[SITE NAME]

ASSENT TO PARTICIPATE IN A RESEARCH STUDY
(Ages 11-17)

STUDY TITLE: Reduction of bloodstream infections from oral organisms in pediatric stem cell transplant: a randomized, multicenter, double-blind, placebo-controlled study evaluating twice-daily oral xylitol

[Site Principal Investigator]
Name of Principal Investigator (study doctor)

[Site Contact Info]
Telephone Number

_____ ____/____/_____
Subject's Name Date of Birth

INTRODUCTION

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about whether xylitol dental wipes are effective at reducing bloodstream infections (BSIs), dental plaque, mucositis (redness and ulcers in the mouth), and gingivitis in patients who undergo hematopoietic stem cell transplant (HSCT). Xylitol is a naturally occurring sugar alcohol that can be found in plums and strawberries. You are being asked to join the study because you will be undergoing transplant.

WHAT WILL HAPPEN IN THE STUDY?

If you agree to join this study, you will be assigned to one of two study groups.

Group 1: Participants will receive the usual clinical oral care plus **xylitol dental wipes**.

Group 2: Participants will receive the usual clinical oral care plus **saline (placebo) dental wipes**. These wipes do not contain xylitol.

The group you are assigned to will be random, like flipping a coin. Neither you nor the study doctor will choose or know which group you are in.

Participants in both groups will continue to receive the usual clinical oral care, which includes daily mouth rinses and tooth brushing.

The nursing team will start applying the wipes approximately 4 days prior to Day 0 of your transplant

and continue through the first 28 days after transplant.

The wipes will be given twice daily, and the nursing team will wipe your teeth for a minimum of 30 seconds. Both the xylitol and saline wipes are grape flavored.

We will also ask you to do the following:

- Oral swab and oral evaluation at Study Day 0, 12, 19 and 33.
- We will ask questions about your oral health at Study Day 0, 12, 19, and 33.
- We will collect clinical information about you through 100 days after transplant.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Your participation in this study may decrease the risk of developing bloodstream infections, dental plaque, mucositis, and gingivitis. There is also a chance being in this study will not help you.

We may learn something from this study that will help other children undergoing transplant in the future.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

We do not think there will be any risks with the xylitol wipes. Xylitol may cause diarrhea and gas, but usually when more than 15 grams are consumed at once (you will receive no more than 1.4 grams per day). You must avoid chewing gum and toothpaste that contains xylitol while you are in the hospital/receiving the intervention.

If you have known allergies to xylitol, grape, or grape flavoring, you cannot be in the study.

The risks of oral swabs and evaluations are small and may include minor discomfort of the cheek area or general discomfort of using the dental wipes

There is also a small risk of your protected health information accidentally being released to unauthorized persons. We will decrease this risk by using password-protected computers and locked offices/cabinets.

There may be other risks that we do not know about yet.

PRIVACY

All personal information that the study doctor will collect about you will be protected and kept private as much as possible. It will only be shared with the people doing the research study or those who are checking that it is being done properly.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it. Take all the time you need to make your choice. Ask us any questions you have at any time.

SIGNATURES

After you have read this form and talked about this research with your parents and the doctors or nurses you need to decide if you want to be in this research.

If you want to be in this research, you should sign or write your name below.

_____	_____
Child's Assent (ages 11-17)	Date
_____	_____
Signature of Person Obtaining Assent	Date