

SWEET and CAPACity Research Studies

Please help our clinic improve by
finding out how we are doing!

These quality assurance research projects are seeking your participation to help us assess the services our diabetes clinic provides in comparison with other diabetes clinics throughout Canada and the world!



**NO extra Blood
Work**



NO extra Visits

Completing these forms today is the **ONLY ACTION** you have to take to help with this initiative.

REB15-0948 – The SWEET Studygroup of diabetes in children: Study of Centre Differences between Pediatric Diabetes Centres (SWEET)

REB21-1460 – The CANadian PediAtric diabetes ConsortIum Study (CAPACity)

This study has been approved by the University of Calgary Conjoint Health Research Ethics Board.

Version 1.0 – 10 March 2022

Please discuss with your team if you
have any questions!

The “SWEET” Studygroup of diabetes in children

(Better control in Pediatric and Adolescent diabetes: Working to create Centers of Reference).

INFORMATION FOR PARENTS

This is a study of centre differences between pediatric diabetes centres

We would like you and your child to take part in a study regarding diabetes in children. It is very important to us that you know exactly why we conduct this study and what this study means for you. Please read this information carefully. Of course, you can talk about this study with third parties or question us if you need to know more.

WHAT IS THE PURPOSE OF THE STUDY?

To improve health and quality of life outcomes of young people with diabetes through the sharing of data between diabetes clinics across the world.

WHY DID WE CHOOSE YOU?

We have approached you because your child is being treated in one of the international reference centres for children with diabetes.

DO YOU HAVE TO PARTICIPATE?

If you don't want to, you don't have to take part. It will not influence how we treat you or your child in our clinic if you don't take part.

WILL YOUR CHILD'S RECORDS AND ANSWERS TO THE QUESTIONNAIRE BE KEPT CONFIDENTIAL?

The doctors and nurses in the clinic will not know which answers you have given because no addresses or names will be documented with the questionnaire or the clinical data. The data will be kept strictly confidential. In that way your answers will have no influence on how we will treat you and your child in the future.

WHAT WILL HAPPEN TO YOU AND YOUR CHILD IF YOU PARTICIPATE?

Your child's data (month and year of birth, gender, date of diagnosis, type of diabetes, height, weight, blood pressure, labs, medications including insulin treatment, hospitalisation and diabetes-related complications) will be documented as usual and – if you approve – will be centrally and anonymously evaluated in Ulm, Germany.

ARE THERE ANY BENEFITS IF YOU PARTICIPATE?

There will be no quick direct benefits for you or your child if you help us with this study, but we hope the results will eventually help us to care better for children with diabetes here in this clinic and worldwide.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The clinical data will only be used for this study. They will not be given to any third party.

Later, the results of the study will be passed on to the leader of your diabetes team during a meeting of the SWEET studygroup so that she can discuss them with you and the whole diabetes team. Results will be presented at professional diabetes meetings and published in medical journals. In that way, the data can help diabetes centres worldwide optimize the care for families like yours. We also intend to share publications and results with you by making them available in our waiting room and/or in our clinic newsletter.

WHO ORGANIZES AND SUPPORTS THE STUDY?

The study is supported by the European Union and the SWEET studygroup (www.sweet-project.eu).

WHO CONTROLS AND MONITORS THE STUDY?

The study is monitored by the participating diabetes centres. The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

WOULD YOU LIKE FURTHER INFORMATION?

If you have further questions concerning matters related to this research, please contact:

Dr. Danièle Pacaud (403) 955-7819 or Heidi and Claire (403) 955-8866

If you have any questions concerning your rights as a possible participant in this research, or if you have any complaints or concerns about the way the trial doctor has carried out the trial, please contact the Chair, Conjoint Health Research Ethics Board., University of Calgary, at 403-220-7990.

**THANK YOU FOR READING THIS INFORMATION:
WE HOPE THAT YOU WILL SUPPORT US.**

YOUR DIABETES TEAM.



UNIVERSITY OF CALGARY STANDARD CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Pediatric Diabetes Registry Studies:

- **SWEET** (Better control in Pediatric and Adolescent diabetes: Working to create CENTers of Reference)
- **CAPACity** (The **CAN**adian **PediA**tric diabetes **C**onsortium)

SPONSOR: University of Calgary

INVESTIGATORS: Dr. Danièle Pacaud

403-955-7819

INTRODUCTION

Dr. Pacaud and associates from the Department of Paediatrics at the University of Calgary are conducting a research study.

