UNIVERSITY OF SASKATCHEWAN

CANBSDS
CANADIAN BONE STRENGTH DEVELOPMENT STUDY

# PARTICIPANT INFORMATION AND CONSENT FORM

**STUDY TITLE**
**Can**adian **B**one **S**trength **D**evelopment in Children with Type 1 Diabetes **S**tudy **(CanBSDS)**

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**SPONSOR OR FUNDING AGENCY**
Canadian Institute of Health Research (CIHR)
Saskatchewan Health Research Foundation (SHRF)
Diabetes Canada

**CONTACT PHONE NUMBER**
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If you are the parent, legal guardian, or authorized representative of an individual being invited to take part in this study, permission from you may be required. The words "you" and "your" always refer to the participant in the study.

This study uses an e-consenting process. This means that you will receive an electronic copy of the consent form and if you agree to participate, will be asked to provide your signature electronically. The option to provide wet-ink (paper) signatures is also available to you, if preferred or required.

## INTRODUCTION

We are inviting you to take part in this research study because we want to assess bone properties, muscle strength, and physical activity in children with type 1 diabetes and compare these bone properties to children who do not have type 1 diabetes. We are also studying how physical activity, nutritional, and hormonal measures are associated to muscle and bone properties and development in children with type 1 diabetes and whether these relationships differ from those we observe in children who do not have this condition.

Previous research studies have shown that the bones of children with type 1 diabetes have a higher risk of fracture (being broken). We are doing this study to get a better understanding of why these changes happen. Our hypothesis is that because type 1 diabetes usually occurs during the growth spurt that happens during puberty, the changes caused by type 1 diabetes may interfere with bone development. Through this study, we hope to understand more about how bones develop and grow in children with type 1 diabetes.

In this study we will be looking at different things that can affect how bones develop and grow. We have tools to take high resolution pictures of the inside of bones, and these pictures tell us about the properties of the bones such as how strong they are, and how the inside structures of the bones look (which influences how easily the bones may break). We also have tools to measure muscle strength and body composition and will be using these in our study. We will also be looking at how other things like the amount and type of physical activity affect the bones. We will look at nutrition and hormones as well, as these are also things that can impact bones.

As you learn more about the study, feel free to ask us as many questions as you would like. Please also feel free to discuss this with your family, friends, or physician before you decide to participate. Once you are done learning about the study and gathering the information you need, if you would like to be a participant in the study, we will ask you to sign the last page of this document.

Please do not feel any pressure to participate in the study. We want you to feel comfortable and excited to join us. If you would prefer not to join that is fine. If you decide to participate, you are still free to withdraw at any time and without giving any reasons for your decision. Your choice to be part of the study (or not) will not impact your access or level of medical care or your relationship with the health authority, your physician, or anyone involved with the study.

Please take time to read the following information carefully. You can ask the researcher to explain any information that you do not clearly understand. You may ask as many questions as you need.

## WHO IS CONDUCTING THE STUDY?

The study is conducted by researchers across Canada at four study locations; University of Calgary/Cummings School of Medicine, University of Saskatchewan/RUH, University of Ottawa/CHEO, and University of Toronto/Sick Kids. The study is supported by research grants from CIHR, SHRF, and Diabetes Canada that have been awarded to the researchers for conducting the study.

The sponsor of this study (CIHR, SHRF, and Diabetes Canada) will reimburse for the costs of undertaking this study. However, neither the institutions nor any of the investigators or staff will receive any direct financial benefit from conducting this study.

Please note that the Saskatchewan research sites, located at the University of Saskatchewan, D-camp (children's summer camp at Christopher Lake for children with Type 1 Diabetes) and the Diabetes Clinic, are under the jurisdiction of the Saskatchewan Health Authority. We are taking all safety precautions to reduce the risk of COVID-19 and expect you to follow public health directives.

