**Institutional Scientific/ Research Committee**

**Study Protocol Submission Form**

**Email id:** [**ircannoor@gmail.com**](mailto:ircannoor@gmail.com)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IRB/SRB Study Proposal No.** | | | | | |  | | | | | | |
| **Title of the Study** | |  | | | | | | | | | | |
| **Clinical Trials: Yes / Not Applicable** | | | | | | | | | | | | |
| **If Yes does the study involve use of :** | | | | | | | | | | | | |
| Drug | Devices | | | Vaccine | | | Alternate system of Medicine | | Any Other (specify): | |  | |
| **Is it approved and marketed in** | | | | India | | | Other countries (specify): | |  | | | |
| **Description of Research protocol including following details:** | | | | | | | | | | | | |
| **Introduction** | | |  | | | | | | | | |
| **Rationale** | | |  | | | | | | | | |
| **Research Question** | | |  | | | | | | | | |
| **Objectives** | | |  | | | | | | | | |
| **Null Hypothesis Ho** | | |  | | | | | | | | |
| **Research Hypothesis Ha** | | |  | | | | | | | | |
| **Proposed study design** | | | | | | | | | | | | |
| **Study design** | | | | |  | | | | | | | |
| **Setting/ place of research** | | | | |  | | | | | | | |
| **Study population** | | | | | Groups | | | Justification | | Power | | |
|  | | | | |  | | |  | |  | | |
| **Sampling procedure** | | | | |  | | | | | | | |
| **Methods of data collection** | | | | |  | | | | | | | |
| **Outcome measurement** | | | | |  | | | | | | | |
| **Plan of Analysis/ Statistical Analysis** | | | | |  | | | | | | | |
| **Storage & disposal procedures of biological / hazardous material (if needed for your project)** | | | | |  | | | | | | | |
| **Duration of study** | | | | |  | | | | | | | |
| **Consent: Attached Not Attached** | | | | | | | | | | | | |
| **If consent is not applicable to your research project / study, please submit a waiver of consent application form and confidentiality statement to IHEC** | | | | | | | | | | | | |
| **Conflict of Interest** | | | | | | | | | | | | |
| 1. Do you have conflict of interest Yes No 2. If yes specify | | | | | | | | | | | | |
| **Storage and archival of study documents** | | | | | | | | | | | | |
| Periodand site of storage | | | | | | | | | | | | |
| **Budget allocation** | | | | | | | | | | | | |
| Budget, if a funding agency/ fund from outside | | | | | | | | | | | | |
| **List of collaboration or held from consultants, if any- willingness certificate** | | | | | | | |  | |  | | |
| **Permission letters** | | | | | | | | | | | | |
| **Permission to collect data from departments (attach permission letters in separate sheet).** **Write below the names of departments and institutions from where samples are to be collected.**  It is the responsibility of the PI to obtain permission from every department of Annoor Dental College involved in data collection (and heads of departments as well as institutions, if samples are collected and/or diagnostic or imaging services are used from the respective departments / institutions) by furnishing all necessary information (including purpose, sample size, cost involved, etc., to the heads of the departments concerned). | | | | | | | | | | | | |
| **Permission to carry out the study elsewhere (outside ADC): Yes** **/ No**  **/ NA** | | | | | | | | | | | | |
| If study will be conducted fully or partially outside the ADC, please describe the need, permission from institution(s), health centre(s), local government/administrative bodies, etc. Attach permission letters obtained already, if any | | | | | | | | | | | | |
| **Signature of PI** | | | | | | | | | | | | |
| Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IRC are the same.  Name:  Designation, Department & Name of the Institution:    Date: Signature of PI | | | | | | | | | | | | |
| **Signature of Guide** | | | | | | | | | | | | |
| I have reviewed this project proposal and consent to guide this project.  Name of the Guide:  Designation, Department:  Date: Signature of the Guide | | | | | | | | | | | | |
| **Forwarded by the Head of PI’s Department** | | | | | | | | | | | | |
| I am forwarding the above project submitted by ……………………………………… Principal Investigator from my Department. I endorse the project and have ‘no objection’ for submission for consideration by the IRC.  I concur with the participants / investigators included in the study.  The department has adequate facilities to carry out this study and the investigators (s) is/ are permitted to use the facilities available in this department to carry out the study.  Name of the Head of the Department:  Signature of the Head of the Department with date: | | | | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Checklist of documents to be submitted with the Study Protocol Submission Form** | | | |
| **Item Description** | **Yes** | **No** | **NA** |
| Covering Letter |  |  |  |
| Protocol submission form |  |  |  |
| Description of proposal (Study Protocol Format) |  |  |  |
| Informed Consent form (in English & regional languages) |  |  |  |
| Waiver of consent |  |  |  |
| Permission letter(s) from heads of departments other than that of the PI, if study involves data collection / uses diagnostic and/or imaging services from other departments |  |  |  |
| Other (specify): |  |  |  |