This consent form is only part of the process of informed consent. It should give you 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 for your records.

You were identified as a possible participant in this study because you are a patient at the Diabetes Clinic at the Alberta Children's Hospital. Your participation in this research study is voluntary.

WHY IS THIS STUDY BEING DONE?

1. To establish **Canadian** clinical standards for treatment of childhood diabetes via the CAPCITY project. To compare each participating clinic against these standards in order to improve the quality of childhood diabetes care in Canada.
2. To establish **international** clinical standards for treatment of childhood diabetes via the SWEET project. To compare each participating clinic against these standards in order to improve the quality of childhood diabetes care in Alberta.
3. To potentially use this valuable data for future research initiatives.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity

PI: Dr. Danièle Pacaud

Version 1.0 5 October 2021

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

People will take part in the studies worldwide. About 2000 people will take part in this study through the University of Calgary.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you volunteer to participate in this study, the researcher will ask you to do the following:

There are 3 parts to this study. Agreeing to participate includes participation in all 3 parts.

- (1) The CAPAClty project,
- (2) The SWEET project,
- (3) Future projects

If you agree to take part in the study, the study team will collect information from your clinical or electronic chart such as month & year of birth, date of diabetes diagnosis, postal code, height & weight, blood test results, diabetes medications, etc. from every visit to the diabetes clinic until you transition to adult care. 'De-identified' information (meaning information that will not include your identity such as name, day of birth, etc.) will be transferred in a secure way through an electronic system to the research database that will be located in a secure place at the University of Calgary.

Your information will be 'anonymized' (meaning that the information will be sent without any identifying details, removing the possibility of linking the information back to you) and then securely transferred to the CAPAClty registry at the University of McGill (Canada) and the SWEET registry at the University of Ulm (Germany). Separate lists of your name and study ID number will be kept at your clinic (by the local Site Director or research coordinator) in a password protected, encrypted file on a password protected, encrypted computer in a locked office. You will also be asked to complete a short questionnaire for the CAPAClty project after completing this form.

At a later date and as part of different study (initiated after receiving Research Ethics Board Approval), the study team may use your data (previously collected in the first part of the study) for future research initiatives.

HOW LONG WILL I BE IN THIS STUDY?

Other than agreeing to participate in the study and completing the survey for the CAPACITY study, you will not be asked to do anything else in this study. Children who entered this study before 7 years of age will be asked to provide assent when they turn 7. At 17 years of age, participants will be asked to sign a re-consent form to make sure they are still willing to participate in the study.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPAClty

PI: Dr. Danièle Pacaud

Version 1.0 5 October 2021

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

There are no risks to your health and the healthcare that you receive from taking part in this study. Study risks include the loss of confidentiality of private information (e.g. name, date of birth, PHN, clinical information, etc.). But, the researchers have put systems in place to make sure that all private information is protected such as encrypted information transfer technology and secure servers with user passwords, virus protection, and battery back-up systems, with restricted access to authorized personnel and 24/7 security measures and monitoring.

Names, medical record numbers and/or PHN's will be kept separately from other information in a password-protected file on an encrypted and password protected computer, in a locked office where your diabetes clinic is located.

ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?

There are no direct benefits to taking part in this study. The research team will not pay you for participation in this study. However, the results of this study will inform a large-scale study that may improve the healthcare services that are available to children and youth with diabetes living in Alberta.

WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. Your decision will not affect the standard medical care you receive.

CAN I STOP BEING IN THE STUDY?

There is no action required from you after signing this form. See withdrawal details below.

WITHDRAWAL OF STUDY DATA

Even if you agree to participate in any part of the study now, you can change your mind and remove yourself from the study at any time without giving reasons and any negative consequences to the medical care, education, or other services to which you are entitled to or presently receiving. If you choose to enter into the study and decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible i.e. your information will be removed from the local database. However, there may be exceptions in which the information will not be withdrawn such as in cases where the information is

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPAClty

PI: Dr. Danièle Pacaud

Version 1.0 5 October 2021

anonymized (meaning it cannot be linked back to your identity by the study team), for example, in the SWEET or CAPACITY registries or where the information has been merged with other information. If you would like to request the withdrawal of your identifiable information, please let the study team know.

