**CLINICAL TRIAL 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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**B. PRINCIPAL INVESTIGATOR DETAILS:**

1. **Name of Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. **Department/Division:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. **Designation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. **Date of Submission:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. **No of ongoing studies:**

Non Funded-Institutional: \_\_\_\_\_

Non –funded-Multicentric: \_\_\_\_\_

Funded: \_\_\_\_\_

1. **Is the PI trained in GCP in last 3 years? If yes, please enclose certificate**

 Yes  No  NA 

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 |
|  |  |  |  |  |
|  |  |  |  |  |
|   |  |  |  |  |

**RESEARCH RELATED DETAILS:**

1. **Tick all categories that apply to your trial:**

Phase – I 

Phase II  Phase III 

Phase IV or Post Marketing Surveillance  Investigational medicinal products  Investigational New drug 

Medical devices  New innovative procedure  Drug/device combination 

Bioavailability/Bioequivalence studies  Non-drug intervention 

Repurposing an existing intervention 

Indian system of medicine (AYUSH) 

Stem cells 

Phytopharmaceutical drug 

Approved drug for any new indication

or new route of administration 

Others (specify) 

1. **Trial design of the study (May choose more than one):**

Randomized 

Factorial  Non randomized 

Stratified 

Parallel 

Adaptive  Cross-over 

Comparison trial 

Cluster 

 Superiority trial 

 Non-inferiority trial 

 Equivalence trial 

 Others (specify) 

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

Non-Funded  Intramural/ Institutional  Extramural 

* 1. In case of extramural, 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. **Future Implications:**
4. **Sample size/ No. of Participants (as applicable)**
5. At site: \_\_\_\_\_\_\_\_\_ India: \_\_\_\_\_\_\_\_\_\_\_ Globally: \_\_\_\_\_\_
6. Number of Groups:

 Control Group: \_\_\_\_\_\_\_\_ Study Group: \_\_\_\_\_\_\_\_

1. Number of Participants:

Control Group: \_\_\_\_\_\_\_\_\_ Study Group: \_\_\_\_\_\_\_\_\_\_\_\_\_

1. Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation
2. **Is there an external laboratory/ outsourcing involved for investigations? Give details**
3. **If there is randomization, how will the participants be allocated to the control and study group(s)?**
4. **Describe the method of allocation, concealment and blinding, if applicable**
5. **List the primary / secondary outcomes of the trial.**
6. **Is there a Contract Research Organization (CRO) /Site Management Organization (SMO) / Any Other Agency such as public relation/Human resource?**

 Yes  No 

1. If yes, Name and Contact details:
2. State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management 

Clinical and medical monitoring  Regulatory affairs 

Data management 

Statistical support 

Medical writing 

 Site management 

Audits, quality control, quality assurance  Finance management 

Recruitment and training  Administrative support 

Others (specify) 

1. **Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details**

Yes  No  NA 

1. **Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.**
2. **Provide details of patent of the drug/s, device/s and biologics.**
3. **Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.**
4. **Provide details of patent of the drug/s, device/s and biologics**.
5. **Is there an initial screening/ use of existing database for participant selection?**

 Yes  No  NA 

 If yes, provide details

1. **Are there any anticipated incidence, frequency and duration of adverse events related to the intervention? If yes, provide details of arrangements made to address** them.

Yes  No  NA 

1. **Does the study use a placebo?**

Yes  No  NA 

If yes, justify the use of the placebo and risks entailed to participants.

1. **Will current standard of care be provided to the control arm in the study?**

 Yes No  NA 

If no, please justify.

1. **Are there any plans to withdraw standard therapy during the study? If yes, please justify.**

Yes  No  NA 

1. **Are there any rules to stop the protocol in case of any adverse events? If yes, please specify.**

Yes  No  NA 

1. **Does the study have a Data and Safety Monitoring Plan? If no, please justify.**  Yes No 
2. **Involvement/consultation of statistician in the study design**

Yes No  NA 

1. **Is there any insurance coverage of the trial? If yes, provide details.** Yes No  NA 

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

 Healthy volunteer  Patient 

 Vulnerable person/ Special groups  Others (Specify) 

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

Children under 18 yrs 

Pregnant or lactating women 

Differently abled (Mental/Physical) 

Employees/Students/Nurses/ Staff 

Elderly 

 Economically & socially disadvantaged 

 Refugees/Migrants/Homeless 

 Terminally Ill (stigmatized/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 

Provide details:

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

Yes  No 

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

English  Hindi  other (*specify*) 

1. **PAYMENT/COMPENSATION:**
2. **Who will bear the costs related to participation and procedures?**

 PI  Institution  Sponsor  Other agencies (specify) 

1. **Is there a provision for free treatment of research related injuries?**

 Yes  No  NA 

 If yes, then who will provide the treatment?

1. **Is there a provision for compensation of research related SAE? If yes, specify**.
2. Yes  No  NA 
3. Sponsor  Institution/ Corpus funds 

Project grants  Insurance 

1. **Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify.**

 Yes  No  NA 

1. **Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.** Yes  No  NA 
2. **STORAGE AND CONFIDENTIALITY:**
3. **Who will be maintaining the data pertaining to the study. How long the data will be stored?**
4. **Whether provisions for maintaining confidentially and privacy of the participants have been addressed?**
5. **PUBLICATION, BENEFIT SHARING AND IPR ISSUES:**
6. **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 |  |  |  |  |  |
|  | Good Clinical Practice (GCP) training of investigators in last 3 years |  |  |  |  |  |
|  | Approval of Scientific Committee |  |  |  |  |  |
|  | EC clearance of other centers |  |  |  |  |  |
|  | Agreement between collaborating partners |  |  |  |  |  |
|  | MTA between collaborating partners |  |  |  |  |  |
|  | Insurance policy/certificate  |  |  |  |  |  |
|  | 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 |  |  |  |  |  |
|  | Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol |  |  |  |  |  |
|  | Plagiarism Check Similarity Report |  |  |  |  |  |
|  |
|  | Copy of the detailed protocol |  |  |  |  |  |
|  | Investigators Brochure (If applicable for drug/biologicals/device trials)  |  |  |  |  |  |
|  | 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** |
|  | CTRI |  |  |  | Enter date |  |
|  | DCGI |  |  |  | Enter date |  |
|  | HMSC |  |  |  | Enter date |  |
|  | NAC-SCRT |  |  |  | Enter date |  |
|  | ICSCR |  |  |  | Enter date |  |
|  | RCGM |  |  |  | Enter date |  |
|  | GEAC |  |  |  | Enter date |  |
|  | BARC |  |  |  | Enter date |  |
|  | 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** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |