Parent Information Sheet/Consent Form

Title	Developing an exercise intervention to support adolescents with type 1 diabetes
Coordinating Principal Investigator **Principal Investigator**	Keely Bebbington Vinutha Shetty (PCH)
Associate Investigator(s)	Brendan Smith, Heather Roby, Eleanor Quested
Location	Perth Children's Hospital

You are being invited to take part in this research project as a participant.

Why are we doing this study?

After talking with young people with type 1 diabetes about the challenges they face being physically active, our team have been working with researchers to help us understand what would make physical activity more interesting and less challenging for young people with type 1 diabetes. By listening to personal experiences of young people with type 1 diabetes, and talking to parents, we hope to understand what might make physical activity more enjoyable for young people with type 1 diabetes. We can then develop a program that makes it easier for them to be active, and make them more confident with their diabetes management.

Who is carrying out the study?

Researchers from the Children's Diabetes Centre at Perth Children's Hospital (PCH) and Telethon Kids Institute and Curtin University are conducting this study.

What does participation in this research involve?

If you and your child decide to take part in this study, you will be asked to sign the consent form below and return it to the researcher. A researcher will arrange a time to talk to you to go through the study and answer any questions you may have before you sign the consent.

You and your child will then be asked to participate in a focus group – for the parents this will be with other parents of children with T1D, this may include a spouse or someone you know or a parent you may not know; the adolescents will have a separate focus group. There will be a maximum of 8 individuals attending each of the focus groups. The focus group will be approximately 45-60 mins in duration.

The discussion in the focus group is designed to explore the appeal of physical activity for your child and the barriers that may prevent your child from engaging in physical activity. We will also ask for input into the development of a physical activity program for adolescents with type 1 diabetes. Questions such as 'Can you describe your/ your child's involvement in physical activity?' and 'Are there any practical challenges that would make it especially difficult for your son/daughter to engage in PA?' are examples of what might be asked.

The audio of the focus groups will be recorded so that researchers can transcribe, or copy out what you say word for word so that the researchers can accurately interpret the information you provide. The recordings and transcripts will only be accessible by the research team.

Do I have to take part?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your child's routine treatment, your relationship with those treating your child or your relationship with Perth Children's Hospital or Telethon Kids Institute.

Is there likely to be a benefit to me?

We cannot guarantee or promise that you will receive any benefits from this research. We hope that you enjoy participating in this research and you may enjoy meeting other families who have similar experiences.

Is there likely to be a benefit to people in the future?

We hope that this research will benefit young people with T1D to be more active and healthy. The information we collect during this study is being used to design an exercise program for adolescents with T1D. This will be trialled in another study and we hope this can move into the community in the future.

What are the possible risks or side effects?

This is a low risk study, meaning we do not anticipate any risks from being involved in this project. In the unlikely event that you become upset or distressed because of participation in the research, we will be able to arrange for counselling or other appropriate support.

We ask participants not to discuss what is spoken about during the focus groups with other people outside of the group.

Where is my information kept?

All information collected for this research project will be treated as confidential and securely stored. Paper records collected during this project will be kept in a locked cabinet in a secure research office in Telethon Kids Institute at Perth Children's Hospital. Electronic data will be stored on a password-protected secure server. Only the researchers on the project team will have access to both the paper and electronic records. At the completion of the study, de-identified files will be archived and stored for a minimum of 5 years; after which all documents for the study will be destroyed according to PCH guidelines.

The results of this research may be presented at conferences or published in professional journals. Personal information will not be identifiable in any results that are published or presented.

What about my privacy?

Findings and research data will be securely stored in line with the National Statement on Ethical Conduct in Human Research (2007). Any publications will report the findings as a whole. No participant will be identified by name or in any other way in any published results.

Who has approved the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Child and Adolescent Health Service Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact:

If you want any further information or would like to participate please contact:

Name	Brendan Smith
Position	Research Assistant
Telephone	(08) 9266 2144
Email	Brendan.smith@telethonkids.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Position	Executive Director of Medical Services at Perth Children's Hospital
Telephone	(08) 6456 2222
Reference	RGS0000004688

Parent as a Participant Consent Form

Title	Developing an exercise intervention for adolescents with T1D
Coordinating Principal Investigator **Principal Investigator**	Keely Bebbington Vinutha Shetty (PCH)
Associate Investigator(s)	Brendan Smith, Heather Roby, Eleanor Quested
Location	Perth Children's Hospital

Declaration by Participant

I have read the Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand that the focus group audio will be recorded.

I agree not to disclose any information discussed during the focus groups to other who were not involved.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that some of the staff working on this study are employed by the Telethon Kids Institute or Curtin University and are not employed by the government of Western Australia. These staff are working with the approval of the Child and Adolescent Health Service (CAHS) and will follow all the required policies and procedures and will safeguard the confidentiality of the participant information.

I freely agree participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my or my child's future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Researcher (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

Parent Consent Form

Title	Developing an exercise intervention for adolescents with T1D
Coordinating Principal Investigator **Principal Investigator**	Keely Bebbington Vinutha Shetty (PCH)
Associate Investigator(s)	Brendan Smith, Heather Roby, Eleanor Quested
Location	Perth Children's Hospital

Declaration by Parent

I have read the Parent Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I understand that the focus group audio will be recorded.

I agree not to disclose any information discussed during the focus groups to other who were not involved.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that some of the staff working on this study are employed by the Telethon Kids Institute or Curtin University and are not employed by the government of Western Australia. These staff are working with the approval of the Child and Adolescent Health Service (CAHS) and will follow all the required policies and procedures and will safeguard the confidentiality of the participant information.

I freely agree to my child participating in this research project as described and understand that I am free to withdraw at any time during the project without affecting my or my child's future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Parent (please print) _____

Name of Child (please print) _____

Signature of Parent _____ Date_____

Declaration by Study Doctor/Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Researcher† (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of, and information concerning, the research project.