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

You will not be paid for your participation in this research study. You will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.

WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy.

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the University of Calgary Conjoint Health Research Ethics Board and/or any other Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number, as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your PHN, Social Insurance Number, initials, etc.).

The study ID will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to your unique study number will not be removed or released without your consent, unless required by law.

The security of all confidential information will be maintained at all times. If the studies were to close because additional funding is not secured, the information collected up to when the study is closed will be held in a secure server. According to University of Calgary policy requirements, the study data will be retained for at least 5 years. After 5 years, all information records can be destroyed per current government standards. The government of Alberta or University of Calgary Conjoint Health Research Ethics Board may also direct that the information records be destroyed before the 5-year mark. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. Further details about these laws are available on request to the study team.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACITY

PI: Dr. Danièle Pacaud

Version 1.0 5 October 2021

HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?

According to University of Calgary policy requirements, the study data will be retained for at least 5 years. After 5 years, all information records can be destroyed per current government standards.

The researchers intend to keep the research data and records in a repository indefinitely. Other researchers will have access to the data for future research. Data collected for this study may be shared with other researchers for future studies that are unknown at this time. Any data shared with other researchers, will not include your name or other personal identifying information.

Any future use of this research data is required to undergo review by a Research Ethics Board.

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 University of Calgary, Alberta Health Services or the Researchers. However, you still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

WHOM MAY I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:

You may contact Heidi Virtanen at 587-943-2751 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.

HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?

Study results will be made available to participants upon request once published.

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

Taking 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.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity

PI: Dr. Danièle Pacaud

Version 1.0 5 October 2021

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

CONTACT FOR FUTURE RESEARCH

University of Calgary researchers may contact me in the future to ask me to take part in other research studies.

- YES
 NO

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 participation in the research project and agree to take part in the study. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. Please indicate your participation via checking yes/no box. If you select “no” we will not ask you again to participate.

I agree to participate in the SWEET study, the CAPAClty study, and future research involving the data already collected.

- YES – please complete signature fields below
 NO – do not complete signature fields below

SIGNATURE OF STUDY PARTICIPANT

 Name of Participant

 Signature of Participant

 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.



UNIVERSITY OF CALGARY PARENTAL CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Pediatric Diabetes Registry Studies:

- **SWEET** (Better control in Pediatric and Adolescent diabetes: Working to create CEnters of Reference)
- **CAPACity** (The **C**Anadian **P**edi**A**tric diabetes **C**onsortium)

SPONSOR: University of Calgary

INVESTIGATORS: Dr. Danièle Pacaud

403-955-7819

INTRODUCTION

Dr. Pacaud and associates from the Department of Paediatrics at the University of Calgary are conducting a research study.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your child's 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 for your records.

Your child was identified as a possible participant in this study because they are a patient at the Diabetes Clinic at the Alberta Children's Hospital. Your child's participation in this research study is voluntary.

WHY IS THIS STUDY BEING DONE?

1. To establish **Canadian** clinical standards for treatment of childhood diabetes via the CAPCity project. To compare each participating clinic against these standards in order to improve the quality of childhood diabetes care in Canada.
2. To establish **international** clinical standards for treatment of childhood diabetes via the SWEET project. To compare each participating clinic against these standards in order to improve the quality of childhood diabetes care in Alberta.
3. To potentially use this valuable data for future research initiatives.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity

PI: Dr. Danièle Pacaud

Parental Consent Form Version 1.0 5 October 2021

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

People will take part in the studies worldwide. About 2000 people will take part in this study through the University of Calgary.

WHAT WILL HAPPEN TO MY CHILD IF THEY TAKE PART IN THIS STUDY?

If your child volunteers to participate in this study, the researcher will ask your child to do the following:

There are 3 parts to this study. Agreeing to participate includes participation in all 3 parts.

- (1) The CAPACity project,
- (2) The SWEET project,
- (3) Future projects

If you agree for your child to take part in the study, the study team will collect information from their clinical or electronic chart such as month & year of birth, date of diabetes diagnosis, postal code, height & weight, blood test results, diabetes medications, etc. from every visit to the diabetes clinic until they transition to adult care. 'De-identified' information (meaning information that will not include your child's identity such as name, day of birth, etc.) will be transferred in a secure way through an electronic system to the research database that will be located in a secure place at the University of Calgary.

