

Supplementary Material 1: Example of participant consent form**CONSENT TO PARTICIPATE IN RESEARCH****TRANSITION AGE YOUTH****TITLE****Evaluating Innovations in Transition to Adult Care: Transition Navigator Trial****SPONSORS**

- Alberta Children's Hospital Research Institute BMO Endowed Award for Healthy Living
- Alberta Health Services, Maternal Newborn Child and Youth Strategic Clinical Network, Health Outcomes Improvement Fund
- Canadian Institutes for Health Research

PRINCIPAL INVESTIGATORS

Susan Samuel, MD, MSc (403) 955-7950	Alberta Children's Hospital
Andrew Mackie, MD, MSc (780) 407-8361	Stollery Children's Hospital
Gina Dimitropoulos, MSW, PhD (403) 220-7332	University of Calgary

CO-INVESTIGATORS: Please see attached list.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child (if your child is not capable of legal consent).

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 the research staff. Take the time to read this carefully and to understand the information. You will receive a copy of this form.

BACKGROUND

Transition to adult care is a difficult time for youth and young adults with chronic health conditions. Many youth and families struggle to get used to the adult care settings, and report difficulties accessing needed services to manage their health conditions into adulthood.

WHAT IS THE PURPOSE OF THE STUDY?

We are evaluating whether a patient navigator service will improve patient health and experience, after transfer to adult care. A navigator is an individual who will be able to provide help and refer you to different services and resources as you transition from pediatric to adult care. We will interview patients and their families to understand needs and difficulties during transition in Alberta and to understand whether a navigator will help overcome barriers to care. We will perform a cost analysis to determine if providing the navigator involvement is cost-saving to the health system.

We intend to recruit 600 youth/young adults and their families over three years, 300 in each major urban area, Edmonton and Calgary. Of these, approximately half will receive the navigator service, and half will receive the usual care in the health system by random selection (meaning a computer will decide which participant goes into which group).

Participants will be contacted and be fully informed of the results of the trial at the end of the study. Everyone in the study will receive periodic newsletters regarding current resources within Alberta for transition to adult care.

WHAT WOULD I HAVE TO DO?

If you consent to be a part of this trial, this is what will happen:

- 1) You will be asked to provide some basic information about yourself.
- 2) You will be asked to provide your Alberta Health Care number and residence postal code, in order for us to find your medical records within Alberta Health Services health records. Examining data from these records will help us understand how you will use the health care system after transfer to adult care.
- 3) You will be asked to complete standardized assessments at enrollment, periodically thereafter and at study end. These assessments will take approximately 10 minutes each.
 - a. Transition Readiness Assessment Questionnaire (20 questions)
 - b. SF-12 (Health Survey) (12 questions)

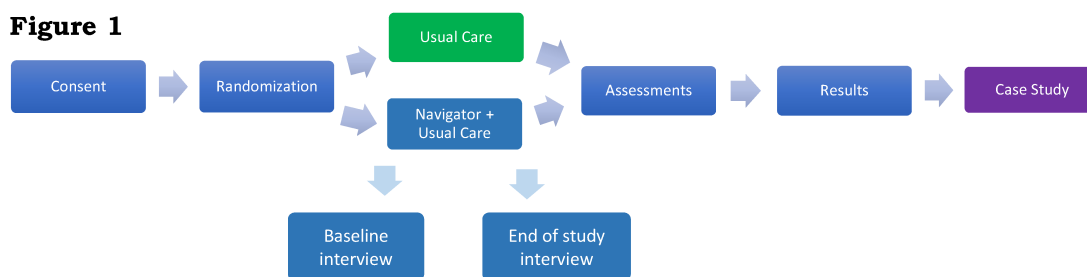
Only a sample of the participants will be contacted. See Figure 1 below.

