FORMAT FOR SUBMISSION OF PROJECTS FOR CLEARANCE BY ETHICAL COMMITTEE OF MIDSR DENTAL COLLEGE AND HOSPITAL LATUR

Name of the Investigator :

Name of the Guide/Co-investigator:

Title of the study

Department:

The research projects / proposal submitted should be as follows:

|  |  |  |
| --- | --- | --- |
| 1. Full Title of Study: | |  |
| 2. Name of Investigators / co- investigators with designation and departments  2.1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    2.2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    2.3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    2.4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    2.5\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Signatures  2.1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2.2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2.3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2.4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  2.5\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 3. Objectives of the study | | 3.1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3.2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3.3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3.4\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3.5\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 4. Justification for conduct of this study | |  |
| 5. Methodology | | 5.1. Number of Patients:  5.2. Inclusion criteria  a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.3. Exclusion criteria  a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.4. Control(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.5. Study design \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.6. Dosages of drug \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.7. Duration of treatment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.8. Investigation specifically related to projects\_\_\_\_\_\_\_\_\_\_  5.9 Permission to use copyrighted Questionnaire/proforma  5.10. Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 6. Permission from Drug Controller  General of India (DCGI) | | 1. Required 2. Not required  3. Received 4. Applied when: |
| 7. Permission from DGFT if applicable | | 1. Required 2. Not required  3. Received 4. Applied when: |
| 8. a) Safety measures for proposed  interventions  b) Results of relevant laboratory tests  c) Result of studies in human  if applicable | | a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 9. Plans to withdraw standard therapy  during conduct of research | | Yes No  Remarks:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 10. Plan for provision of coverage for  medical risk (s) during the study  period | |  |
| 11. How you will maintain  confidentiality of subject? | |  |
| 12. **Total Budget (Approx. in Rs.)**  Who will bear the cost of investigation / implants drugs / contrasts? | | 1. Patient 2. Project 3. Exempted  4. Other Agencies (Name)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 13. Participant Information Sheet  *(mark √ if yes)* | Attached English version  Attached Hindi version Certified that Hindi version is a true translation of English version | |
| 14. **Participant Informed Consent Form**  (mark √ if yes) | Attached English version  Attached Hindi version Certified that Hindi version is a true translation of English version | |
| 15. Conflict of interest for any other  investigator(s) (if yes, please  explain in brief | | 1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Yes No  2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Yes No  3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Yes No  4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Yes No |
| 16. Whether any work on this project  has started or not? | | (mark √ if yes, X if no)  *(Please enclose a separate certificate to this effect).* |
| 17.Attached documents  (If any) | | 17.1 Covering letter, through proper channel.  17.2 Copy of the detailed protocol is mandatory.  17.3 Brief CV of Investigators (including No. of projects  with Principal Investigator)  17.4 Investigator’s Brochure  17.5 Undertaking that the study shall be done in  accordance with ICMR and GCP guidelines  17.6 In case of multicentric study, IEC clearance of other  centres must be provided  17.7 Definite undertaking as to who will bear the  expenditure of injury related to the project  17.8 In case an insurance cover is intended, Insurance  certificate must be provided (as per ICMR guidelines)  17.9 Permission as mentioned in column 5.9  17.10 Certificate/undertaking as mentioned in column 16  17.11 Investigator should provide undertaking what they  will do with the leftover sample tissue.  17.12 Others |
| 18. In case of Participants doing clinical trials they should apply for Clinical Trial Registry - India | |  |