Your child's information will be 'anonymized' (meaning that the information will be sent without any identifying details, removing the possibility of linking the information back to them) and then securely transferred to the CAPACity registry at the University of McGill (Canada) and the SWEET registry at the University of Ulm (Germany). Separate lists of your child's name and study ID number will be kept at your child's clinic (by the local Site Director or research coordinator) in a password protected, encrypted file on a password protected, encrypted computer in a locked office. You will also be asked to complete a short questionnaire for the CAPACity project after completing this form.

At a later date and as part of different study (initiated after receiving Research Ethics Board Approval), the study team may use your child's data (previously collected in the first part of the study) for future research initiatives.

HOW LONG WILL MY CHILD BE IN THIS STUDY?

Other than agreeing to participate in the study and completing the survey for the CAPACITY study, you/your child will not be asked to do anything else in this study. Children who entered this study before 7 years of age will be asked to provide assent when they turn 7. At 17 years of age, participants will be asked to sign a re-consent form to make sure they are still willing to participate in the study.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity

PI: Dr. Danièle Pacaud

Parental Consent Form Version 1.0 5 October 2021

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

There are no risks to your child's health and the healthcare that they receive from taking part in this study. Study risks include the loss of confidentiality of private information (e.g. name, date of birth, PHN, clinical information, etc.). But, the researchers have put systems in place to make sure that all private information is protected such as encrypted information transfer technology and secure servers with user passwords, virus protection, and battery back-up systems, with restricted access to authorized personnel and 24/7 security measures and monitoring.

Names, medical record numbers and/or PHN's will be kept separately from other information in a password-protected file on an encrypted and password protected computer, in a locked office where your diabetes clinic is located.

ARE THERE ANY POTENTIAL BENEFITS IF MY CHILD PARTICIPATES?

There are no direct benefits to taking part in this study. The research team will not pay your child for participation in this study. However, the results of this study will inform a large-scale study that may improve the healthcare services that are available to children and youth with diabetes living in Alberta.

WHAT OTHER CHOICES DOES MY CHILD HAVE IF I CHOOSE FOR MY CHILD NOT TO PARTICIPATE?

You are free to choose that your child not participate in the study. If you decide not to have them take part in this study, there will be no penalty to your child. Your decision will not affect the standard medical care your child receives.

CAN MY CHILD STOP BEING IN THE STUDY?

There is no action required from you or your child after signing this form. See withdrawal details below.

WITHDRAWAL OF STUDY DATA

Even if you agree for your child to participate in any part of the study now, you can change your mind and remove your child from the study at any time without giving reasons and any negative consequences to the medical care, education, or other services to which your child is entitled to or presently receiving. If you choose for your child to enter into the study and decide to withdraw at a later time, you have the right to request the withdrawal of your child's information collected during the study. This request will be respected to the extent possible i.e. your child's information will be removed from the local database. However, there may be exceptions in which the information will not be withdrawn such as in cases where the information is anonymized

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity

PI: Dr. Danièle Pacaud

Parental Consent Form Version 1.0 5 October 2021

(meaning it cannot be linked back to your child's identity by the study team), for example, in the SWEET or CAPACITY registries or where the information has been merged with other information. If you would like to request the withdrawal of your child's identifiable information, please let the study team know.

WILL MY CHILD BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

Your child will not be paid for participation in this research study. You/your child will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.

WILL INFORMATION ABOUT MY CHILD AND THEIR PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your child's private information is kept confidential. Information about your child will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy.

Your child's confidentiality will be respected. However, research records and health or other source records identifying your child may be inspected in the presence of the Investigator or his or her designate by representatives of the University of Calgary Conjoint Health Research Ethics Board and/or any other Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your child's identity will be published without your consent, nor will any information or records that disclose your child's identity be removed or released without your consent unless required by law.

Your child will be assigned a unique study number, as a participant in this study. This number will not include any personal information that could identify them (e.g., it will not include their PHN, Social Insurance Number, initials, etc.).

