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**The list of documents required for submission of the Clinical Trial for approval from the JSSDCH IEC**

1. Covering letter to the Member Secretary JSS Dental College & Hospital Institutional Ethics Committee requesting ethical clearance (One copy)

2. Curriculum vitae of Principal investigator and Co-investigators.

3. Checklist for submission of the Research Protocol for approval from the JSSDCH IEC.

4. Application form for a clinical trial with sign and seal of all investigators (One Copy)

5. Research proposal (One Copy) as per Form 3 with cover page and index (Research proposal must be signed by Principal Investigator, Co-investigator(s) with date)

6. Case Record/Report Form (One Copy)

7. Participant / Patient information sheet in English and Hindi/another local language (One Copy)

8. Consent form in English and Hindi/another local language (One Copy)

9. Assent form in English and Hindi/another local language, if applicable (One Copy)

10. Undertaking to report all Serious Adverse Events (SAE) to JSSDCH IEC (if applicable) (One copy)

11. Undertaking to comply with Good Clinical Practices (GCP) guidelines for human studies (One copy)

12. Undertaking that the study is not yet initiated.

13. Soft copy of all documents submitted on JSSDCH IEC portal; <https://jssuni.edu.in/jssaher/dental-college/dch-iec-home.html>. Please ensure that the latest soft copy is being submitted. (One Copy)

14. Investigator Brochure

15. DCGI approval letter

16. CTRI registration document

17. Insurance Certificate

18. Draft Clinical Trial Agreement

19. Other Ethics committee approval letter (One Copy)

Note: (1) If approval from more than one Ethics Committee, mention the number and attach all the approval letters. (2) If rejected by any Ethics Committee, please attach comments of the respective Ethics Committee.

20. Any other relevant document (as per clinical trial application form) (One Copy)

**Documents required for submission of the Clinical Trial for approval from the JSSDCH IEC**

## ANNEXURE. 6: Form II

**CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING CLINICAL TRIALS**

1. **Title Page**
	1. The full title of the clinical study.
	2. Protocol/Study number, and protocol version number with date
	3. The IND (investigational new drug) name/number of the investigational drug
	4. Complete name and address of the Sponsor and contract research organization if any
	5. List of the Investigators who are conducting the study, their respective institutional affiliations, and site locations
	6. Name (s) of clinical laboratories and other departments and /or facilities participating in the study.

## Table of Contents

A complete Table of Contents including a list of all Appendices.

1. Background and Introduction
	1. Preclinical experience
	2. Clinical experience

Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends the existing date should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological, and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.

1. Study Rationale

This section should describe a summary of the background information relevant to the study design and protocol methodology. The reason for performing this study in the particular included by the protocol should be provided.

3. A Study Objective (s) (primary as well as secondary) and their logical relations to the study design.

## Study Design

* 1. Overview of the study design: Including a description of the type of study (i.e., double-blind, multicentre, placebo-controlled, etc.), a detail of the specific treatment groups and the number of study participants in each group and investigative site, Subject number assignment, and the type, sequence, and duration of study periods.
	2. Flow chart of the study
	3. A brief description of the methods and procedures to be used during the study.
	4. Discussion of Study design: This discussion details the rationale for the design chosen for this study.
1. **Study Population:** the number of Subjects required to be enrolled in the study at the Investigative site and by all sites along with a brief description of the nature of the Subject population required is also mentioned.
2. **Subject Eligibility**
	1. Inclusion Criteria
	2. Exclusion Criteria
3. **Study Assessments** – plan procedures and methods to be described in detail
4. Study Conduct stating the types of study activities that would be included in this section would be medical history, type of physical examination, blood or urine testing electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review, etc.

Each visit should be described separately as visit I, Visit 2, etc.

Discontinued Subjects: Describes the circumstances for subject withdrawal, dropouts, or other reasons for discontinuation of subjects. State how dropouts would be managed if they would be replaced

Describe the method of handling protocol waivers, if any. The person(s) who approves all such waivers should be identified and the criteria used for specific waivers should be provided.

Describe how protocol violations will be treated, including conditions where the study will be terminated for non-compliance with the protocol.

1. **Study treatment**
	1. Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drugs(s), their doses, frequency, and duration of concomitant should be stated.
	2. Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations, details of the product stability, storage requirement, and dispensing requirement should be provided.
	3. Dose modification for study drug toxicity: rules for changing the dose or stopping the study drug should be provided.
	4. Possible drug interactions
	5. Concomitant therapy: the drugs that are permitted during the study and the conditions under which they may be used are detailed here. Describe the drugs that a subject is not allowed to use during parts of or the entire study. If any washout period for prohibited medication is needed before enrolment, these should be described here.
	6. Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the investigator and/or the subject.
	7. Unblinding procedures: If the study is blinded, the circumstances in which unblinding may be done and the mechanism to be used for unblinding should be given.
2. Adverse Events Description of expected adverse events should be given.
3. **Ethical Considerations**: Give the Summary of:
	1. Risk/benefit assessment:
	2. Ethics Committee review and communications
	3. Informed consent process
	4. Statement of subject confidentially including ownership of date coding procedures
4. **Study Monitoring and Supervision**: a description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring

Case Record (CRF) completion requirements, including who gets which copies of the forms and any specifics required in filling out the forms CRF corrections requirements, including who is authorized to make corrections on the CRF and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

Investigator study files, including what needs to be stored following study completion should be described.

1. **Investigational Product Management**
	1. Give Investigational product description and packaging (stating all ingredients and the formulations of the investigational drug and any placebos used in the study)
	2. The precise dosing required during the study
	3. Method of assigning treatments to subjects and the Subject identification code numbering system
	4. Method of assigning treatments to subjects and the subject identification code numbering system
	5. Storage conditions for study substances
	6. Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed, and returned /destroyed.
	7. Describe the policy and procedure for handling unused investigational products.
2. **Data Analysis:**

Provide details of the statistical approach to be followed including sample size, how the sample was determined, assumptions made in making this determination, efficacy endpoints (primary as well as secondary), and safety endpoints.

Statistical analysis: Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used, and the methods used for missing data: method of evaluation of data for treatment failures, non-compliance, and Subject withdrawals: rationale and conditions for any interim analysis if planned.

Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable

1. **Undertaking by the investigators**
2. **Appendices:** Provide a study synopsis, copies of the informed consent documents (patients information sheet, informed consent form, etc.): CRF and other data collection forms; a summary of relevant pre-clinical safety information, and any other documents in the clinical protocol.