Project Submission / Research Protocol Overview

Name/Names of all Investigator / Investigator (Candidate/student) *(underline principle investigator)* **Name of Institution and Address**	
Course of the study and subject:	
Date of admission of the course	
Title	
Need for the study /Introduction / background ***Give the background, including human or animal research relevant to the design of the proposed study. When new techniques or procedure are to be used, provide a description of preliminary work. When an investigation drug is to be used, animal data and phase I or II data on the drug should be included. A summary of how the study may help in the future should be included in the protocol.***	

REVIEW OF LITERATURE	
Aims / Objectives ***Clearly state the aims or objectives of the study. Whenever possible this should be in the form of a hypothesis.***	
Design of the Study	
Phase-I, Phase-II, Phase-III, Phase-IV, NA	
Randomized [Double or single blind], Open [ ]	
If multicentric, is KCDSH the co-coordinating centre?	
Epidemiological [ ] Survey [ ] Observational [ ]	
Case control [ ], Any other (Specify)	
Study methodology / MATERIALS AND METHODS : ***Explain, in sequence, the conduct of study and all data collection procedures.***	
SOURCE OF DATA	
METHODS OF COLLECTION OF DATA	

Describe the involvement of human subjects including initial evaluation procedures and screening tests, phases, medical/surgical procedures and sequence of the study. Separate standard and experimental aspects of the study as much as possible. Give brief account of procedures for treatment, dose adjustments, etc. Describe the randomization procedure, if applicable. Specify if procedure involves banking of biological samples. Define stop points and criteria for withdrawing subjects from the study.	
ELIGIBILITY /INCLUSION CRITERIA / EXCLUSION CRITERIA ***(Explain inclusion and exclusion criteria; To be stated clearly in the summary) (specific explanation if participants will include Minor, Pregnant woman, Neonate, Person incompetent to give informed consent, Normal/ Healthy volunteer, Student, Staff of the institute).***	
SAMPLING TECHNIQUE : ***How many subjects will be screened? How many subjects are likely to be enrolled?***	

CLINICAL MEASUREMENTS : VARIABLES / OUTCOMES TO BE ESTIMATED ***Enumerate the variables, outcomes and end points that will be measured. Try to separate variables as response and explanatory variables. Describe the type and frequency of tests, admissions, outpatient visits, etc used to obtain these variables or variables.***	
DESCRIBE BENEFITS TO THE SUBJECT/PARTICIPANT IN THIS STUDY. ALSO DESCRIBE THE BENEFITS, IF ANY, TO THE SOCIETY.	
Power estimates ***Describe power calculations, if the study involves statistical comparisons between two or more groups. Mention evidence to support that adequate number of subjects can be enrolled during the study period by the investigators.***	
Statistical Analysis of the variables / data ***Describe how the variables obtained during the study will be statistically analyzed. e.g. Univariate comparison or Cox- proportional hazards model, etc***	

Describe all possible risks and discomfort for subjects due to use of intervention and / or data collection methods proposed. Describe expected degree and frequency of such risks, discomfort, side effects of drug etc.	
If the procedures in the trial are invasive or potentially harmful, describe what arrangements have been made for treatment of the complications arising from the trial?	
Does your study involve testing of drug/s, device/s and/or biologics?	***Yes. [ ]*** ***No [ ]***
Are they already approved by the regulatory authorities and available in the market or are they new ones?	***Already approved [ ]*** ***New one [ ]***
Who has prepared and /or is manufacturing the drug/s, device/s and biologics under investigation?	
Who holds the patent or IND/IDE of the drug/s, device/s and biologics under investigation?	

What are the reasonable possibilities of the availability after the study of the investigational drug(s), device(s) and biologics for the study participants/subjects if it is found to be effective?		
Does the study require any investigation or intervention to be done on humans or animals? Does the study require any investigation or intervention to be done on humans or animals?		
Does your study require permission from regulatory authorities?	***Yes [ ]***	***No [ ]***
If yes,		
(i) from DCGI	***Yes [ ]***	***No [ ]***
(ii) from the ICMR	***Yes [ ]***	***No [ ]***
(iii) From other govt. departments	***Yes [ ]***	***No [ ]***
If yes, specify the department Whether permission is obtained	***Yes [ ]***	***No [ ]***
Does your study require you to send human biological material outside India?	***Yes [ ]***	***No [ ]***
If yes, have you obtained permission of the Principal, KCDSH?	***Yes [ ]***	***No [ ]***
Has KCSDH and the foreign party signed agreement/MOU for that? ***If yes, attach a copy of agreement/MOU***	***Yes [ ]***	***No [ ]***

