	HITEC-Institute of Medical Sciences		
	Synopsis Submission Form for IRB and ERB Approval		
	IRB-Form-01	ISSUE # 01	ISSUE DATE: 06-05-2021

Research Cell

HITEC-IMS

Proposal Submission Form

Title:_____

_____

Researcher/Co-researcher:

1. **Name, designation, department, mobile, email**
2. _____
3. _____

Supervisor:
Name, designation, department, mobile, email

Researchers' contribution: (Proposing the research project, Drafting of the initial research proposal, construction of research questionnaire, data collection, data analysis, literature search, manuscript writing, any other)

1._____

2_____

3._____

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1. Introduction:

a. Brief review:

b. Previous related studies:

c. Rationale of the study:

2. Objective(s) of the Study:

3. Hypothesis:

4. Operational Definitions:

5. Methodology:

a. Study Design:
b. Study setting:
c. Study duration:
d. Study population
   i. Brief explanation of subjects (e.g. age range, sex)
   ii. Inclusion/Exclusion Criteria
e. Informed written/verbal consent:
f. Sample Size:
g. Sampling technique:
h. Data collection procedure: Proforma/the Data collection form/the questionnaireshould be attached with the synopsis as Annexure A
i. Statistical analysis:

6. The relevance and expected outcome/impact of the proposed study?

7. Collaborating Labs/Department (if any):
8. Conflict of interest:
9. Estimated Budget:
10. Funding Source:
11. Ethical Consideration: (Consent form should be attached with the synopsis as Annexure B). Fill in the following points

- Study will be performed on human subjects ☐ or animal subjects ☐
- Does the study involve participants who are particularly vulnerable? (patients with sensitive medical conditions e.g., HIV/AIDS, drug addiction) or are unable to give informed consent (e.g., children, people with learning disabilities)?

● Written/oral informed consent obtained:	Yes	No
● Specify the type of consent taken:		

• Have you obtained prior consent with the explicit right of the participants to include them or to withdraw from the study at their will?		
• Confidentiality & privacy of the participants will be maintained		
• Any known/potential risks to the participants		
• If yes, then mention nature and degree of risk/adverse effects:		
• How will these be managed? who will bear the cost?		
• Any monetary benefit will be given to the participant (for medication, test or investigation done):		
• Is there any potential conflict of interest relating to the study? If yes, then have you declared the nature of conflict?(This declaration should be made a part of any existing proforma)		
• Will drugs, placebos, or other substances (e.g., food or drink constituents, dietary supplements) be administered to the study participants?		
• Does this study involve handling, transportation and storage of Infectious agents, toxins, or chemicals (pathogenic to humans, animals, or plants)?		
• If answer is yes, then are the standard biosafety measures (contamination control spill response, waste management, use of protective apparel, and inventory control) ensured for the execution of this project?		
• If the study involves distribution of questionnaires to the participants, has the right to Response Omission and Anonymity been provided to them?		
• In case of animal studies, have you considered alternatives (*in-vitro* systems, computer simulations and/or mathematical models) to reduce or replace the use of animals as far as possible?		
• Will you make sure that the health of humans/animals be given prior consideration and avoid or minimize discomfort, distress, and all procedures will be kept aseptic, painless and minimally intrusive?		
• Will you provide adequate care to all humans/animals and ailing study subjects shall be properly treated by the qualified care providers and will be removed from further study?		
• Will you share study findings with the participants and IRB/ERB HITEC-IMS if/ when asked?		
• Will you make sure that the results are only used for research purpose and information disseminated only through research publication / conference papers/presentations?		
• Will you make sure that the health of humans/animals be given prior consideration and avoid or minimize discomfort, distress, and all procedures will be kept aseptic, painless and minimally intrusive? If Yes give brief Detail:_____		

12. Total number of references_____. How many are older than 5 years?
(preferably >80% should be within 5 years) _____

13. List of References:

Name of focal Person: _____

Date: _____

Name of Head of the Department: _____

Date: _____

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