PARTICIPANT INFORMATION SHEET AND CONSENT FORM

What factors influence the participation and non-participation of young people with type 1 diabetes and their parents in research?

Short Title	Factors influencing participation in research
Protocol Number	Version 3: 24.11.2020
Project Sponsor	Perth Children's Hospital Foundation
Coordinating Principal Investigator	Alison Roberts
Associate Investigator(s)	Professor Tim Jones; Associate Professor Fenella Gill; Post Doc Research Fellow Leanne Fried; Joanne O'Dea; Nirubasini Paramalingam; Heather Roby
Location	Perth Children's Hospital

This Participant Information and consent form is five pages long. Please make sure you have all the pages.

Why are we doing the study?

There are many reasons as to why people choose whether or not to participate in research and we would like to investigate if these are the same for those living with Type 1 Diabetes, in Western Australia. The project seeks to explore the knowledge, attitudes, expectations and experiences of young people with T1D and their parents about participation in research.

Who is carrying out the study?

This study is being carried out by the Children's Diabetes Centre (CDC) at Perth Children's Hospital (PCH) and Telethon Kids Institute (TKI). The project has been funded by the Perth Children's Hospital Foundation (PCHF) grant.

Who can be involved?

Adolescents and young adults aged 13-25 years with a T1D diagnosis and parents of adolescents and young adults with T1D. Separate focus groups will be conducted for adolescents, young adults and parents.

Do I have to take part?

No, participation in any research project is voluntary. If you decide to take part and then later have a change of mind, then you can withdraw from the study at any time.

Not taking part or withdrawing from this study will not change the way you or your child is treated at PCH or affect their relationship with those treating them.

What you will be asked to do if you decide to take part in this study?

If you decide to take part in the study you will be asked to participate in a focus group that will give you the opportunity to discuss your knowledge, attitudes, expectations and experiences of research. There will be approximately three to four people in each focus group and these will be completed using Zoom, a video communication/conferencing software program. You can participate as much or as little as desired in the discussion. The focus group discussion will last for approximately 45 minutes.

The focus groups will be recorded using both audio and video recording, the discussion will then be transcribed to allow accuracy in understanding the issues. All information collected by staff will be confidential and will not be discussed with anyone other than the research team. Each participant will be given an identification (ID) number; no participant name or identifying information will be included in the report. You will receive a reimbursement for your time on completion of the online focus group.

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

By investigating young people's understandings, experience and expectations of research, we aim to ensure that our research is relevant and acceptable to the diabetes community. Your input will help us ensure that our research projects suit your needs and values, along with all young people with type 1 diabetes. The outcomes of this study will contribute to towards ensuring our research aligns with the values of the diabetes community, not only in what we investigate but the methods we select and how we involve and communicate with participants.

What are the possible risks and/or side effects?

This is a low-level risk study; this means that no risks are anticipated. In the unlikely event you become upset because of participation in this research, we will encourage you to contact the study coordinator or appropriate support agencies to discuss your concerns. A contact card with contact details of the study coordinator and support agencies will be provided to you at enrolment.

Additionally, as participants you will be reminded to only discuss topics and experiences you feel comfortable discussing. You will be asked to initial on the consent form to agree not to disclose the discussions with those not involved in the focus group. This is to prevent biasing other participants or potential participants and to maintain confidentiality of all participants. Despite all efforts being made, confidentiality cannot be guaranteed.

Where is the collected information gained from the focus group kept?

All information collected in connection to this research project that can identify you will remain confidential.

Your data will be de-identified, meaning your name will be removed and the information coded so that no one can associate what has been said with you. All other study information collected for this research project including identifiable documents, will be treated as private and securely stored.

All electronic data including audio and video recordings will be stored in a password-protected database on a computer server located at Perth Children's Hospital. Paper records will be maintained in limited access facilities at the Telethon Kids Institute in Perth.

Your information will only be used for the purpose of this research project and will only be disclosed with your permission, except as required by law.

What about my privacy?

Once the information gathered from the focus groups is collated, all names will be removed. Any data that is published and/or presented will be provided in such a way that you cannot be identified.

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 interview 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?

This study has been approved by the Child and Adolescent Health Service (CAHS) Human Research Ethics Committee (RGS 0000003952). This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. 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 would like further information about the study please contact:

Name: Alison Roberts

Position: Research Nurse

Telephone: +61 423 209 349

Email: alison.roberts@health.wa.gov.au

Complaints / Human Ethics contact

If you have any concerns or complaints regarding this study, you can contact:

Position: Executive Director of Medical Services at Perth Children's Hospital

Telephone: (08) 6456 2222.

Reference: Please quote project number RGS0000003952

THANK YOU FOR YOUR TIME

CONSENT FOR PARTICIPANT

PLEASE NOTE THAT PARTICIPATION IN RESEARCH STUDIES IS VOLUNTARY AND YOU CAN WITHDRAW AT ANY TIME WITH NO IMPACT ON CURRENT OR FUTURE CARE.

I …… (Full Name)
have read the information explaining the study entitled:
What factors influence the participation and non-participation of young people with type 1 diabetes and their parents in research?

Please initial:

……. I have read and understood the information given to me, dated 24.11.2020, and had my questions answered to my satisfaction.

……. I understand that the focus group discussions will be audiotaped and video recorded.

……. I understand I may withdraw from the study at any stage and withdrawal will not impact on routine care.

……. I agree that research data gathered from this study may be published, provided that names are not used.

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

Participant signature…… Dated…….....

I..... (Investigator's full name)
have explained the above to the signatories who stated that he/she understood the same.

Signature..... Dated…….....

REVOCATION OF CONSENT FORM FOR ADULT PARTICIPANT

Full Project Title: What factors influence the participation and non-participation of young people with type 1 diabetes and their parents in research?

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise treatment by, or relationship with Perth Children's Hospital.

Participant's Name (printed) …….

Signature …… Date …….