[SITE NAME]

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of research study: 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

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are a participant 18 years or older: This is a consent form. It explains this research study. If you agree to participate, then you will sign this form. If you sign this form, you will receive a signed copy of it for your records.

If you are the parent/Guardian of a participant who is a minor younger than 18 years: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Investigator:
[Site Principal Investigator]

Contact Info:
[Site Contact Info]

Funding:
National Institute of Dental and Craniofacial Research (NIDCR)

Reason for the study:

The purpose of this study is to determine whether dental wipes that contain a chemical called xylitol are effective at reducing bloodstream infections (BSIs), dental plaque, mucositis (redness and ulcers in the mouth), or gingivitis in patients who undergo hematopoietic stem cell transplant. Xylitol is a naturally occurring sugar alcohol that can be found in plums and strawberries.

Dental plaque and gingivitis (inflammation of the gums) are associated with bacteremia (bloodstream infection) from oral bacteria organisms and xylitol dental wipes may improve both gingivitis as well as oral plaque. We would like to know whether the addition of twice-daily dental xylitol-wipe application to current oral care practices decreases infections from oral flora bacteria through reduction of gingivitis and oral plaque.

We are asking you and other children and young adults who will undergo transplant to participate so we can learn more about what effects dental hygiene may have on transplant patients.

Procedures:

If you agree to participate in this study, you will be randomized to one of two study arms.

Arm 1: Participants will receive standard clinical oral care plus **xylitol dental wipe** application twice daily through the first 28 days after transplant.

Arm 2: Participants will receive standard clinical oral care plus **saline grape flavored (placebo) dental** wipe application twice daily through the first 28 days after transplant.

Being randomized means you will be put into a study arm by chance, like flipping a coin. Neither you nor the study doctor will choose if you receive the xylitol wipes or the saline (placebo) wipes. A placebo looks the same as an intervention, but it is designed to not have any effect. You will have an equal chance of being given each intervention. Neither you nor the study doctor will know which intervention you are getting.

The nursing team will apply the wipes twice daily by wiping your teeth for a minimum of 30 seconds. This will start approximately 4 days before your transplant and will continue until 28 days after transplant. If you are discharged from the hospital early, we will stop the administration of wipes. Both the xylitol and saline wipes are grape flavored and look exactly the same. The nursing team will not know which dental wipe you were assigned.

A member of the study team will perform an oral evaluation and obtain three oral swabs at Study Days 0, 12, 19 and 33. Additionally, you will be asked to answer a questionnaire regarding your oral health at these time points.

The study team will collect clinical data from the electronic medical chart through 100 days after transplant.

Risks to Participate:

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.

Patients with known allergies to xylitol, grape, or grape flavoring cannot be in this study.

The risks of oral swabs and evaluations are minimal and may include minor discomfort of the cheek, gums, and/or tongue 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 minimize this risk by storing study data on secure, password protected computers, and documents will be stored under lock and key with access restricted to qualified personnel involved in this research study.

Benefits to Participate:

Your participation in this study may decrease the risk of developing bloodstream infections, dental plaque, mucositis, and gingivitis. There is also a chance you will not receive a direct benefit from your participation in this study. The knowledge gained in this study will have the potential to improve outcomes for future transplant patients.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. Instead of being in this study, you can choose not to be in it.

Cost to Participate:

You and your insurance company will be charged for the healthcare services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

The xylitol and placebo (saline) dental wipes, oral evaluations and testing of the oral swaps will be provided by the study.

Payment:

You will not be paid for your participation in this study.

Additional Study Information:

If I have questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• General study questions • Research-related injuries • Any research concerns or complaints	*[Site PI]*	Phone: *[Site telephone number]*
• Your child's rights as a research participant	**CCHMC Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	**Phone:** (513) 636-8039

Total number of participants:

We anticipate approximately 419 patients undergoing transplant will participate in this research study at three different transplant centers: Cincinnati Children's Hospital Medical Center (CCHMC), Boston Children's Hospital, and Children's Hospital Colorado (Denver).

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you. If you decide to leave the research study, written notice should be given to the investigator.

If you choose to stop being in the research, you will have several options of what the study team will do with the samples and collected data.

1. You stop receiving the dental wipe intervention, and the study team will continue to collect oral sample swabs and perform oral assessments. All data and samples will be stored.
2. You continue the dental wipe intervention, but the study team will stop collecting oral swabs **or** perform oral assessments. All data and samples that has been collected or will be collected will be stored.
3. You stop receiving the dental wipe intervention, and the study team will stop collecting oral sample swabs **and** stop performing oral assessments. All data and samples that have been collected will be stored, and the study team will continue to collect information from the medical chart.
4. You stop receiving the dental wipe intervention, and the study team will stop collecting oral sample swabs **and** stop performing oral assessments. No further clinical data will be obtained, but the stored oral swabs and clinical data will be retained.
5. You stop receiving the dental wipe intervention, and the study team will stop collecting oral sample swabs **and** stop performing oral assessments. No further clinical data will be obtained. All previously stored oral swabs we be destroyed and previously obtained clinical data will be deleted.

In addition, your participation may also be stopped by the study doctor without regard to your consent if you experience a study-related adverse effect or if the study doctor feels it is in your best interest.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the study.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the Institutional Review Board (hospital group that reviews and monitors research) and other representatives of this organization.

Samples and/or data collected for or generated from this study could be shared and used for future research without your additional informed consent. The samples and/or data will be given a unique code and will not include information that can identify you.

Samples and/or data may be shared with other collaborators at *[site name]* and possibly with outside collaborators, who may be at another institution or for-profit company. If you decide to withdraw your consent from this research study, samples and medical information that have already been distributed to researchers prior to withdrawal of consent as well as any data obtained from the distributed sample will not be destroyed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

[Add Site specific HIPAA language]

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____	____/____/_____
Subject's Printed Name	Date of Birth
_____	_____
Signature of Research Participant Indicating Consent (ages 18 and older)	Date
_____	_____
Signature of Parent or Legally Authorized Representative*	Date

_____

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____	_____
Signature of Individual Obtaining Consent	Date

The signature line below is to be used only when an interpreter or a witness is required (phone consents) for the consent process.

_____	_____
Signature of Person Present During Consent	Date