Government Dental College& Hospital

 Raipur, Chhattisgarh-492001

 **PROFORMA FOR INSTITUTIONAL ETHICS COMMITTEE**

 **CLEARANCE OF STUDY/RESEARCH PROJECTS**

Note : 1. All columns should be clearly filled up. Use additional sheets, if necessary.

1. Send five copies of the proforma duly signed by the applicant.

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| 1. | Full title of the study/ Research Project | Distraction osteogenesis in patient with temporomandibular joint ankylosis prior to release of joint.  |
| 2 | In case of MDS thesis/Ph.D2.1 Name & signatures of the candidate2.2 Department2.3 Batch of admission to course2.4 Month & year of submission of thesis | \_ |
| 3. | Name of the Principal Investigator/Supervisor, Designation, address and signature | Dr. Biju pappachan  |
| 4. | Name of the Co- Investigators /Co-supervisors, designation, address andsignature | - |
| 5. | Name of the department(s) where research is proposed to be carried out |   |
| 6. | Name of the department(s) that would collaborate in the project. |   |
| 7. | Name of outside institution(s) that would collaborate in the study. |  |
| 8. | In case the study is multi-centric give details of all other centers, investigators etc. |  |
| 9. | Name and address of agency proposed to fund the project/ study and whether any such grant is already available. | Non |
| 10. | Duration of the proposed study/project with phasing and limitations, if any. | 5 years |

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| 11. Brief description of work to be undertaken, material methods etc. :1. Objectives of the study/research project
2. Brief justification about need of study/research project
3. Methodology

 A. Number of Patients: B. Inclusion criteria a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ C. Exclusion criteria a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ D. Control(s) E. Study design F. Dosages of drug G. Duration of treatment H. Investigation specifically related to projects I. Permission to use copyrighted Questionnaire/proforma J. Others |
| 12. | Permission from Drug ControllerGeneral of India (DCGI) | 1 . Not required |
| 13. | Anticipated risks involved in the implementation of the project and remedies suggested (This needs to be given in full details)**RISKS*** Procedural
* Adverse drug reaction due to investigational drug treatment
* Invasive investigation
* Any other risk

Explain measure to counter/compensate the above risk factors |  |
| 14. | Are the necessary facilities available in the department where the research/study is proposed to be carried out? If so, give details thereof. Will patient/subject be sent to other places? Give reasons thereof. (letter of permission/willingness to cooperate from other department(s)/institution(s). |  |
| 15. | Details of facilities which are not available in the department and are proposed to be sought from other Department. (letter of permission/ willingness to cooperate from other department(s). |  |
| 16. | Details of facilities which are not available in Govt. Dental Dollege, Raipur, are to be availed of from other institution(s) (letter of permission/ willingness to cooperate from other institution(s). |  |
| 17. | A.Details of Costs Involved (Appx. in Rs.)B. Who will bear the costs of therequirements? 1. Patient 2. Project 3. Exempted4. Other Agencies (Name)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |   |
| 18. | A) Consent is necessary from the participating subject. A copy of proposed Consent Form in English and Hindi must be enclosed.**Consent form*** Does it have the name of the institution at the top
* Does it also have the name, address and telephone No. of the candidate and Guide/Investigators etc

B) Patient Information Sheet informing patient about* Freedom of individual to withdraw from research.
* Publication, if any including photograph and pedigree chart
* Duration of participation in study
* Benefit that may be expected as an outcome of research to the subject
* Alternative procedure or treatment if available.
* His right to prevent use of his/her biological sample(s) at any time during the conduct of research
* Foreseeable discomfort or risk to the subject
* Extent to which confidentiality of record could be maintained
* Responsibility of investigator
* Provision of compensation of risk

C) Case Record Form |  |
| 19. | Whether clearance has been obtained from any other agency related to the proposed study/ project, if so details thereof. |  |
| 20. | Whether clearance is necessary from any other agency? If so, details thereof |  |
| 21. | Is there any provision to compensate the investigators/victims in case of mishaps? If so, details thereof. |  |
| 22. | In case the project is sponsored by a private agency, particularly a multinational agency having business interest in India, whether prior approval of the competent authority has been obtained? |  |
| 23**.** | Full justification of Project keeping in view the policies and programmes of the Government including details of current knowledge on the subject and therein. | . |
| 24. | Has the project been sent to any other Institution/Body for Ethical Clearance? If yes, give details. |  |
| 25. | Any other information which may be useful for consideration of the project by the IEC |  |
| 26. | Attached documents;A. Covering letter, through proper channel.B. Copy of the detailed protocol is mandatoryC. Undertaking that the study shall be done in accordance with ICMR and GCP guidelinesD. In case of multicentric study, IEC clearance of other centers must be providedE. Definite undertaking as to who will bear theexpenditure of injury related to the projectF. In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)G. Permission to use copyrighted Questionnaire/proformaH. In case of Clinical trials, proof of registration of Clinical trial with ICMR needs to be submittedI. Investigator should provide undertaking what they will do with the leftover sample tissue.G. Others: Permission letters and other necessary documents as per above mentioned Performa |  |