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**Checklist for submission of the Research Protocol for approval from the JSSDCH IEC**

**P T O**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| S No | Particulars | Yes | No | Reason for “No” | JSSDCH IEC Secretariat to confirm |
|  | Covering letter to the Member Secretary JSS Dental College & Hospital Institutional Ethics Committee requesting ethical clearance |  |  |  |  |
|  | Research Protocol two hard copies |  |  |  |  |
|  | Research Project proposal – soft copy sent by e-mail: [**jssdchiec@gmail.com**](mailto:jssdchiec@gmail.com) and to be submitted by using the Google forms mentioned on the JSSDCH IEC website. (Please note that there should be no discrepancy between the hard copy and the soft copy submitted) |  |  |  |  |
|  | Briefly signed copy of the Curriculum Vitae (CV) of All the Investigators (including PI, Co-PI, and Guide) not more than two pages focusing on research activities and research training. |  |  |  |  |
|  | Brief description of the proposal Including the following: |  |  |  |  |
|  | 1. Title of the study |  |  |  |  |
|  | 1. Rationale and background information |  |  |  |  |
|  | 1. Review of literature: Around 3 to 5 relevant articles. |  |  |  |  |
|  | 1. Aims & Objectives |  |  |  |  |
|  | 1. Methodology |  |  |  |  |
|  | 1. Study design: Prospective/Retrospective Observational/Interventional |  |  |  |  |
| 1. Type & duration of the study |  |  |  |  |
| 1. Study setting & source of data |  |  |  |  |
| 1. Sample size and its estimation including sampling procedure |  |  |  |  |
| 1. Inclusion criteria |  |  |  |  |
| 1. Exclusion criteria |  |  |  |  |
| 1. Details on discontinuation/withdrawal of participant from study criteria (Example: Occurrence of complications or noncompliance by the participant) |  |  |  |  |
| 1. Details of clinical examination/data collection tools   (if applicable) (attach anonymized clinical data collection  proforma) **Annexure 2** |  |  |  |  |
|  | 1. Details of the questionnaire (if applicable)   (attach anonymized questionnaire wherever necessary with translation) **Annexure 2** |  |  |  |  |
|  | 1. Vulnerable participant (Example: Children, pregnant women, students, Psychiatric illness, etc.) (if yes, justify) |  |  |  |  |
|  | 1. Timeline of the study: **Annexure 3** |  |  |  |  |
|  | 1. Details of investigations done (if applicable) |  |  |  |  |
|  | 1. Letter of Participation / Permission from Collaborators  * Like other Departments/Institutions for doing the research |  |  |  |  |
| * Whether samples will be sent outside the Institution Material Transfer Agreement (as applicable) |  |  |  |  |
| * Memorandum of Understanding (as applicable): **Annexure 4** |  |  |  |  |
|  | 1. Details on whether the data/samples/tissues are likely to be shared with others |  |  |  |  |
|  | 1. Use of placebo (if yes, justify) |  |  |  |  |
|  | 1. Budget/Expenditure and how the finances will be met: **Annexure 5** |  |  |  |  |
|  | Principal Investigator/Co-Investigators signatures  Guide's/ Co guide's signatures where ever applicable |  |  |  |  |
|  | Patient Informed Consent/Assent/Parental consent - WHO design: In English: **Annexure 1** |  |  |  |  |
| 1. Is the language simple and clear such that an eight-standard student (English or vernacular) will find it easy to understand |  |  |  |  |
| 1. Whether contact person details are provided in the ICF |  |  |  |  |
| 1. Whether the PI has assured the privacy of participants & confidentiality |  |  |  |  |
| 1. Has the PI taken consent for publication |  |  |  |  |
| 1. Assent form: 7 to 18 Years of age |  |  |  |  |
| 1. Parental consent form: From Birth to 18 Years of age |  |  |  |  |
| 1. Informed consent documents in Regional languages |  |  |  |  |
|  | In the case of a multi-centric study, Ethical clearance of other centers |  |  |  |  |
|  | Statement of Conflict of Interest if applicable |  |  |  |  |
|  | Ethical Issues |  |  |  |  |
|  | 1. Recruitment of participants will start only after the ethical clearance |  |  |  |  |
|  | 1. Protection of vulnerable participants |  |  |  |  |
|  | 1. Disposal of tissue samples |  |  |  |  |
|  | 1. Maintenance of privacy of participants |  |  |  |  |
|  | 1. Maintenance of confidentiality of data |  |  |  |  |
|  | 1. Sharing of samples/data |  |  |  |  |
|  | 1. Compensation to participants |  |  |  |  |
|  | 1. Ensuring the standard of care for participants |  |  |  |  |
|  | 1. Redacting of MRD files/Radiographic material/histopathology slides/blood and tissue samples |  |  |  |  |

Name of the PG/PI with Signature and Date:

**Note: Please tick for Yes or No.**

**Please write as N A (Not Applicable) wherever required**