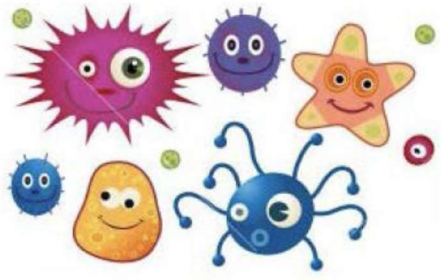
UNIVERSITY OF CALGARY

RESEARCH INFORMATION SHEET

Name of Study: **Determinants of Partial Remission in Type 1 Diabetes**

Who is Eligible: Who is eligible for this study? All children attending the Alberta Children's Hospital, newly diagnosed with Type 1 Diabetes

Meet 7 billion friends that you didn't know you had!



Do you have "healthy" bacteria in your tummy?

UNIVERSITY OF CALGARY

HONEYMOON

Phase in Type 1 Diabetes

A Research Study at the Alberta Children's Hospital is looking for children newly diagnosed with Type 1 Diabetes to study why some kids enjoy a longer honeymoon phase.

If you are interested or would like more info, please contact: Tetsuro at 403-955-7758 or tetsuro.okada@albertahealthservices.ca

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Poster Version 2.0 Date: December 10, 2021 Ethics ID # REB18-1875.
This study has been approved by the University of Calgary Conjoint Health Research Ethics Board

Type 1 Diabetes Honeymoon Study
Tetsuro – Research Coordinator
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tetsuro.okada@albertahealthservices.ca

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PEDIATRIC CONSENT FORM
(Parents/Guardians)

TITLE: Determinants of Partial Remission in Type 1 Diabetes (T1D)

SPONSOR: Alberta Children's Hospital Foundation

PRINCIPAL INVESTIGATOR: Dr. Carol Huang 403-955-7819

CO-INVESTIAGORS: Dr. Raylene Reimer, Dr. Jon Meddings, Dr. Josephine Ho, Dr. Daniele Pacaud

STUDY COORDINATOR: Tetsuro Okada **403-955-7758**

This consent form is only part of the process of informed consent. It should give you and your child the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

We all have a wide variety of bacteria in our gut/bowels. Both animal and human studies found that there is a difference in the composition of bacteria in the gut between those that develop diabetes and those that did not develop diabetes. Specifically, there is evidence linking an abnormal gut bacterial composition with leakiness of the bowel wall, causing inflammation and the development of Type 1 Diabetes (T1D).

At the time of diagnosis, many patients still have *some* functioning beta cells (cells that produce insulin) so that in the first year of T1D, about 50% of patients will experience partial remission. During this period, their insulin requirements are low and they have excellent blood glucose control. We do not know what determines who will experience a partial remission and what determines the duration of partial remission, but it is believed that the gut bacterial composition could be a factor. Since patients who experience partial remission have fewer long-term diabetes-related complications, understanding the relationship between gut bacterial composition, intestinal permeability, and the duration of partial remission is important. To date, there have been no studies evaluating the impact of the gut bacterial composition on partial remission of T1D.

In this small initial study, we will recruit patients with T1D from the diabetes clinic at the Alberta Children's Hospital within one month of diagnosis and follow them for two years, evaluating gut bacterial composition, intestinal permeability and beta cell function.

We aim to enroll a total of 50 patients from the Alberta Children's Hospital diabetes clinic in this study.

WHAT IS THE PURPOSE OF THE STUDY?

This small study will provide a first look at gut bacterial composition and intestinal permeability as factors involved in partial remission of T1D in children newly diagnosed. This information may help us develop therapies to optimize gut bacterial composition at the onset of diagnosis to initiate and/or prolong partial remission, and therefore enhance clinical outcomes and reduce complications.

UNIVERSITY OF CALGARY

WHAT WOULD MY CHILD HAVE TO DO?

There will be a baseline visit and additional visits at 1, 3, 6, 9, 12, 18, and 24 months.

Study visit components are described below, followed by the visit schedule and required components.

Questionnaire (age, gender, date of T1D diagnosis, current medications, other medical conditions, number of episodes of severe hypoglycemia and ketoacidosis, insulin requirements). May be filled out online or in person.

