |  |  |  |  |  |
|  | Agreement between collaborating partners |  |  |  |  |  |
|  | MTA between collaborating partners |  |  |  |  |  |
|  | Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification |  |  |  |  |  |
|  | Copy of contract or agreement signed with the sponsor or donor agency |  |  |  |  |  |
|  | Plagiarism Similarity Report  |   |   |   |  |  |
| **PROPOSAL RELATED** |
|  | Copy of the detailed protocol |  |  |  |  |  |
|  | Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated) |  |  |  |  |  |
|  | Assent form for minors (12-18 years) (English and Translated) |  |  |  |  |  |
|  | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated) |  |  |  |  |  |
|  | Advertisement/material to recruit participants (fliers, posters etc) |  |  |  |  |  |
| **PERMISSION FROM GOVERNING AUTHORITIES** |
|  | **Other Registration/ permissions** | **Required** | **Not required** | **Received** | **Applied dd/mm/yy** | **EC Remarks** |
|  | Tribal Board |  |  |  | Enter date |  |
|  | Others (Specify) |  |  |  | Enter date |  |
| **ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY** |
|  | **Item**  | **YES**  | **NO** | **NA** | **Enclosure no.** | **EC remarks** |
|  |  |  |  |  |  |  |