**WHY IS THIS STUDY BEING DONE?**

This study is being done because we want to better understand the underlying reasons for higher fracture risk in children with type 1 diabetes. Previous research has demonstrated that children with type 1 diabetes have lower bone mineral density and muscle mass. However, it is poorly understood how physical activity levels, muscle force production, bone microarchitecture, and metabolism (the chemical reactions in the body's cells that change food into energy) in children with type 1 diabetes differ from children who do not have this condition. This study will contribute to the understanding of bone and muscle health in children with type 1 diabetes.

**WHO CAN PARTICIPATE IN THE STUDY**

You are eligible to participate in this study if you are 10-11 years old (female) or 11-12 years old (male). Participants will have the option to disclose or not to disclose gender in study questionnaires.
If you have type 1 diabetes, to be eligible to participate, the time from your initial diagnosis must be $\geq 0.5$ years (about 6 months).

Children without type 1 diabetes who have a history of pathologic low trauma or vertebral fractures will not be eligible to participate in the study.

**WHAT DOES THE STUDY INVOLVE?**

This study is a Canada-wide, 4-year longitudinal study which means that we will have children visit us for measurements each year for 4 years at the same time of year. The same activities and measurements will be done at each visit so we can learn and compare how things change in their bones and bodies over the 4 years.

The reason for looking at bones at this time in your life and for this duration is because this is a window of time when the bones are fast growing.

The total time requirement for participation is 2 hours for each study visit. With your cooperation, we will do our best to schedule the study visits for those children with type 1 diabetes to be on the same day as their regular visits to the Diabetes Clinic.

The following study visits and measurements will be taken at the Physical Activity Complex (PAC) center, and the Williams building at the University of Saskatchewan. During the study visit, for the measurement sessions, you can wear clean athletic shorts, a t-shirt, or tank top, and running shoes.

Your parent/guardian is welcome to attend and watch the measurement sessions. However, it is not mandatory that they attend the sessions with you. If study questionnaires have not been completed ahead of time, we will ask your parent/guardian to stay and complete these during your measurement session. You will always be accompanied by an adult research assistant for the measurement sessions and your parent/guardian can plan to pick you up when the measurement sessions are complete.

Each year, during the study visit, the following testing procedures will be followed.

**Testing Procedure:**

1. You be asked to complete four questionnaires. The first questionnaire is a seven-day-recall, Physical Activity Questionnaire for Children that asks about your physical activity in the past seven days. In addition to the past seven days, you will be asked to specify the amount of participation (times per year) in activities/sports that load the forearm (such as gymnastics, wrestling, or baseball) you have participated in. The second questionnaire is regarding background information, such as your sex, gender, handedness, and fracture history. This questionnaire also includes questions related to musculoskeletal health (for example, previous fracture history, medication use, such as corticosteroids that may affect bone health, and other disease or drugs affecting bone and muscle health). The third questionnaire is a self-assessment that you will do in private, for this assessment, you will be asked to circle a drawing that best represents your current stage of physical development. The fourth questionnaire is an automated self-administered 24-hour food recall (ASA24). For this questionnaire, you will report all the foods you ate in the last 24-hours. This questionnaire is completed online and will take about 30 minutes to complete. Information collected from the ASA24 will provide us with an estimate of daily intake of nutrients that contribute to bone growth and strength such as calcium, protein, and vitamin D. Depending on your age and reading level you may need the help of your parent or guardian in completing this questionnaire.
    - These four questionnaires will be collected at the time of the testing procedure at the College of Kinesiology, University of Saskatchewan. If a questionnaire(s) is (are) not returned or fully completed, a research assistant may contact you to conduct a phone interview. You are not required to answer any questions that you do not feel comfortable answering. Please see the contact information sheet on the first page of this consent form.

2. Upon arrival, we will measure your weight, height, and sitting height, as well as forearm and lower leg lengths. We will also ask which arm you prefer to perform daily tasks (e.g., writing) and which leg you prefer to kick a ball to find out your dominant arm and leg.

3. Your dominant forearm and lower leg will be scanned with peripheral quantitative computed tomography (pQCT), a bone and muscle imaging tool. A technician will help to position you

comfortably on a chair before taking a total of four scans (two scans/limb). Each scan takes about 90 seconds. You will need to keep still while taking the scan so that a clear image can be obtained, much like when taking a photo. The scan does not cause any discomfort or heat for you.

