A. CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING NON- CLINICAL studies (Thesis/ Projects/ Dissertations) – other than clinical trials.

The researcher should submit an appropriate application to the IEC in a prescribed format at least 14 days in advance to IEC meeting date along with a covering letter.

Number of Copies: 04 and 01 soft copies (CD)

1. **Title Page**
   a. Full title of the clinical study,
   b. The name of the investigational drug I (If any)
   c. List of the Investigators who are conducting the study, their respective institutional affiliations (Guide/Co Guide, PI/Co PI)
   d. Name(s) of clinical laboratories and other departments and/or facilities participating in the study.(If any)

2. Table of Contents

Detail review of Literature pertaining to the study

Previous clinical work must be reviewed here .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 and previous efficacy and safety experience should be described.

Hypothesis of the study must be mentioned.

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

There can be only one primary objective

4. **Study Design**

   a. 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 number of study Subjects in each group and

investigative site, and the type of enrolment, sequence and duration of study periods.

b. Flow chart of the study
c. A detailed description of the methods and procedures to be used during the study (Methodology)
d. Possible outcome of the study,

5. **Study Population:** the number of Subjects required to be enrolled in the study at the site along with a brief description of the nature of the Subject population required is also mentioned- age, sex, race etc

6. **Subject Eligibility:-**

a. Inclusion Criteria
b. Exclusion Criteria

7. **Study Assessments of end points** – plan, procedures and methods to be described in detail

8. 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, adverse event review, etc.

Each visit should be described separately as Visit 1, Visit 2, etc.

9. **Study Treatment**

a. Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos if they are part of the treatment plan. If applicable, concomitant drug(s), their doses, frequency, and duration of concomitant treatment should be stated.
b. Study drug supplies and administration: A statement about who is going to provide the study medication and dispensing should be provided.
c. Possible drug interactions
d. Permissible Concomitant therapy: Details must be provided Where ever necessary.

e. Details of the study procedures to be conducted in the study (surgical, Orthopaedics & other allied subjects)

f. Details of any new device / materials used for the study purpose must be described in detail.

10. **Adverse Events** :- Description of expected adverse events should be given

11**. Informed consent Form** at least two languages English, Kannada (or any vernacular language)

12. Principal Investigator's [PI] undertaking

13**. Ethical issues involved in the project**

14**. Investigational Product Management**

a. Give Investigational product description and packaging (Dosage form , presentation form etc.)

b. The precise dosing required during the study

15. **Data Analysis:**

Provide details of the statistical approach to be followed including sample size, how the sample size was determined,

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.

a	**Signature of the P I (Candidate):**	
b	**Name , designation of Guide (In block letter) and Remarks of the guide with Signature.**	
c	**Name , designation of Co Guide (In block letter) with Signature.**	
d	**Signature & Remarks of the Head of the Department**	
e	**Signature of the Principal**	
	For Office Use	
f	**Remarks of the IEC**	

b. UNDERTAKING BY THE INVESTIGATOR FOR NON - CLINICAL TRIAL PROJECTS (Other than clinical trials).

1. Full name, address of the Principal Investigator or Investigators.

2. Name and address of the medical college, hospital or other facility where the study will be conducted

3. Name and address of all clinical laboratory facilities to be used in the study.

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

5. Names of the other members of the research team (Co- Investigators) who will be assisting the Investigator in the conduct of the investigation (s).

6. Title of the Study to be conducted by the Investigator.

7. Commitments:

   (i) I have reviewed the study design and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

   (ii) I agree to conduct the study in accordance with the current design of study. I will not implement any deviation from or changes of the study design without opinion from the Ethics Committee through amendment.

   (iii) I agree to personally conduct and/or supervise the study trial at the site.

(iv) I agree to inform all Subjects, that the drugs/ procedures followed are being used for investigational purposes

(v) I agree to report to the IEC all adverse experiences that occur in the course of the study.

(vi) I have read and understood the information including the potential risks and side effects of the drug.

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced

(viii) I agree to maintain adequate and accurate records and to make those records available for Ethics Committee,

(ix) I agree to promptly report to the Ethics Committee all changes in the study activities

(x) I agree to inform all unexpected serious adverse events to the Ethics Committee **within 7 days of** their occurrence to IEC.

(xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

Signature of Principal Investigator with Date

c. INFORMED CONSENT for Non Clinical trial Projects (Other than Clinical Trial projects)

1. Checklist for study Subject's informed consent documents

1.1 Essential Elements:

a) Statement that the study involves research and explanation of the purpose of the research
b) Expected duration of the Subject's participation
c) Description of the procedures to be followed, including all invasive procedures and
d) Description of any reasonably foreseeable risks or discomforts to the Subject
e) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
f) Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
g) Treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
h) Compensation and/or treatment(s) available to the Subject in the event of a study -related injury
i) An explanation about whom to contact for study related queries, rights of Subjects and in the event of any injury
j) The anticipated prorated payment, if any, to the Subject for participating in the trial
k) Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled.

1.2 Additional elements, which may be required

Approximate number of Subjects enrolled in the study

2. Format of informed consent form for Subjects participating in a non clinical trial

Informed Consent form to participate in a non clinical trial

Study Title:

Subject's Initials: _____ Subject's Name:_____

Date of Birth / Age: _____

		Please initial box (Subject)
(i)	I confirm that I have read and understood the information sheet dated ___ for the above study and have had the opportunity to ask questions.	[ ]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
(iii)	I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]

(iv)	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[ ]
(v)	I agree to take part in the above study.	[ ]

Signature (or Thumb impression) of the Subject with date: _____

Signature of the Witness: _____ Date: _____/_____/_____

Name of the Witness: _____

Name and Signature of the Principal Investigator with date: _____