14.6 Appendix 6: Format of Informed Consent Document

INFORMED CONSENT DOCUMENT

DEPT. OF XXXXXXX MGM DETNTAL COLLEGE & HOSPITAL, KAMOTHE

Project Title: _____

II Introduction:

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation.

Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant.

III Purpose of the study:

It is well known that people who suffer from XXXXX are at high risk for XXXXX. XXXXXXX medications are commonly prescribed to such patients to prevent the occurrence of XXXXX. XXXX is a new drug/dentalmaterial, which has been found to XXXXXXXXX in initial studies. The study plans to study the efficacy and safety of this drug in patients having XXXXXX.

IV Expected duration of the study and number of subjects:

You will be one of approximately XXX people who will participate in this study. You will be in the study for about XXX days. (If multicentric study – mention that the study is also being carried out at xxx other centres).

V Study procedures to be followed:

If you agree to participate in this study you will a) be asked about previous medical problems, your current health and your medications; b) have a brief physical examination (to give details);c) need to undergo baseline investigation such as XXXXXX(to give details)

The study staff will review the results of these evaluations & test. If you are eligible to participate you will

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At each visit, a) you will be asked about your health, side effects of medications, b) your physical examination will be carried out c) you will be given a new supply of study drug.

VI Risks and discomforts of participating:

The study testing 2 different therapies in high risk people that may prevent XXXXXX.

Based on studies in animals and other studies with people, the drug(s) used in this study may cause some side effects. The known risks and side effects associated with the drugs/dental material proposed for use here are summarized below.

Side effects of test drug/ dental material – XXXXX (Give Details)

Side effects of standard drug/dental material – XXXXX (Give Details)

Other side effects that you may experience could include XXXXX (Mention allergic reactions to the medication, itching rash and pain at the injection site wherever applicable)

Finally new problems or side effects other than those that have been seen before could occur during this study. You will therefore be asked about side effects at each visit. It is important that you report any of the side effects described in this document or any other side effects to the study physician immediately at the numbers listed below.

While collecting blood from your vein, you will have to undergo the discomfort of brief pain or rarely develop bruising or even a minor infection. In case this occurs appropriate management will be provided.

Because the safety of the study drugs for an unborn foetus or newborn is unknown, if you intend to become pregnant, are pregnant or are breastfeeding you cannot participate in this study. If you are a woman who is able to have children, you will be required to undergo a urine pregnancy test. If you are

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Your participation in this study may provide information that may in the future help other patients suffering from XXXXX.

VIII What happens when the study stops?

Because this is a research trial, the test drug will not be available at the end of this trial for XXXXXX. Alternate therapy, if appropriate, will be provided once the trial is finished. Occasionally the company sponsoring the research may stop the study early – if this occurs the reason(s) will be explained to you.

IX Compensation for participation:

Participation in this study will be at no cost to you. No compensation will be provided for your participation. Payment for things such as lost wages is not available.

X Compensation for study related injury:

For academic studies: You will be provided medical care at this institute for any physical injury or illness that occurs as a direct result of your participation in this study. This medical care will be at no cost to you. You will not give up any of your legal rights by signing this form.

For sponsored studies – The company has insurance for covering study related expenses. The study sponsor will compensate anyone whose health suffers as a result of participation in this trial. You do not have to prove it was anyone's fault; if the health problem arose because of your participation in this trial, you will be compensated. You will not give up any of your legal rights by signing this form.

XI Right to withdraw from the study:

Participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute. If you decide to

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If you have questions about this study is being run, drug side effects or a possible research related illness or injury, contact the study doctor XXXXXXXX, designation, department XXX at telephone number XXXXXX during the office hours, or at XXXXX at outside office hours.

If you have any questions about your rights as a research participant, or complaints regarding the research study, you may contact Dr. Srivalli Natarajan, who is the Member Secretary of Ethics Committee for Research on Human Subjects on the following telephone number 02227436604 extension 7920.

XIII Consent:

- I have read or have had read to me the information given in the Informed Consent Document for this study entitled "**XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX**".
- I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trial and what I will be expected to do. My questions have been answered satisfactorily.
- I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which am otherwise entitled.
- I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will informed to me.
- Institutional review board authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.
- I understand that my identity will not be revealed in any report or publication.

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Project Title:

_____

II Introduction: