Application to the
University of Hyderabad Institutional Ethics Committee
For Approval of a Research Project

Basic Information	
1. Title of the Project	
2. Name of the Applicant	
3. Principal Investigator	
3.1.Affiliation (Department, Institute)	
3.2. Address	
3.3. Contact No	
3.4. Email	
4. Co-Investigator 1	
4.1. Affiliation (Department, Institute)	
4.2. Address	
4.3. Contact No	
4.4. Email	
5. Co-Investigator 2	
5.1. Affiliation (Department, Institute)	
5.2. Address	
5.3. Contact No	
5.4. Email	
6. Co-Investigator*	
6.1. Affiliation (Department, Institute)	
6.2. Address	
6.3. Contact No	
6.4. Email	
7. Application Date	

**Additional box may be added, if space is inadequate*

Outline of Proposed Research

1. **Background:**
   (In 100-200 words, background about the study, rationale and need for the study. Provide relevant references)

2. **Aims and Objectives:**

3. **Hypothesis (as applicable):**

4. **Research category (Quantitative, Qualitative, Mixed, Applied, Basic etc) and Research/Study Design:** ***(Ex: Qualitative – Exploratory)***

5. **Methodology:**

   Study Area:

   Institutions of collaboration:

   Study/Performance Sites:

   Target Respondents & Age group + Gender (clearly mention vulnerability):

   Sampling process and sample size:

Risks, Benefits, Safety & Other Controls

1. What are the potential risks involved? State any potential or known hazards of the procedure listed in the methodology and how does the investigator intend to overcome this aspect.

2. Does this study involve ionizing radi**ation, hazardous substances,** invasive procedures (including radiological imaging, venipuncture, or any other invasive procedures or intimate physical examination)? If yes, please justify

3. What are the compensations for Unexpected Risks?

4. If there are any novel interventions to be used in the study which is not the medically-accepted 'treatment of choice' within the local context, explain why a novel intervention is being tested, and what arrangements will be made to switch subjects over to the 'treatment of choice' if the experimental intervention is not effective.

5. What are the potential benefits to the subjects?

6. What are the potential severe adverse events (SAE) anticipated in this proposed study?

Type of SAE	Likelihood of Occurrence	Strategy to reduce occurrence

What will be the likelihood of occurrence and strategies to reduce the occurrence?

7. Please state whether subjects will have to bear any expenses related to medicines or investigations or travel or if they have to forego their work/pay in relation to participation or any other costs in relation to the study. State how the expenses would be met.

8. Will the subjects receive financial benefit / other material benefit as a result of participation in this study? Please specify.

Consent, Confidentiality

1. How will informed consent be obtained and by whom? *(Mandatorily provide a copy of the participant information sheet and consent form)*

2. Is **allocation involved in selection of participants** i.e. will participants know they are part of the research? Yes / No, If yes (allocation – random/nonrandom/selected etc), explain how and why?

3. What procedures will ensure the confidentiality of participants? Will the identifiable information be removed? How will data be stored and for how long?

4. How will results be disseminated? What information will be fed back to the subjects and/or participating organization?

Conflict of Interest/Sponsored/Proprietary Interest

1. Please state any conflict of interest/sponsorship/proprietary interest is involved in the study and its team? (financial / non-financial) – Provide supportive documents as annexures.

Declaration by the Principal Investigator

I certify that the information provided by me is complete and correct. I understand that as principal Investigator, I will take full responsibility for the protection of rights and welfare of all participants/study subjects including the conduct of study and ethical performance of the project. I agree to comply will all rules and regulations of IEC and University of Hyderabad for the conduct of the study / trial.

I hereby declare that:

- Qualified personnel according to IEC guidelines will conduct the study.
- No change will be made in the protocol or consent form until approved by the IEC.
- Legally effective informed consent will be taken from Human subjects as applicable.
- Adverse events will be reported to IEC as per ICH GCP/DCGI Adverse event reporting policy.
- I further certify that the proposed research is not currently being conducted and will not begin until IEC approval has been obtained.

Sl.No	Research Team	Signature	Date
1	**Principal Investigator**		
2	**Co-Investigator 1**		
3	**Co-Investigator 2**		
4	**Co-Investigator 3**		
5	**Co-Investigator 4**		

NOTE: All proposals submitted will be subjected to technical review or specialty expert sub-committee whetting and those comments will have to be clarified appropriately before it is taken up for consideration of the IEC.

Details of Exemption/Expedited from Full Review

1. **Are you requesting for:**
   a) Exemption from full review – Yes/No
   b) Expedited Review - Yes/No

2. **Under which category are you claiming this? Please highlight in the list by encircling.**

A. Exemption from Full Review of EC

i. Research on data in the public domain/ systematic reviews or meta-analyses;
ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person;
iii. Quality control and quality assurance audits in the institution;
iv. Comparison among instructional techniques, curricula, or classroom management methods;
v. Consumer acceptance studies related to taste and food quality;
vi. Public health programs by government agencies.

B. Expedited review from EC

i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and of left-over clinical samples.
ii. Involves clinical documentation materials that are non-identifiable (data, documents, records).
iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)).
iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal.
v. Minor deviation from originally approved research causing no risk or minimal risk.
vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.
vii. For multi-centre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre.
viii. Research during emergencies and disasters ***(See Section 12 of ICMR Ethical Guidelines, 2017 - https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)***

3. **Justification for claim in Point 2 above:**

Human Research during COVID-19 pandemic times

1. Will you be carrying out this Research during Covid-19 Pandemic times? Yes/No

2. If Yes - highlight the steps of how you will take to ensure health/safety/wellbeing/protection of stakeholders of this research.