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Protocol Title: Oral supplementation of 2'-fucosyllactose in allogeneic bone marrow transplant recipients to maintain intestinal homeostasis

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CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of research study: Oral supplementation of 2'-fucosyllactose in allogeneic bone marrow transplant recipients to maintain intestinal homeostasis

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

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.

[redacted]

Contact Info:
513-636-4200 and ask for the BMT physician on call

Funding:
St. Baldrick's Foundation

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:
Chemotherapy and radiation used in patients undergoing allogeneic hematopoietic stem cell transplant (HSCT) disrupts the intestinal system which can lead to post-transplant complications such as blood stream infections (BSI) and acute graft versus host disease (GVHD). 2'-fucosyllactose is a supplement found in human milk that can help regulate the immune system and prevent intestinal pathogens from staying in the intestine. The purpose of this study is to see if 2'-fucosyllactose (referred to as 2FL supplementation throughout this document) will help intestinal inflammation in patients undergoing HSCT and to see if it will reduce the incidence of blood stream infections and acute graft versus host disease.

2-fucosyllactose is investigational and has not been definitively confirmed to help intestinal inflammation or reduce the incidence of blood stream infections and acute graft versus host disease in patients undergoing HSCT. This means it is not approved for this use by the U.S. Food and Drug Administration (FDA).

Procedures:
If you decide to participate in this study, you will be asked to take 2FL supplementation once daily starting one week prior to chemotherapy and/or radiation through 30 days post-transplant. The 2FL supplementation will be provided in powder form in individual packets and should be mixed with food

or drink. If you are unable to eat or drink the supplementation, it may be administered through your feeding tube. If you throw up within 30 minutes of administration of 2FL, it may be administered again. Stool, blood (approximately ½ teaspoon per time point), and urine will be collected prior to the first dose of 2FL supplementation and then on day +7, day +14 and day +30 post-transplant.

If you are enrolled in the HSCT repository we may obtain the samples from the repository. If you are not enrolled in the HSCT repository or if a sample is not available from the repository for any reason, we will collect the samples according to the schedule noted above.

Clinical data pertaining to your transplant will be collected from your medical record for the study up to 100 days post-transplant.

Additional information about the study procedures can be found under ***"Detailed Procedures".***

Risks to Participate:
2FL supplementation has been safely administered to healthy infants and adults without complications, however, its safety has not been determined in patients undergoing transplant.

The most common risks associated with 2FL supplementation are:

- Allergic reaction
- Gastrointestinal discomfort (nausea, abdominal pain, indigestion, reflux, diarrhea, constipation, gas, rumbling and bloating)

There are no known adverse effects of 2FL supplementation to an unborn child. However, if you are a female of childbearing age, it is advised that appropriate birth control methods be utilized during the study and for 30 days following your last dose of 2FL supplementation. Your study doctor can discuss appropriate methods of birth control with you. If you should become pregnant during the study, you must notify your study doctor immediately.

Additional information about the risks of this study can be found under ***"Detailed Risks".***

Benefits to Participate:
We cannot promise any benefits to you or others from participating in this research. However, your participation in this study may decrease the risk of developing a blood stream infection or acute graft versus host disease. Knowledge gained from this study may lead to benefits in post-transplant care in the future.

There is also a chance you will not receive a direct benefit from your participation in this study.

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:
There are no added costs to participate in this research. The 2FL supplementation will be provided by the study. You or your insurance provider will not be billed for any tests and/or procedures performed for the purposes of this research. This includes the collection of the stool and blood samples.

You or your insurance company will be billed for all procedures or services performed as part of standard clinical care, including all costs related to your transplant.

Payment:
You will receive $50 on day +7 and an additional $50 on day +30 if you take 60% of the planned doses of 2FL prior to these defined timepoints. You will receive this payment in the form of a reloadable debit card (ClinCard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address.

If you do not have a social security number or tax identification number, you will be offered a gift card instead of the ClinCard.

Additional Study Information:

The following is more detailed information about this study in addition to the **"Key Information"**.

If I have questions or would like to know about:

Who to talk to…	**You can call …**
• General study questions • Research-related injuries • Any research concerns or complaints	The Principal Investigator [redacted]
• Your rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.

Total number of participants:
We anticipate approximately 65 patients undergoing transplant will participate in this research study.

Detailed Procedures:
If you are outpatient, you will be asked to record your doses of 2FL supplementation in a study diary. If you miss a dose, the reason why you missed the dose should be recorded. The study diary will be reviewed by study staff to assess compliance.

Change of Mind/Study Withdrawal:
You can leave the research at any time; it will not be held against you. If you decide to withdraw from the study, any data and samples collected for the study before you decided to withdraw will be kept, however, no new data or samples will be collected.

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

Detailed Risks:
Blood draws may involve minor pain, bleeding, bruising, and risk of infection.

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.

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

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 IRB 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 Cincinnati Children's 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.

If injured while in the study:
If you believe that you have been injured as a result of this research, you should contact the principal investigator [redacted] as soon as possible to discuss the concerns. Treatment for injuries is available at Cincinnati Children's. If you go to the Emergency Room or to another hospital or doctor, it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

Cincinnati Children's follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH
To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children's medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will never expire.

Will your other medical care be impacted?

By signing this document, you agree to participate in this research study and give permission to Cincinnati Children's to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

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.

_____	_____
Signature of Research Participant Indicating Assent (ages 11-17)	Date
_____	_____
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 for the consent process.

_____	_____
Signature of Person Present During Consent	Date