- 4) If you are randomized into the “patient navigator” group, you will be contacted by a patient navigator to assist in your transition and transfer process. The navigator will work with you to ensure that you are able to access appropriate healthcare services in the adult system, and guide you to resources you may need. The navigator will be available to you

for up to 24 months. If you are assigned to this group, you will receive further information regarding this service. You may be contacted at the beginning of the study for a telephone interview (approximately 45 minutes) by research staff to ask you some questions about your upcoming move from pediatric to adult healthcare. At the end of the study, you may be asked to participate in another telephone interview (approximately 45 minutes) to reflect on your experiences around the transition to adult healthcare. Only a sample of the participants will be contacted for these interviews. See Figure 1 below.

- 5) If you are randomized into the “usual care” group, you will receive the usual support that your clinic and healthcare teams provide.
- 6) We will observe your progress through the adult health care system by tracking how you use the health system (hospitalizations, emergency room visits, primary care visits).
- 7) A small number of participants (5 to 10) who experience a good or bad transition outcome will be asked to participate in more detailed interviews to understand the root cause of the outcomes. This is called a case study (approximately 1-2 hours).
- 8) You will have the opportunity to journal/ write your story during transition on the researcher’s database (REDCap). This is optional.
- 9) At the end of the study, we will contact you or your nominated delegate (parent or guardian) to complete an End of Study form which will ask you the some basic questions about your life at that time (education, employment, satisfaction with health care, income, extended medical insurance etc.)
- 10) This study does not affect routine care.

Figure 1



WHAT ARE THE RISKS?

There are no known risks to you associated with this study, and in particular when receiving support from the patient navigator. You are always in control of the information you share with study staff/researchers and your health care professionals.

If you experience discomfort, distress or get upset during your interactions with the navigator, you can decline navigator assistance at any time, yet you may choose to continue in the study. Should you be asked to participate in interviews or focus groups, you may experience a range of responses during and after the interview process, including feelings of discomfort and for some, distress. If you become upset during or after completing the interview, please mention it to the researcher. A member of the research team will be available to find you support if needed. We will also provide you with a list of community resources that can be accessed if you need additional support.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study there may or may not be a direct benefit to you. There is no guarantee that this research will help you. The information we get from this study may help us to provide better services and support in the future for youth and their families who are transitioning into the adult healthcare system.

DO I HAVE TO PARTICIPATE?

Participation in this study is voluntary and you may withdraw from the study at any time without jeopardizing your health care. If you wish to withdraw, please contact the study coordinator, listed on the last page.

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

You will be given a gift card or cash value of \$25 after you have enrolled in the study and completed the baseline questionnaires. You will receive another gift card or cash value of \$25 at the end of the study. You will be reimbursed if you incur parking costs while you are participating in research.

WILL MY RECORDS BE KEPT PRIVATE?

Your personal and health information will be only accessible to the research team members who are conducting the data analysis. We will use the personal health information number provided to find records with Alberta Health Services administrative datasets (healthcare records), in order to understand how the health care system is being used to get medical care. All the data will be kept on password protected network computers, with controlled access. All paper documents will be locked up in a secured research area. In addition, authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical study records held at the Alberta Children's Hospital for quality assurance purposes.

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 researchers or sponsors. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

Signature page follows.

SIGNATURES

Your signature on this form indicates that you understood to your satisfaction the information regarding your participation in the research project and agree to participate. 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: Dr. Susan Samuel (403) 955-7950 or Study Coordinator: Gurkeet Lalli (403) 955-2769.

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.

I agree to allow the researchers and/or navigator to contact my parents or guardians as needed to facilitate care and to disclose medical information to my parents/guardians. My parent or guardian can participate in the study if they are interested.

YES NO

I agree to allow the researchers to contact me at the end of the study. (See number 9 above). If I am unable to respond, I hereby nominate the following person to answer in my stead, and you have my permission to contact the delegate.

YES NO

Name of Delegate: _____

Contact Information for Delegate: _____

I agree to allow the researchers to contact me for future studies related to transition to adult care.

YES NO

Printed name of participant (or legal representative on behalf of participant)

Signature of participant (or legal representative on behalf of participant) *Date*

Printed name of person who explained consent *Signature* *Date*