The study ID will be used on any research-related information collected about your child during the course of this study, so that their identity will be kept confidential. Information that contains your child's identity will remain only with the Principal Investigator and/or designate. The list that matches your child's name to their unique study number will not be removed or released without your consent, unless required by law.

The security of all confidential information will be maintained at all times. If the studies were to close because additional funding is not secured, the information collected up to when the study is closed will be held in a secure server. According to University of Calgary policy requirements, the study data will be retained for at least 5 years. After 5 years, all information records can be destroyed per current government standards. The government of Alberta or University of Calgary Conjoint Health Research Ethics Board may also direct that the information records be destroyed before the 5-year mark.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACITY

PI: Dr. Danièle Pacaud

Parental Consent Form Version 1.0 5 October 2021

Your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that their privacy is respected. Further details about these laws are available on request to the study team.

HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?

According to University of Calgary policy requirements, the study data will be retained for at least 5 years. After 5 years, all information records can be destroyed per current government standards.

The researchers intend to keep the research data and records in a repository indefinitely. Other researchers will have access to the data for future research. Data collected for this study may be shared with other researchers for future studies that are unknown at this time. Any data shared with other researchers, will not include your child's name or other personal identifying information.

Any future use of this research data is required to undergo review by a Research Ethics Board.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL THEY 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 or your child by the University of Calgary, Alberta Health Services or the Researchers. However, you/your child still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

WHOM MAY I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:

You may contact Heidi Virtanen at 587-943-2751 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 child's rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?

Study results will be made available to participants upon request once published.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACITY

PI: Dr. Danièle Pacaud

Parental Consent Form Version 1.0 5 October 2021

WHAT ARE MY CHILD'S RIGHTS IF THEY TAKE PART IN THIS STUDY?

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

- You have a right to have all of your questions answered before deciding whether your child takes part.
- Your decision will not affect the standard medical care your child receives
- If you decide for your child to take part, they may leave the study at any time

CONTACT FOR FUTURE RESEARCH

University of Calgary researchers may contact me in the future to ask about my child taking part in other research studies.

- YES
- NO

HOW DO I INDICATE MY AGREEMENT FOR MY CHILD TO PARTICIPATE?

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 have them take part in the study. In no way does this waive your child's legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. Please indicate your child's participation via checking yes/no box. If you select "no" we will not ask you again to have your child participate.

I agree to my child participating in the SWEET study, the CAPACity study, and future research involving the data already collected.

- YES – please complete signature fields below
- NO – do not complete signature fields below

Name of Child: _____

SIGNATURE OF PARENT/LEGAL GUARDIAN

Name of Parent/Legal Guardian

Signature of Parent/Legal 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.



**UNIVERSITY OF CALGARY
GENERAL ASSENT TO PARTICIPATE IN RESEARCH**

TITLE: Pediatric Diabetes Registry Studies:

- **SWEET** (Better control in Pediatric and Adolescent diabetes: Working to create CEnTers of Reference)
- **CAPAClty** (The **CA**nadian **PediA**tric diabetes **C**onsortlum)

SPONSOR: University of Calgary

INVESTIGATORS: Dr. Danièle Pacaud
403-955-7819

INTRODUCTION

A research study is a way to find out new information about something. People don't need to participate in a research study if they don't want to participate.

You can talk this over with your parents/guardians before you decide whether or not to participate. We will also ask your parents/guardians to give their permission for you to take part in this study. But even if your parents/guardians say "yes" you can still decide not to do this.

WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this research study because we are trying to learn more about children with type 1 diabetes. We are asking you to be in the study because you are a patient at the diabetes clinic at the Alberta Children's Hospital. About 2000 people from Calgary will be in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study, here are some things that will happen:

- You will be part of:
 - The CAPAClty project

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPAClty

PI: Dr. Danièle Pacaud

General Assent Form Version 1.0 18 August 2021

- The SWEET project
- Future projects

- The study team will look at your medical chart to collect information (ex. month and year of birth, date of diabetes diagnosis, postal code, height & weight, blood test results, diabetes medications, etc) from all of your visits to the diabetes clinic at the Alberta Children's Hospital.
- Any information about who you are (like your name or birthdate) will be removed to protect your privacy. The information from your medical chart will be shared with a team of researchers in Germany and another team of researchers in Quebec, Canada.
- You will be asked to complete a short survey for the CAPAClty project after completing this form.
- In the future, our study team may use some of this information from your medical chart for other research projects.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

There is no risk to your health if you participate in this study.

