INSTITUTIONAL ETHICS COMMITTEE / RESEARCH COMMITTEE

Sri Venkateswara Dental College & Hospital

INFORMED CONSENT DOCUMENT – PART 1

PATIENT INFORMATION SHEET (DATED: VERSION:)

STUDY TITLE:

SIMPLIFIED TITLE:

Principal Investigator (PI):

Dear Respondent,

We invite you to participate in this study. Before you participate in this study, it is important for you to understand why this is being carried out.

If you have any doubts regarding the procedure / purpose / intent of the study or if you desire to know more about the purported study, you are free to ask the Principal investigator or contact person. You can discuss with your doctor, relatives and friends.

KINDLY ASK AND UNDERSTAND THE FOLLOWING

- Who is organizing the research study?

  PI SHOULD ENTER NAME, DESIGNATION OF THE INVESTIGATORS, SPONSORS ETC

- What is the purpose of the study?

  PI SHOULD ENTER THE SIMPLIFIED BACKGROUND OF STUDY AND AIMS/OBJECTIVES IN SIMPLE LANGUAGE

- Why have you been chosen?

  PI SHOULD EXPLAIN WHY THE PARTICIPANT HAS BEEN CHOSEN

- Do you necessarily have to take part in the said study (if you desire more information, you are free to ask the contact person mentioned below.)
    - IT IS UP TO YOU ONLY TO DECIDE
    - YOU CAN WITHDRAW AT ANY TIME
    - THIS WILL NOT AFFECT ANY TREATMENT/PROCEDURE/BENEFIT YOU WOULD NORMALLY RECEIVE IN THE INSTITUTION
    - IF YOU DECIDE TO TAKE PART, YOU CAN SIGN THE INFORMED CONSENT FORM AND KEEP A COPY

- What will happen to you if you do indeed take part?

  PI SHOULD INCLUDE THE FOLLOWING DETAILS

    - DURATION OF STUDY
    - HOW LONG PATIENT IS ENROLLED
    - HOW MANY VISITS ARE REQUIRED
    - TIME AND DURATION OF VISIT
    - NATURE OF PROCEDURES
    - COMPENSATION FOR VISIT GIVEN OR NOT (TRAVEL EXPENSES ETC)
    - TYPE OF STUDY – BLINDING, PLACEBO DETAILS

- What is required of you?

  PI SHOULD INFORM ABOUT ANY LIFESTYLE RESTRICTIONS (SMOKING, DRINKING, DRIVING VEHICLES, EXISTING MEDICATIONS, SPORTS AND PHYSICAL ACTIVITIES ETC)

- What is the procedure or drug that is being tested?

  INCLUDE SHORT DESCRIPTION OF DRUG/PROCEDURE INCLUDING ITS APPROVALS, STAGE OF DEVELOPMENT, DOSAGE, METHODS ETC

- What are the other alternatives for diagnosed entities / treatment involved?

  INCLUDE THE ALTERNATE PROCEDURES / TREATMENT AVAILABLE

- What are the possible benefits of taking part in the study?

  INCLUDE THE BENEFITS OF THE STUDY IN SIMPLE TERMS WITHOUT UNDUE INDUCEMENT. IF NO BENEFIT PLS INFORM PATIENT

- What are the possible disadvantages / risks involved by participating in the study?

  INCLUDE THE EXPECTED RISKS IN SIMPLE TERMS AND WHAT ARE THE PROCEDURES TO FOLLOW IN CASE OF AN EVENT WHETHER EXPECTED OR NOT. ANY FINDINGS OF PATIENT (HIV, HIGH BP

INFECTION) THAT HE/SHE IS UNAWARE MAY ALSO BE COMMUNICATED TO PATIENT DURING THE STUDY

- Will confidentiality/privacy be maintained at every phase of the study?

  INCLUDE HOW YOU PLAN TO MAINTAIN PRIVACY AND CONFIDENTIALITY, INCLUDING BLINDING, DE-IDENTIFICATION, CODING ETC

- What will happen to the results of the study?

  INFORM WHAT YOU PLAN TO DO WITH THE RESULTS. EXPLAIN THE CHANGES IN TREATMENT IF ANY AFTER THE TRIAL IS CONCLUDED/DISCONTINUED WITH REASONS.

- Which competent body has reviewed the study?

  INFORM IF ANY ORGANIZATION/COMMITTEE HAS REVIEWED THE STUDY AND APPROVED IT.

- What if new information becomes available at a later date which has a bearing on the study?

  INFORM THAT NEW INFORMATION WILL BE INTIMATED TO THE PATIENT. IF REQUIRED PATIENT/STUDY MIGHT BE DISCONTINUED.

CONTACT PERSON: **CONTACT:**

Name of the Principal Investigator:-

Designation:-

Name of the Institute:-

Contact no:

Email id:

I wish to thank you for taking your time and for your cooperation in participating in the study titled

_____

_____

Date: Signature of Principal Investigator. Place:

Signature of witness:

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INFORMED CONSENT DOCUMENT – PART 2

INFORMED CONSENT FORM

PARTICIPANT'S NAME: **Age:** **Gender:**

ADDRESS:

PHONE NUMBER:

ALTERNATE NUMBER:

The details of the study have been provided to me in writing and explained to me in my own mother tongue in the PI sheet dated :_____. I was encouraged to ask doubts regarding the study. I confirm that I have understood the purpose and procedure of the above study. I understand that my participation in the study is voluntary and that I am free to withdraw from the study at any time, without giving any reason whatsoever.

I was assured that the result of the study will be used only for scientific purpose (s) and I hereby declare that I will not restrict the use of the results. I have also received a copy of the consent form elaborating the "Information for participants of the study". I give my full consent for my participation in the above-mentioned study.

Signature/Left thumb impression of the participant/LAR: **DATE:**

Signature/Left thumb impression of the witness: **DATE:**