Participant Information Sheet

PIS(For Study Participants/Parents of children who would participate in the study)

Title of Project:_____. ***PIS IDENTIFIER NO :***

Principal Investigator:

Name : ***Designation:***

Contact details: Tel No : _____ ***Email Id :***

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients. This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is this research study about? _____

2. Who is the sponsorer for this study?_____

3. What information is known about this type of research study?_____

_____

4. Why is this research study being done? _____

5. How will the research study be done?_____

6. What do you have to do if you agree to take part in the research study?_____

_____

9. What are the possible benefits to you by being in the research study?_____

_____

10. What are the possible risks and inconveniences that you may face by being in the research study? _____

_____

11. What are the tests that will be performed on the participant/ biological sample?____

_____

12. How long will you be in the research study?_____

13. How long the biological samples will be stored and how will it be disposed? _____

_____

14. Under what conditions will your Participation in the study be terminated?_____

_____

15. What will happen if you change your mind about participation in this research study?

_____

17. How will your privacy and confidentiality be maintained?_____

_____

18. Will you have to bear any Expenses or Costs by participating in the research study?__

_____

19. Whom do you call if you have questions or problems?_____

a. Research related : _____

b. Regarding rights as a Participant : _____

Ask a question about the study procedures or treatments :

Dr. .....

Department.....

Phone : _____ . , time to contact : anytime/ 9.00am to 5.00 pm

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee ***through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form)***

Dr. Joann Pauline George

Member- Secretary,

Tel.No.: 9448541637 Email : ethicalcommittee@kcdsh.org

Time to contact- 9.00am to 5.00 pm

The Krishnadevaraya College of Dental Sciences and Hospital Ethics Committee for (KCDSHEC) Research comprises of a group of people like doctors, researchers, and community people (non scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute . Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records