4. Your dominant forearm and lower leg will be scanned with another scanner called high resolution peripheral quantitative computed tomography (HR-pQCT). This scanner measures fine details of bone we will use to estimate bone strength. A technician will help to position you comfortably on a special chair before taking a total of four scans (two scans/limb). Each scan takes approximately 3 minutes. You will need to keep still while taking the scan so that a clear image can be obtained, much like when taking a photo. The scan does not cause any discomfort or heat for you.

5. Your whole body, lower back and hip will be scanned using a third scanner called dual energy x-ray absorptiometry (DXA). This scanner measures body composition, such as areal bone density, body fat and muscle mass. A technologist will help position you comfortably on a special bed before taking total of three scans (your body, lower back and hip). Total scanning time is about 20 minutes. The scanning does not cause any discomfort or heat for you.

6. Your hand strength will be measured using a special device called a handheld dynamometer. For this test, you will be asked to squeeze the device for 3 seconds.

7. Leg strength will be tested using a long jump test. For this test, you will be asked to jump as far forward as you can. You will be asked to perform this jump three times.

8. To assess bone impacts and physical activity, you will be asked to wear a small monitor on your waist called an accelerometer. This monitor is non-invasive and does not cause any pain or discomfort. You will bring this home and wear it on your right hip for 7 days. The accelerometer will record your physical activity levels during the week. We will also provide you with instructions and a recording sheet. We will provide you with a pre-paid and pre-addressed envelope and once the 7 days are complete you can mail the accelerometer and recording sheet back to us.

The questionnaires in this study can be filled out online or in paper/ink form (except the ASA24 needs to be completed online - see below). For those completed online, the questionnaires will be hosted by REDCap. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies. Data is hosted at the University of Saskatchewan. Please see the following for more information on the *REDCap Privacy Policy* (https://projectredcap.org/software/mobile-app/privacypolicy/).

All participants will be asked to complete the 24-hour food recall using the ASA24 respondent website. Participant confidentiality is of the utmost important within the ASA24 system. Researchers do not provide the ASA24 system with any personally identifiable data for associated with study respondents, nor do the respondents provide any personally identifiable information. Only CanBSDS study investigator(s) and the ASA24 operations team can access response data. Access is gained through usernames and strong passwords. Please see the following for more information on the *ASA24*

*Respondent Confidentiality Statement*
(https://epi.grants.cancer.gov/asa24/respondent/confidentiality.html)

There is an optional photo taken of you during this study for publication purposes. Your face will be obscured and will not be recognized by the public. You can opt-in or out of this option on the consent form at the end of this document.

**Measurements at the Diabetes Clinic:**

For participants with type 1 diabetes, as part of your regular standard of care at the Diabetes Clinic, the research team would like to collect a 5 mL blood sample (1 tsp). This sample will be used to evaluate your hormones and markers related to bone growth and development. The researchers will do their best to arrange this blood draw to be at the same time as your routine blood draw to eliminate the need for an additional needle poke. Once the blood samples are evaluated for hormones and markers related to bone growth and development for this study they will be stored at the Western College of Veterinary Medicine (Dr. Unniappan Lab) for 5 years and will then be disposed of by appropriate means.

**Health Records**

For participants with type 1 diabetes, the researchers also ask for your permission to access your records which are maintained by the Saskatchewan Health Authority for the purposes of:

- Collecting your records of height and weight from the Diabetes Clinic visits and any available glucose monitoring reports from the annual appointments since the initial visit.

For participants with type 1 diabetes who wish to participate in study measures at the summer D-Camp, the procedures will be as listed above, with two exceptions:

1. The bone scan with high resolution of pQCT (#4 above) will not be performed at the camp. Instead, participants will be invited to have high resolution pQCT scans taken at the College of Kinesiology after the camp.
2. Participants will have the option of wearing an activity monitor (Actigraph accelerometer) during the camp activities to record their physical activity.

**WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

If you choose to participate in this study, you may not benefit directly. You will, however, be provided with images of the bones and muscles scanned and results from the performance measures, should you request them. This information is used to answer the research question and cannot be used for diagnostic purposes of bone or muscle health. Knowledge gained from this study may provide essential information that can be applied to the therapy of children with or without type 1 diabetes to optimize bone strength development and fracture prevention.

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

If you choose to participate in this study, there is a minor risk that involves exposure to small amounts of radiation during the pQCT, HR-pQCT and DXA scans. The amount of radiation you will be exposed to is low, with the amount from the pQCT being ~3 microSV, from the HR-pQCT being ~20 microSv, and from DXA being ~51 microSv. If we need to repeat HR-pQCT scan due to movement artifacts, we will do so only once per scan. The maximum effective dose of radiation will be 51-71 microSv. This maximum dose is comparable to the amount of background radiation a person receives in about one week from naturally occurring sources in Saskatchewan. For reference, radiation dose for pediatric chest, abdomen or pelvic x-ray ranges between 50-300 microSv. (Types and sources of radiation - cnsc-ccsn.gc.ca).

There is also minor pain when completing the blood test for those participants with type 1 diabetes.

Another risk of participating in this study is the inadvertent release of your personal health information. The researchers have taken measures to protect the privacy of your information and this risk is considered very small.

If you choose to provide your signature electronically, you will receive the consent form through a secure electronic link from the research team. There are inherent risks involved with sending information electronically, especially when using public devices and personal email accounts. Please follow common security measures to protect your personal information and feel free to discuss this with the study team if you require more information.

**WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?**

During this study, new information that may affect your willingness to continue to participate will be provided to you by the researcher. Researchers and research assistants will provide you with an image and description of your bone scans after measurement. If there is any information in the scan or other measures that warrant medical attention, the study doctor (Dr. Nour) will contact your family physician.

**WHAT HAPPENS IF I DECIDE TO WITHDRAW?**

Your decision to participate in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. There will be no penalty or loss of benefits if you choose to withdraw. Your future relationships within the Saskatchewan's Pediatric Endocrinology and Diabetes team, University of Saskatchewan and with your medical practitioner will not be affected.

If you choose to enter the study and then decide to withdraw later, all data collected about you during enrolment will be retained for analysis.

**WHAT HAPPENS IF SOMETHING GOES WRONG?**

If an adverse event related to the study occurs, trained staff will be available throughout the conduct of the study and will respond immediately. Necessary medical treatment will be made available at no additional cost to you. By signing this document, you do not waive any of your legal rights.

**WILL I BE INFORMED OF THE RESULTS OF THE STUDY?**

After your participation, if you wish to receive the information and have provided your contact email on the last page of this document, you will receive the images of your bones and muscles and the results of your grip strength and jump tests in comparison to reference data. Reports addressing study objectives will also be emailed to you if you wish to receive this information.

**WHAT WILL THE STUDY COST ME?**

You will not be charged for any research-related procedures. You will not be paid for participating in this study. Compensation of $25 for baseline measurements, $50 for participation at 1-year follow up, $100 for participation at 2-year follow up, and $150 for participation at 3-year follow up will be provided to your parent/guardian to cover your time and out-of-pocket expenses such as travel, parking, or meals. If you decide to withdraw early from this study, your compensation will be proportional to your time in the study. Any personal information collected as a record of compensation payment will be stored separately from the data for 7 years for auditing purposes.

**WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?**

In Saskatchewan, the Health Information Protection Act (HIPA) defines how the privacy of your personal health information must be maintained so that your privacy will be respected. Your confidentiality will be respected. Information that discloses your identity will not be attached to any data, nor mentioned in any study report, nor be made available to anyone except the research team. No information that discloses your identity will be released or published without your specific consent to the disclosure, or as required by law. A special number (which will not include their initials, date of birth, name, or address) will be used. The same number will be used for labeling all forms and tubes related to blood collection, analysis, and storage. Blood samples will be analyzed and stored at the Western College of Veterinary Medicine (Dr. Unniappan Lab) for 5 years.

