|  |  |
| --- | --- |
| dff | **Emmanuel Hospital Association** |
| **Institutional ETHICS COMMITTEE** |

**APPLICATION FOR APPROVAL OF A RESEARCH PROJECT - 2025**

**Project Title:** ………………………………………………………………………………………………………………

 …….………………………………….…………………………………………………………………….

1. BASIC INFORMATION: Version No. ………………

|  |  |
| --- | --- |
| Name of EHA Principal Investigator (Indian)Address for correspondence:Phone no:E mail: |  |
| Other Principal Investigator:  (if any) E mail address:Mobile No.  |  |
| Other Co- Investigators: E mail address:Mobile No. |  |
| Collaborator: National / Overseas |  |
| University: |  |
| Funding Agency / Sponsoring Organization:Address:Phone:E mail: |  |
| Site contact details: [place(s) where research will take place]Name:Address:Phone no:E mail:  |  |
| Approved budget for the research: |  |
| Research start datePeriod of data collection |   ………………………………..From…..………..………. to……………………..  |
| Date of submission: |  |

2. **JUSTIFICATION OF RESEARCH:**

|  |
| --- |
| Rationale for undertaking the research in the light of existing knowledge- (100-200 words) |

3. **AIMS/ OBJECTIVES/ OUTCOMES:**

|  |
| --- |
| 3.1 Hypothesis or research question: 3.2 Overall aim:3.3 Objectives: 3.4 Expected Outcomes: |

4. **STUDY DESIGN:**

|  |
| --- |
| Give a detailed description of the methodology of the proposed research (1-2 pages). |

|  |
| --- |
| 4.1 Participant recruitment procedure: Who are the research participants? (Eg: adult men, adolescents, age etc.). Explain how the participants will be recruited. 4.2 i. What are the Inclusion criteria for entry of participants in the research? ii. What are the exclusion criteria for entry of participants in the research?4.3 Inclusion and exclusion criteria for control participants, if any:* 1. Number of Participants:
1. Sample size for quantitative date collection: What is the sample size? Justify the sample size. What sample size calculations were done to determine the number of participants? Mention the plans for statistical analysis of the study.
2. Qualitative data collection:

FGDs =Interviews =In depth Interviews =Key Informant Interviews =Self-administered questionnaire =Case studies =Others (Specify)…………….……………. |

5. **RISKS AND BENEFITS:**

|  |
| --- |
| 5.1. What are the potential risks to the participants? (State social and emotional risks as well as more obvious physical risks).5.2. What is your risk management plan?5.3. What will be the compensation for unexpected risks?5.4. What are the potential benefits to the participants? |

6. SAFETY AND OTHER CONTROLS:

|  |
| --- |
| 6.1 Does this study involve ionizing radiation, hazardous substances, or hazardous or invasive procedures (including radiological imaging, vein puncture, or intimate physical examination)?Yes/NoIf yes, please justify: |

7. INFORMED CONSENT:

|  |
| --- |
| 7.1 What will be the procedure for seeking Informed Consent from research participants? How will “research”, “randomization”, “risks and benefits” be explained? 7.2 What will be the procedure for seeking Informed Consent from parents/guardians etc. of research participants who are children, mentally/ physically challenged? How will assent be obtained from these research participants?7.3. How will it be made clear that participants are under no compulsion to participate and may withdraw at any time without jeopardizing any service delivery or their relationship with the researcher?7.4. Details of consent if the participants are audio –taped / video-taped? 7.5. Provide a copy of Plain Language Statement and Informed Consent Forms in English.7.6. Details of proposed compensation and reimbursement of incidental expenses.7.7. Statement of probable ethical issues and steps taken to tackle the same. |

8. CONFIDENTIALITY:

|  |
| --- |
| 8.1 What procedures will ensure the confidentiality of participants?8.2 The raw data collected will be locked and protected. *I agree / disagree*8.3 The electronic data will be pass -word protected. *I agree / disagree* |

9. **OWNERSHIP & STORAGE OF DATA:**

|  |
| --- |
| 9.1 The data collected during the research will be stored and maintained by EHA Principal Investigator. The other Principal Investigators will have a copy of the data.*I agree / disagree*9.2 All the Principal Investigators will be responsible for the safety of the data.*I agree / disagree* |

10. **POTENTIAL CONFLICT OF INTEREST:** (any financial interest for researchers)

|  |
| --- |
|  Conflict of Interest: *Yes / No* |

11. **REPORT:**

|  |
| --- |
| 11.1 The research report will be finalized after all the principal investigators agree with the report.*I agree / disagree* |

12. **PLANS FOR PUBLICATION & DISSEMINATION:**

|  |
| --- |
| 12. 1 All the Principal Investigators with mutual agreement will publish Articles/ Reports. *I agree/ disagree* 12. 2 How will results be disseminated? 12.3 What information will be fed back to the participants and/or participating organization? |
| **REVIEW FEE DETAILS**  |
| Date: |  |
| Amount: |  |
| Cheque number (if any) |  |
| Transaction ID |  |

CHECK LIST:

1. Proposal [ ]
2. Tools for data collection [ ]
3. Consent form [ ]
4. Role of researchers [ ]
5. Recent CV of Investigators indicating qualification & experience particularly in research (find attached CV format ) [ ]
6. Non-refundable Review fees- [ ]

**RESEARCH PROTOCOL REVIEW FEE**

 Review fess (if applicable) as Cheque drawn in favor of “Emmanuel Hospital Association” or by online transfer to

|  |
| --- |
| Account name: Emmanuel Hospital AssociationAccount Number: 3812023724Name of Bank: Kotak Mahindra Bank, Nehru PlaceIFSC code:   KKBK0000201 |

**Note:**  Kindly note that this fees is non refundable

|  |  |  |
| --- | --- | --- |
| **S. No** | **Particulars** | **Fees (INR)** |
| 1 | EHA Research (Not funded Research) |  No fee |
| 2 | EHA Research (Funded – up to 10 Lacs) |   10,000 |
| 3 | EHA Research (Funded - > 10 Lacs to 50 Lacs) |  15,000 |
| 4 | EHA Research (Funded - > 50 Lacs  |   20,000 |
| 5 | PG Diploma (Indian Student) |   500 |
| 6 | Masters (Indian student) |  750 |
| 7 | PhD research (Indian student) |  1000 |
| 8 | Overseas student (Wheaton college etc.) |   2500 |
|  |