If study will be conducted fully or partially outside the KCDSH, please describe the need for permission from institution(s), health centre(s), local government/administrative bodies, etc.	
Describe how you define adverse events in your study, how and to whom you propose to report them, and what rules you will use for stopping the study due to adverse events.	
In what way will you ensure the confidentiality and privacy of the subjects?	
If some procedures in this trial are emotionally upsetting describe what arrangements have been made for psychological counseling?	
Describe (i) How, where, when and by whom the Informed Consent will be obtained. (ii) how much time the subject/ participant will be given to consider participation and decide, (iii) describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, etc. (iv) Describe how you will assess that information is correctly understood by the participant.	
Who will be maintaining the trial records and where?	
For how long will the data be stored? Give details of where they will be stored, who will access	

Describe briefly, if any, the financial and other interests of any of the investigators and /or close relative/s, with the sponsor/s and outcome of the study.	
Have you made provision for insuring yourself, and against any legal action that may arise out of this project?	
Have you made provision for insuring trial subjects for any accidental unforeseen trial related injury?	
How is it intended the results of the study will be reported and disseminated?	***- Peer reviewed scientific journals*** ***- Other publication*** ***- Conference presentation*** ***- Internal report*** ***- Submission to regulatory authorities*** ***- Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators*** ***- Other ……..***
REFERENCES	

Investigators Declaration	
1	***This research project (including collection of blood or tissues samples for research) will not be started until the final approval of the KCDSH-EC has been obtained.***
2	***We agree to undertake research proposal involving human subjects in accordance with the ICH-GCP and ICMR ethical guidelines, 2018. We will not modify the research protocol, consent, etc without prior approval by the KCDSH-EC.***
3	***The investigators agree to obtain a properly informed and understood consent for all trial subjects before their inclusion in the trial in the informed consent form that is approved by the KCDSH-EC. Participants will receive an 'information sheet' which will detail the project design in simple understandable layperson's language.***
4	***The investigators agree to report within a week all serious adverse events (SAE) associated with the trial in the SAE form to the KCDSH-EC. within 24 hours.***
5	***The investigators agree to submit/email periodic 6 monthly progress report of the trial in the appropriate form. A final report will be submitted at the end of the trial.***
6	***Details of funding and budget (optional)***
7	***For all research proposals that are sponsored by a pharmaceutical or biomedical company, we the investigators will ensure that the Sponsor Company will underwrite all expenses such that neither the hospital nor the study participants are made to spend while participating in the trial. The investigators will also ensure that in the event of complications arising directly due to the trial or litigation, the cost of management or legal fees will be borne by the Sponsor Company totally.***
9	***The investigators will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the Krishnadevaraya College of Dental Sciences and Hospital Ethics Committee, approved protocol.***
10	***All data collected during the research project, will remain the property of Krishnadevaraya College of Dental Sciences and Hospital.***
11	***The case records (source documents) will be made available to members of the SRC or KCDSH-EC any time for random verification and monitoring. The case records (source documents) will be preserved in the premises of for at least 5 years after the last approval of application or publication.***

Investigators Declaration	
12	***The investigators promise to ensure that there is no falsification of data when compared to the source documents. We agree to clarify any doubts or discrepancies that may arise during the data monitoring evaluation.***
13	***All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc will be first presented to the staff members of before they are released or presented elsewhere. The investigators will submit/email a copy of the abstract to the SRC and KCDSH-EC well in advance of any proposed presentation at national or international conferences or seminars.***
14	***The investigators will not issue any press release before the data and conclusions have been peer-reviewed by the staff or published in a peer-reviewed journal.***
15	***The investigators will constantly inform the KCDSH-EC about amendments in the study protocol, data collection forms, informed consent forms, budget expenses, salaries, other trial documents, etc. as and when they occur. No major changes in the treatment arms or the study protocol or randomization technique will be carried out without prior permission of the KCDSH-EC.***
16	***The investigators realize that the KCDSH-EC is particular that all aspects of the study are in accordance with the ICH-GCP and ICMR ethical guidelines, 2018. The investigators will comply with all policies and guidelines of the and affiliating/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.***

Krishnadevaraya College of Dental Sciences and Hospital Ethics Committee APPROVAL			
The members of the Krishnadevaraya College of Dental Sciences and Hospital Ethics Committee met on ..... at Krishnadevaraya College of Dental Sciences and Hospital and reviewed the above named project with all the documents listed above. The ethics committee after careful deliberations has granted final approval to the project. The above mentioned project / study may now be undertaken at Krishnadevaraya College of Dental Sciences and Hospital in accordance with the study protocol submitted by the investigators, subject to fulfilling other institutional regulations.			
Secretary		***Chairperson***	
Name:		***Name:***	

Krishnadevaraya College of Dental Sciences and Hospital Ethics Committee APPROVAL			
Date:		***Date:***	