There is a small risk to your privacy if your personal information was released, but the study team have taken many steps to protect your privacy and not allowing this to happen.

WILL THE STUDY HELP OTHERS?

This study might find out things that will help other children with type 1 diabetes someday.

WHO WILL SEE THE INFORMATION COLLECTED ABOUT ME?

The information collected about you during this study will be kept safely locked up. Nobody will read it except the people doing the research. The study information about you will not be given to your parents/guardians. The researchers won't tell your friends or anyone else that you are in this study, or share any information about you.

DO I HAVE TO BE IN THE STUDY?

You don't have to be in the study. It is up to you. No one will be upset if you don't want to do this study. You can say yes, or you can say no. You can also take more time to think about being in the study.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPAClty

PI: Dr. Danièle Pacaud

General Assent Form Version 1.0 18 August 2021

If you want to stop, then 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 say yes now then want to stop later.

WHAT DO I GET FOR BEING IN THE STUDY?

You will not be paid to be in this study.

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

The Research Team:

You can ask any questions that you may have about the study. If you have a question later that you didn't think of now, either you can call or have your parents call [study coordinator] at [xxx-xxx-xxxx]. You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

WOULD YOU LIKE TO BE IN THIS RESEARCH STUDY?

If you decide to be in the study, then please write your name below. You can change your mind and stop being part of the study at any time. All you have to do is tell us. It's okay. The researchers and your parents won't be upset with you

- Yes, I want to be in this study. No, I don't want to do this.

Name of Participant

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING ASSENT

Name of Person who received assent

Signature of Person who received assent

Date

You will be given a copy of this paper to keep.

Ethics ID: REB15-0948; REB21-1460
Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity
PI: Dr. Danièle Pacaud
General Assent Form Version 1.0 18 August 2021



**UNIVERSITY OF CALGARY
ASSENT FOR CHILD (7-10) TO PARTICIPATE IN RESEARCH**

TITLE: Pediatric Diabetes Registry Studies:

- **SWEET** (Better control in Pediatric and Adolescent diabetes: Working to create CENTers of Reference)
- **CAPACity** (The **CAN**adian **PediA**tric diabetes **C**onsortium)

SPONSOR: University of Calgary

INVESTIGATORS: Dr. Danièle Pacaud

403-995-7819

My name is Heidi Virtanen.

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We want to find out more about children with type 1 diabetes. We are asking you to be in the study because you are followed by the diabetes clinic at the Alberta Children's Hospital. About 2000 children will be in this study.

We want to tell you about some things that will happen to you if you are in this study.

- The study team will look at your medical chart. Some of the information about your diabetes will be shared with other doctors in Canada and Germany trying to learn more about children with type 1 diabetes. The other doctors won't know who you are or any of your private information.
- This information will be collected for as long as you are followed by the diabetes clinic.
- Your parent/guardian will fill out a short survey about you.
- The study team will keep who you are private.
- We may learn something that will help other children with type 1 diabetes some day.

You don't have to join this study. It is up to you. You can say yes or you can say no. It's OK if you say yes and then you change your mind later. If you want to stop, then all

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity

PI: Dr. Danièle Pacaud

Assent Form Age 7-10 Version 1.0 18 August 2021

you have to do is tell us or your [parents/guardian] you want to stop. No one will be mad at you if you don't want to be in the study or if you say yes now then want to stop later.

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 us or your [parents/guardian] that you have a question.

We will also talk to your parents about this study. You can talk this over with them before you decide.

If you have a question later that you didn't think of now, you can call or have your parents call [xxxxxxx] at [xxx-xxx-xxxx].

WOULD YOU LIKE TO BE IN THIS RESEARCH STUDY?

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

Name of Child

Date

Name of Person who received assent

Signature of Person who received assent

Date

You will be given a copy of this paper to keep.

Ethics ID: REB15-0948; REB21-1460

Study Title: Pediatric Diabetes Registry Studies: SWEET and CAPACity

PI: Dr. Danièle Pacaud

Assent Form Age 7-10 Version 1.0 18 August 2021