Measurements (height, weight)

Blood glucose logs from continuous glucose monitor (CGM) or flash glucose monitor (FGM) digital download or self-monitored blood glucose logs. We will take a copy of your logs or a digital download to understand changes in your blood glucose levels and insulin requirements.

HbA1c Test and Details about Diagnosis information will be collected from your child's medical chart. This test measures average blood glucose level for the last 2-3 months prior to the test.

Mixed Meal Tolerance Test your child will arrive to clinic fasting. You will get special instructions about diet and insulin dosing before the test. To make the blood sampling easier for the test, an intravenous needle and plastic tube (IV) will be placed in your child's vein. The IV will be kept in place during the test. Two blood samples, ten minutes apart (one teaspoon of blood for each sample) will be taken through the IV. Your child will then drink a meal replacement beverage (like "Boost") which has glucose as well as fats and proteins. Blood samples will be drawn through the IV at regular intervals for 2 hours to measure glycemic control and beta cell function (C-peptide, glucose, insulin, proinsulin) in response to a "meal".

Gut Leakiness Test the night before your child's study visit, after their regular evening meal and 3 hours before bedtime, they will drink a solution containing lactulose and mannitol in 200 mL of water. We will ask you to collect all of your child's urine for the following 12 hrs and bring it into the clinic within 24 hrs after collection.

Stool Sample will be collected at home. One tablespoon of stool will be placed in a pre-labelled tube, placed in a biohazard bag and stored in the home freezer (-20°C). Stool samples will be brought to the clinic on cold packs within 3 days of collection.

Baseline Visit: Fasting, ~3 hours

- Eligibility Screen and Informed Consent
- Questionnaire
- Measurements
- Blood glucose logs
- Mixed Meal Tolerance Test
- Gut Leakiness Test
- Stool Sample

3 Month Visit: ~30 minutes

- Questionnaire
- Measurements
- Blood glucose logs
- Gut Leakiness Test
- Stool Sample

6 Month Visit: Fasting, ~3 hours

- Questionnaire
- Measurements
- Blood glucose logs
- Mixed Meal Tolerance Test
- Gut Leakiness Test
- Stool Sample

9 Month Visit: ~30 minutes

- Questionnaire
- Measurements
- Blood glucose logs
- Gut Leakiness Test
- Stool Sample

12 Month Visit: Fasting, ~3 hours

- Questionnaire
- Measurements
- Blood glucose logs
- Mixed Meal Tolerance Test
- Gut Leakiness Test
- Stool Sample

18 Month Visit: ~30 minutes

- Questionnaire
- Measurements
- Blood glucose logs

24 Month Visit: ~30 minutes

- Questionnaire
- Measurements
- Blood glucose logs

WHAT ARE THE RISKS?

Your child could have discomfort and/or a bruise when they get their blood drawn. Once in a while, some people may faint. It is rare, but some people may get an infection, a small blood clot, swelling of the vein and surrounding tissue or bleeding where the needle enters the skin. Some people may feel nauseous when they complete the Mixed Meal Tolerance Test. The Mixed Meal Tolerance Test requires drinking a product which contains milk and soy ingredients. People with severe allergies to these could have a reaction. If your child has a known allergy to either of these ingredients, please let us know. It is possible we may need to advise you to avoid the Mixed Meal Tolerance Tests.

The intestine leakiness drink contains a small amount of lactulose and mannitol, which are not absorbed into your child's system, therefore is not likely to cause side effects. Diarrhea and nausea are seen with much higher doses.

ARE THERE ANY BENEFITS FOR MY CHILD?

There is no guarantee that your child will benefit from this study. During the study we will share with you information about your child's health and diabetes. The information we get from this study may help us to provide better treatments in the future for patients newly diagnosed with T1D.

DOES MY CHILD HAVE TO PARTICIPATE?

Your child will continue to have regular standard treatments through the diabetes clinic and their usual diabetes team. Participation in this study is voluntary and your child may withdraw from it at any time without jeopardizing their health care. To withdraw, let a member of the research team know that you don't wish to participate anymore. You can contact either the study coordinator (403-955-7758) or investigator (403-955-7819) if you wish to withdraw your child from the study. Also, let them if you would like your child's data erased from the study. The researcher can also withdraw your child from the study. If new information becomes available that might affect your child's willingness to participate in the study, you will be informed as soon as possible.

WHAT ELSE DOES MY CHILD'S PARTICIPATION INVOLVE?

