Model Patient Information sheet, Model Patient Consent Form, and **Model Investigator Brochure** are only for Guidance. Necessary changes are required in the context to study design.

MODEL PATIENT INFORMATION SHEET

(Prepare in English and Regional Languages)

Subject Initials:

Enrolment No:

Title of study:
Efficacy and Safety of Ofloxacin and its Combination with Dexamethasone in Chronic Suppurative Otitis Media- A Randomized, Double Blind, Parallel Group, Comparative Study.

Introduction
Doctor suggested you to take part inthe study because you have Chronic Suppurative Otitis Media (CSOM). You will be given Ofloxacin ear drops or combination (Ofloxacin and Dexamethasone)

Information about drugs
Both of these Eardrops are used in CSOM.
Both type of Ear drops clear the discharge and improve the hearing in CSOM patients. As these medications are given by ototopical route there are least chances of systemic absorption and systemic side effects.

Study Methodology

In total 120 patients will participate in study. Patients will be divided into two groups (60 patients in each group), one group will receive ofloxacin ear drops while another group will receive dual combination of ofloxacin and dexamethasone eardrops. The treatment will be given for 3weeks and patient will be called on day 14 day 21, and on day 28 for assessment of response to treatment. During each visit in addition to general and systemic examination, otoscopy for otorrhoea, size estimates of the Tympenic membrane perforation. If antibiotic sensitivity shows that ofloxacin is resistant to the organism then you will be excluded from the study. You will be given another antibiotic which shows activity against that organism. Sample for bacteriological examination will be taken at the starting of treatment and at the end of treatment if otorrhoea persist after completion of treatment. Puretone audiometry will be done on the day of starting the treatment and on the day of completion of Treatment.

Drug dosage for participant

One group will receive Ofloxacin Ear drops. Second group will receive Ofloxacin (0.3%) and Dexamethasone (O.l%) combination. Drugs would be taken twice in a day. Three drops should be taken twice daily.

Otherdrugs

Patient should not take any other drug during this study unless prescribed by doctor. If anyone require to take other drugs then principal investigator will decide whether he or she continue to participate in study.

Rescuemedication

If rescue medication is needed then patient will be hospitalised and proper treatment will be given.

About quitting the study

You participate in the study willingly so you can quit the study any time during the course of the study. It will not affect your medical treatment and doctor will give you optional treatment. If investigator comes to know that these medications are not beneficial or you do not follow his advice then he can relieve you from the study. In any of the above circumstances, it will not affect your medical treatment and doctor will give optional treatment.

New information

If any new information comes to know related to this study, you will be immediately informed.

Confidentiality

All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it

Responsibilities during the study

You should follow investigator's advice and should take medication regularly. You should inform the doctor about any adverse even occurring during the study. If you are female patient, you should not become pregnant within 30days after completion of the study.

Uses of new information

Result of this study will be used for publication and will be shown on conferences related to scientific research If you are asked about your treatment then you can contact your investigator at any time. If any new information comes to know related to your health during this study, you will be immediately informed.

Contact Persons: For Further information & questions, you can contact us on following

address

Principal Investigator's name

Contact Nowith Address:

Co-Investigator's name (If
Any)

ContactNo:

Address:

In case of any conflicts, you can contact of the Parul University Institutional Ethics Committee for Human Research, Vadodara at the following address,

Dr. Viral Desai
Member secretary,
Parul University Institutional Ethics Committee for Human Research
Mob No.9904112368
Email id-viralvision@rediffmail.com

Participant's Name: Participant's Signature:

(Provide a one copy to participant in the language he/she understand after signed and preserve acknowledge on the copy).

Investigator's Name:

Investigator's Signature:

MODEL INFORMED CONSENT FORM

Protocol Title

Principal
Investigator:

Subject
Initials:

Subject Age: years Gender: Male/ Female

Address-

Screening No:

Enrolment No:

Contact Number:

I _____, have read the information in this form or it has been read to me). I was free to ask any questions and they have been answered. I am over18 years of age and exercising my free power of choice, hereby give my consent to be included as a participant in "**Protocol Title"**

1. I have read and understood this consent form and the information provided to me. ( )
2. I have had the consent document explained to me. ( )
3. I have been explained about the nature of the study. ( )
4. My rights and responsibilities have been explained to me by the investigator. ( )
5. I have been advised about the risks associated with my participation in the study. ( )
6. I have informed the investigator of all the treatments I am taking or have taken in the past ___months including any *desi (alternative*) treatments. ( )
7. I agree to cooperate with the investigator and I will inform him/ her immediately if I suffer unusual symptoms. ( )
8. I have not participated in any research study within the past _____year(s)___month(s). ( )
9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital. ( )
10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent. ( )
11. I hereby give permission to the investigator to release the information obtained from

me as result of participation in this study to the sponsors, regulatory authorities, government agencies and ethics committee. I understand that they may inspect my original records. ( )

12. My identity will be kept confidential if my data are publicly presented. ( )
13. If, despite following the instruction, I am physically harmed because of any substance or any procedure as stipulated in the study plan, my treatment will be carried out free at the investigational site/the sponsor will bear all the expenses.( )
14. I have had my questions answered to my satisfaction ( )
15. I have decided to be in the research study. ( )

I am aware, that if I have any questions during the study, I should contact at one of the addresses listed in participant information sheet. By signing this consent form, I attest that the information given in this document has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

Name and signature /thumb impression of participant
(or legal representative if participant incompetent):

Signature Name

Date Time

Name and signature of impartial witness (required for illiterate patients):

Signature Name

Date Time

Name and signature of the investigator or his representative obtaining consent

Signature Name

Date Time

INVESTIGATOR'S DECLARATION
PU IECHR

Study Title

1. We certify that, we have determined that the proposal here in is not unnecessarily duplicative of previously reported research.
2. We certify that, we are qualified by education, training and have enough experience to do such a study.
3. For procedures listed under proposal, we certify that we have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described here in which may cause less pain or distress to the patient.
4. We certified that, study will be initiated only upon review and approval of scientific intent by PU IECHR and getting a certificate from PU IECHR.
5. We will do necessary changes in our study protocol as per the suggestions given by respected PU IECHR members during meeting before getting approval letter and bound to submit the changes to PU IECHR. We will obtain approval from the PU IECHR before making any significant changes in this study Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agent so human pathogens), if apply.
6. We will do our study according to ICH-GCP guidelines and maintain all the study related records. Whenever asked,we are bound to produce to PU IECHR.
7. We will report adverse drug reaction to Pharmaco vigilance Cell & PU IECHR whenever, we come across the adverse drug reaction while doing research work. (If Applicable)
8. We certify that, we will follow the recommendations of PU IECHR and Govt.of Gujarat rules and regulation issued from time to time.
9. We certify that, record of all premature termination of a study with a summary of the reasons/final report after completion of the study including microfilms, CDs and Video recordings; will submit to the PU IECHR.

Principal Investigator Co Investigator

Name & Sign Name & Sign

Head of Department, Name & Sign