The study data, including questionnaires and scan information, will be stored securely in a locked cabinet contained within a locked office under the supervision of Dr. Kontulainen and/or by approved electronic storage methods within the University of Saskatchewan, by the study team for a minimum of 5 years after the end of the research project's records collection and recording period. Research records and medical records identifying you may be inspected by the University of Saskatchewan Biomedical Research Ethics Board, or regulatory authorities for quality assurance and monitoring purposes. Your information and results of the study will also be recorded on a computer database. Only the investigators and research assistants will have access to these study records. However, research records identifying you, including the history of diagnosis of type 1 diabetes, bone fracture, disease, or medication that influence bone or joint health, may be inspected in the presence of Dr. Kontulainen or her designate by a representative of

the University of Saskatchewan Research Ethics Board for the purpose of monitoring the research. However, no records which identify your child by name or initials will be allowed to leave Dr. Kontulainen's research lab.

It is the intention of the research team to publish results of this research in scientific journals and to present the findings at related conferences and workshops, but your identity will not be disclosed.

With your permission, your family physician may be informed of your participation in this study and may be consulted regarding their health and treatment.

**WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?**

If you have any questions or desire further information about this study before or during participation, you can contact Dr. Saija Kontulainen (Principal Investigator) by phone at (306) 966-1077 or email at saija.kontulainen@usask.ca, or Dr. Stacey Woods (Study Research Coordinator) by phone at (306) 966-1096 or email at srw051@usask.ca.

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Chair of the University of Saskatchewan Biomedical Research Ethics Board, at 306-966-2975 (out of town calls 1-888-966-2975) or in writing at ethics.office@usask.ca. The Biomedical Research Ethics Board is a group of individuals (scientists, physicians, ethicists, lawyers, and members of the community) that provide an independent review of human research studies. This study has been reviewed and approved on ethical grounds by the University of Saskatchewan Biomedical Research Ethics Board.

UNIVERSITY OF SASKATCHEWAN

CANBSDS
CANADIAN BONE STRENGTH DEVELOPMENT STUDY

## CONSENT TO PARTICIPATE

**Study Title:**
**Can**adian **B**one **S**trength **D**evelopment in Children
with Type 1 Diabetes **S**tudy **(CanBSDS)**

- I have read (or someone has read to me) the information in this consent form.
- I understand the purpose and procedures and the possible risks and benefits of the study.
- I understand that this study may not provide any benefits to me.
- I was given sufficient time to think about it.
- I had the opportunity to ask questions and have received satisfactory answers.
- I understand that I am free to withdraw from this study at any time for any reason and I understand that the decision to stop taking part will not affect my future medical care/relationships.
- I give permission for the collection, use and disclosure of my personal health information for research purposes, as described in this consent form.
- I understand that by signing this document I do not waive any of my legal rights.
- I will be given a signed and dated copy of this consent form.

My signature below indicates that I agree to participate in this study:

Printed name of child participant: Signature Date

_____ _____ ____/____/_____

Printed name of person obtaining consent: (e.g., Study Coordinator) Signature Date

_____ _____ ____/____/_____

Consent Signature of Parent/ Legal Guardian/Authorized Representative

Date (dd/mm/yyyy)

_____ ____/____/_____

Printed Name of Parent/ Legal Guardian/Authorized Representative

Relationship to Participant

_____ _____

**STATEMENT OF PERSON EXPLAINING CONSENT**

I have explained to the participant and their parent/legal guardian/authorized representative the nature and purpose of the above study. The participant and their parent/legal guardian/authorized representative signing this form have been given enough time to review the information. There has been an opportunity to ask questions and receive answers regarding the nature, risks, and benefits of participation in this research study. The participant and their parent/legal guardian/authorized representative appear to understand the nature and purpose of the study and the demands required of participation.

Signature of Person conducting consent discussion

Date (dd/mmm/yyyy)

_____ ____/____/_____

Printed Name of Person conducting consent discussion

_____

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I agree to have my photo taken to be published with the data collected. My face will be obscured and unrecognizable to the public.

Yes No

I would like to receive the results of my tests, images, and study findings.

Yes, email: _____ No