There are no other things involved.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

The costs of parking for each visit will be reimbursed.

WILL MY CHILD'S RECORDS BE KEPT PRIVATE?

Only the researchers and designated research assistants will have access to the information collected. All paper files will be kept in locked offices at the Alberta Children's Hospital and data will be stored in password protected computers. The University of Calgary Conjoint Health Research Ethics Board will have access to the records.

Online follow-up and consent forms are hosted by Qualtrics. Qualtrics is an online survey platform with servers located in Toronto, Ontario, Canada. All data are encrypted and stored directly on its servers. Researcher access to the survey data is password-protected and the transmission is encrypted. Survey responses cannot be linked to your computer. Only the online forms will be stored by Qualtrics, not any health information or study visit data.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

In the event that your child suffers injury as a result of participating in this research, no compensation will be provided to you by the Department of Pediatrics, the University of Calgary, the Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

UNIVERSITY OF CALGARY

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your child's participation in the research project and agree to their participation as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw your child from the study at any time without jeopardizing their health care. If you have further questions concerning matters related to this research, please contact:

Tetsuro Okada 403-955-7758

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Parent/Guardian's Name	Signature	Date
Child's Name	Signature (if able to read consent. If not, read & sign assent)	Date
Investigator/Delegate's Name	Signature	Date

The investigator or a member of the research team will, as appropriate, explain to your child the research and his or her involvement. They will seek your child's ongoing cooperation throughout the study.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

MATURE MINOR CONSENT FORM
(Ages ¬15+)

TITLE: Determinants of Partial Remission in Type 1 Diabetes (T1D)

SPONSOR: Alberta Children's Hospital Foundation

PRINCIPAL INVESTIGATOR: Dr. Carol Huang 403-955-7819

CO-INVESTIAGORS: Dr. Raylene Reimer, Dr. Jon Meddings, Dr. Josephine Ho, Dr. Daniele Pacaud

STUDY COORDINATOR: Tetsuro Okada **403-955-7758**

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3 Month Visit: ~30 minutes

- Questionnaire
- Measurements
- Gut Leakiness Test
- Stool Sample

6 Month Visit: Fasting, ~3 hours

- Questionnaire
- Measurements
- Mixed Meal Tolerance Test
- Gut Leakiness Test
- Stool Sample

9 Month Visit: ~30 minutes

- Questionnaire
- Measurements
- Gut Leakiness Test
- Stool Sample

12 Month Visit: Fasting, ~3 hours

- Questionnaire
- Measurements
- Mixed Meal Tolerance Test
- Gut Leakiness Test
- Stool Sample

18 Month Visit: ~30 minutes

- Questionnaire
- Measurements

24 Month Visit: ~30 minutes

- Questionnaire
- Measurements

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DO I HAVE TO PARTICIPATE?

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WHAT ELSE DOES MY PARTICIPATION INVOLVE?

There are no other things involved.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

The costs of parking for each visit will be reimbursed.

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IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the Department of Pediatrics, the University of Calgary, the Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to your participation as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Tetsuro Okada 403-955-7758

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair of the Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Participant's Name	Signature	Date
Investigator/Delegate's Name	Signature	Date

The investigator or a member of the research team will, as appropriate, explain the research and your involvement. They will seek your ongoing cooperation throughout the study.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

PEDIATRIC ASSENT FORM
(AGE 7-14 YEARS)

Project Title: Determinants of Partial Remission in Type 1 Diabetes (T1D)

Principal Investigator: Dr. Carol Huang

We want to tell you about a research study we are doing. A research study is a way to learn more about something. You are being asked to join the study because you have recently been diagnosed with type 1 diabetes. We want to do this study to find out if different types of tummy bacteria affect your diabetes when first diagnosed.

If you agree to join this study, it will last two years (with a visit at the beginning, 3, 6, 9, 12, 18 and 24 months). To see what kinds of tummy bacteria you have and how it affects your diabetes, we need to do a few extra tests on your urine (pee), stool (poop), and blood. Just before baseline, 3, 6, 9 and 12 month visits, we want you to take a special drink, and it should not have any bad effect on your body, but if people drink a lot more of it, it can make their poop watery and their stomach feel full. Then we want you or your parents to keep a little bit of your urine (pee) and your stool (poop). At the baseline, 6 month and 12 month visits, you will come in on an empty stomach and drink another special drink that has sugars, fats and protein and we will take some blood samples over the next 2 hours. To make it easier to collect the blood, an intravenous needle and tube will be placed in your vein throughout the test. You have to avoid any food or drink other than water for 10 hours before this visit. You could have discomfort and/or a bruise when you get your blood drawn. Once in a while, some people may faint. It is rare, but some people may get an infection, a small blood clot, swelling of the vein and surrounding tissue or bleeding where the needle enters the skin.

