SUBJECT INFORMATION AND CONSENT FORM

TRIUMPH – Transitioning Young Adults with Inflammatory Bowel Disease with Multidisciplinary Healthcare Clinics

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If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say “you” or “your” in this consent form, we mean you and/or your child; “we” means the doctors and the other staff.

You are being invited to participate in a research study. Your participation is entirely voluntary. Before you give your consent, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at anytime and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Background

Inflammatory bowel disease (IBD) such as Crohn’s disease and ulcerative colitis is a chronic illness that can begin in a very young age. Patients who are diagnosed in their childhood often will need ongoing care and management into their adulthood. Multidisciplinary IBD Transition clinic has been established at BC Children’s Hospital to facilitate the transition of young adults with IBD. It aims to empower the

adolescents with IBD and provide comprehensive care. It allows easier care transfer to adult gastroenterologists. However, its efficacy and impacts on these patients has not yet been fully evaluated. We are inviting you to participate in this study as you have inflammatory bowel disease and have transitioned to, or at an appropriate age to transition to be cared by an adult gastroenterologist.

Objectives

1. To evaluate impact of IBD Transition clinic on overall health in subjects with IBD
2. To explore resources required for IBD Transition clinic
3. To examine obstacles for successful transition into adult care in pediatric subjects with IBD

Who can participate?

All subjects age 14 and above with IBD who have and will be assessed at BC Children's Hospital during the study period can participate in the study.

Who should not participate?

Subjects without IBD or age less than 14 should not participate in the study.

What is involved?

There will be no change to management or treatment for your disease.

Only the following items will be obtained for this study:

1. Basic demographic data including diagnosis, gender, age, medication usage and co-morbidities. This will be obtained from reviewing the subjects' hospital and clinic charts.
2. Questionnaire to determine subjects' Beliefs about medicine.
3. Questionnaire to determine subjects' understanding of their current health.
4. Objective health status based on hospital admission records, surgical pathology, and recent bloodwork. This will be obtained from reviewing the subjects' hospital and clinic charts.

Cross-sectional study:

You are mailed or emailed this study subject information. Once you agree to participate, please sign the consent form. Please mail or email back the signed consent using the self-addressed envelope provided. Two questionnaires will also be mailed to you. Complete the two questionnaires (Beliefs about medicine and Cross-sectional Subjective Clinical Status) and mail them back using the self-addressed envelope provided. The questionnaires can also be done online. If you opt for that, you will be given a password protected survey token via email. We aim to recruit total of 200 participants with 100 in the study and 100 in the control arms.

Longitudinal study arm:

Once you agree to participate, you will sign this consent form. This form will be kept confidentially. You will be asked to fill out two questionnaires (Beliefs about medicine and Longitudinal Subjective Clinical Status) at your initial visit and the 6-month follow up. Approximately additional 30 minutes will be required at these two visits to complete the two questionnaires. No particular additional study visits are required. We aim to recruit total of 500 participants with 250 in the study and 250 in the control arms.

What are the possible harms and side effects?

There is no or minimal risk in this study. No additional procedures or interventions are being proposed.

What are the benefits?

You may not directly benefit from participation in this study. We hope that the information learned from this study can be used in the future to benefit other people with a similar disease.

What happens if I decide to withdraw my consent to participate?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

What will the study cost me?
You will not be paid or asked to pay for participating.

Will my taking part in this study be kept confidential?
Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives, and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study 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 the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Who do I contact if I have questions about the study during my participation?
If you have any questions or desire further information about this study before or during participation, you can contact:

Dr. Nancy Fu	(604) 709-5015
Dr. Brian Bressler	(604) 688-6332
Dr. Kevan Jacobson	(604) 875-2736

Who do I contact if I have questions or concerns about my rights as a subjects during the study?
If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 or (toll free) 1-877-822-8598.

Please return the completed consent form to:
Dr Nancy Fu
C/O Dr. Brian Bressler
Division of Gastroenterology
Pacific Gastroenterology Associates
770 - 1190 Hornby Street
Vancouver, B.C., V6Z 2K5

SUBJECT STUDY CONSENT

I consent to participate in this study (**TRIUMPH – Transitioning Young Adults with Inflammatory Bowel Disease with Multidisciplinary Healthcare Clinics)** and grant permission to use the compiled data for research and publication. Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else.

- I have read and understood the subject information and consent form.
- I authorize access to my health record as described in this consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I have read this form and I freely consent to participate in this study.
- I have been told that I will receive a dated and signed copy of this form.

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/subject to the extent that he/she is able to understand it, that all questions have been answered, and that the child/subject assents to participating in the research.

_____	_____	_____
Name of subject or legally authorized representative	Signature	Date
_____	_____	_____
Name of the person obtaining consent	Signature	Date

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, please indicate language: _____

Was the subject assisted during the consent process in one of the ways listed below?
□ YES □ NO

If yes, please check the relevant box and complete the signature space below:
□ The consent form was read to the subject, and the person signing below attests that the study was accurately explained to, and apparently understood by, the subject. (Please check if the subject is unable to read.)
□ The person signing below acted as an interpreter/translator for the subject, during the consent process. (Please check if an interpreter/translator assisted during the consent process.)

_____	_____	_____
Name of the person assisting in the Consent Discussion	Signature	Date

SUBJECT ASSENT TO PARTICIPATE IN RESEARCH

Children age 14 – 17

STUDY:
TRIUMPH – Transitioning Young Adults with Inflammatory Bowel Disease with Multidisciplinary Healthcare Clinics

I have had the opportunity to read this consent form, to ask about my participation in this research, and to discuss my participation with my parents/guardians. All my questions have been answered. I understand that I may withdraw from this research at anytime, and that this will not interfere with the availability to me of other health care. I have received a copy of this consent form. I assent to participate in this study.

_____	_____	_____
Name of the subject	Signature	Date