QASSIM UNIVERSITY / COLLEGE OF DENTISTRY

Parental Informed Consent Form

Study Title: Heavier Salivary Colonisation by Mutans Streptococci and Lactobacilli Without Excess Caries in Children with Congenital Heart Disease: A Case-Control Study

Principal Investigator: Dr. Shahad Alkhuwaiter

Institution: Qassim University, College of Dentistry / Prince Sultan Cardiac Centre, Qassim

Ethics Approval No.: Research Ethics Committee of the Qassim Health Cluster, Saudi Arabia (approval number H-04-Q-001)

Contact with Investigator: sh.alkhuwaiter@qu.edu.sa

Dear Parent / Legal Guardian,

Your child is being invited to take part in a research study. Please read this form carefully. Take as much time as you need, and feel free to ask the research team any questions before deciding.

1. Study Objectives

The purpose of this study is to compare tooth decay (measured by the number of decayed, missing, and filled primary teeth, known as the dmft index) and the types of bacteria that cause tooth decay (*Streptococcus mutans* and *Lactobacillus acidophilus*) in the mouths of children with congenital heart disease (CHD) and healthy children in Qassim Province, Saudi Arabia. We hope that the results will help improve dental prevention and care for children with heart conditions.

The study includes 60 children aged 3 to 10 years: 30 children with confirmed CHD and 30 healthy children.

2. Duration of the Study

Your child's participation will take place in **one visit lasting approximately 20 to 30 minutes**. No follow-up visits are required for the study. The overall research project is expected to last about 4 months.

3. Study Sponsor

This study is self-funded by the research team and has no commercial sponsor. The sponsor has no role in deciding how your child's information will be used, and the research team has no financial interest in the results.

4. Participation Is Voluntary

Your child's participation is entirely voluntary. You are free to decide whether or not your child takes part. Your decision will not affect the dental or medical care that your child receives at Qassim

University Dental Clinic, Prince Sultan Cardiac Centre, or any other healthcare facility, now or in the future.

5. Freedom of Withdrawal

You may withdraw your child from the study at any time, without giving a reason and without any penalty or loss of benefits. Your child may also stop at any moment during the examination if he or she feels uncomfortable. If you withdraw, the information already collected may be removed from the study upon your request, provided it has not yet been anonymized and analyzed.

6. Study Procedures

If you agree, the following will take place during a single visit:

1. **Questionnaire and records:** You will be asked brief questions about your child's age, nationality, region of residence, language, and oral hygiene habits. For children with CHD, the type of heart condition will be confirmed from the medical file.
2. **Dental examination:** A dentist will examine your child's teeth using a disposable mirror and dental probe under good lighting, following World Health Organization (WHO) criteria, to count decayed, missing, and filled primary teeth. No X-rays are required for this study.
3. **Saliva collection:** Your child will be asked to let saliva collect in the mouth and spit it into a clean, sterile container (unstimulated saliva), which usually takes a few minutes. No needles or injections are involved. Children should not eat, drink, or brush their teeth for at least one hour before the sample is collected.
4. **Laboratory testing:** The saliva sample will be taken to the laboratory and grown on special culture media to detect and count *Streptococcus mutans* and *Lactobacillus acidophilus*. The samples will be used only for this purpose and will be discarded safely after testing.

7. Expected Benefits

There may be no direct benefit to your child from taking part. However, your child will receive a free dental examination, and you will be informed of the findings. If dental decay or other oral problems are found, you will be advised and, where needed, referred for appropriate treatment. The information gained may help dentists and cardiologists provide better preventive dental care for children with congenital heart disease in the future. There is no payment for participation.

8. Expected Risks

The risks of this study are **minimal**. The dental examination is similar to a routine check-up and may cause brief discomfort or tiredness, or occasional gagging or anxiety in young children. Saliva collection is painless and non-invasive. The study does not involve any medication, injection, or invasive procedure. Standard infection-control measures (gloves, disposable instruments, sterilization) will be followed. There is also a small risk of loss of privacy, which the team will minimize as described below. Should your child become distressed, the examination will be paused or stopped.

9. Confidentiality

Your child's personal information will be kept strictly confidential. Each child will be given a code number, and names or identifying details will not appear on study data sheets, laboratory samples, or in any publication. The key linking names to codes will be kept separately in a locked cabinet or password-protected file, accessible only to the research team. Authorized representatives of the ethics committee may review study records to ensure the research is conducted properly, and they are bound by confidentiality.

10. How Information and Results Will Be Used

The information and laboratory results will be combined with those of other children and analyzed statistically. The overall results will be presented in scientific journals and at conferences, and may be used to inform dental and pediatric cardiology practice. Only group results will be reported; no individual child or family will be identifiable.

11. How New Information Will Be Communicated

If any new information becomes available during the study that might affect your child's health or your willingness to continue, you will be informed promptly by the research team. If the examination reveals a dental problem needing treatment, you will be told on the same day or contacted afterward and guided to the appropriate care. You may ask about the study results at any time, and a summary of the findings can be provided to you on request after the study is completed.

12. Contact Information

If you have questions about the study, or concerns about your child's rights as a research participant, you may contact:

Principal Investigator: Dr. Shahad Alkhuwaiter, sh.alkhuwaiter@qu.edu.sa

13. Consent Statement

I have read (or have had read to me) the information above, in an Arabic language I understand. I have had the chance to ask questions, and my questions have been answered satisfactorily. I understand that participation is voluntary and that I may withdraw my child at any time without any effect on his or her care. I voluntarily agree for my child to participate in this study.

Child's name / file number: _____ Age: _____

Parent / Legal Guardian

Name: _____ Relationship to child: _____

Signature: _____ Date: ____ / ____ / _____

Person Obtaining Consent (Researcher)

I confirm that I have explained the purpose, procedures, benefits, and risks of this study to the parent/guardian, and that he/she has given consent freely.

Name: _____ Signature: _____ Date: ___ / ___ / _____