We will ask you some questions at each of your visits and collect some information from your medical chart.

Learning more about tummy bacteria in those newly diagnosed with type 1 diabetes may help other children newly diagnosed with diabetes some day.

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study, ask Tetsuro at 403-955-7758.

Would you like to be in this research study?

_____ Yes, I will be in this research study. _____ No, I don't want to do this.

_____	_____	_____
Child's name	Signature of the child	Date
_____	_____	_____
Person obtaining assent	Signature	Date

UNIVERSITY OF CALGARY CONSENT
ADDITIONAL INFORMATION FOR CONTINUING RESEARCH PARTICIPANTS

TITLE: Determinants of Partial Remission in Type 1 Diabetes (T1D)

SPONSOR: Alberta Children's Hospital Foundation

PRINCIPAL INVESTIGATOR: Dr. Carol Huang 403-955-7819

CO-INVESTIGATORS: Dr. Raylene Reimer, Dr. Jon Meddings, Dr. Josephine Ho, Dr. Daniele Pacaud

Primary Site Contact: Tetsuro Okada **403-955-7758**

You are participating in the above named research study. When you agreed to participate, the researchers told you they would share any new information about the study that might affect your willingness to continue to participate in the study.

The study now involves new risk information that are described below. The researchers will explain the new risk information and then ask for your consent to continue participating in the study. With the exception of the information provided below, all of the information provided to you previously still applies.

WHAT ARE THE NEW PROCEDURES INVOLVED IN THIS STUDY?

In accordance with the Alberta Health Services (AHS) and University of Calgary guidelines during the COVID-19 pandemic, all members of the public and staff must wear personal protective equipment (PPE) while on-site. The participant and any accompanying family members will be provided with a surgical mask upon entry to the site and asked to sanitize their hands. The provided mask must be worn throughout the study visit.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

The potential for exposure to COVID-19 is increased due to the increased time within a healthcare facility and exposure to research staff while attending the study visit. Travel

to and from the healthcare facility via public transit may increase the risk of contracting COVID-19.

The research staff will minimize contact and maintain physical distancing where appropriate to mitigate the risk of transmitting COVID-19 to the participant. Personal protective equipment such as masks and (where appropriate) gloves must be worn by the participant, observing family members and research staff during the entirety of the interaction. Sanitization of testing areas, multiuse equipment and surfaces will be done in accordance with Alberta Health Services Infection Prevention and Control standards.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

Participation in this study is voluntary and the participant may withdraw from it at any time without jeopardizing their health care. Should you not wish to participate in in-person research activities at this time, you can continue with remote collections of study samples or telehealth visits (where applicable), foregoing the in-person activity until you are comfortable attending study visits.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT CONTINUING IN THIS STUDY?

The Research Team:
You may contact Tetsuro Okada at 403-955-7758 with any questions or concerns about the research or your participation in this study.

Conjoint Health Research Ethics Board (CHREB):
If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

WHAT ARE MY RIGHTS IF I DECIDE TO CONTINUE TO TAKE PART IN THIS STUDY?

Continuing to take part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you.

- You have a right to have all of your questions answered before deciding whether to continue to take part.
- Your decision will not affect the medical care you receive
- If you decide to continue to take part, you can leave the study at any time.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Your signature on this form indicates that you have understood to your satisfaction the information regarding your continued participation in the research project and agree to

continue to take part. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

SIGNATURE OF STUDY PARTICIPANT (For participants 7 years and older)

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PARENT OR GUARDIAN (For participants less than 18 years old)

_____
Name of Parent or Guardian

_____ _____
Signature of Parent or Guardian Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

SIGNATURE OF THE WITNESS

_____
Name of Witness

_____ _____
Signature of Witness Date

A signed copy of this consent form has been given to you to keep for your records and reference.