E-Consent for IMPAACT Clinical Validation Study

Please read the following text for information regarding the IMPAACT Clinical Validation Study (Research Protocol H18-00362-A009).

You will be given the opportunity to consent at the bottom of the page. If you provide consent, you will automatically be taken to the surveys to be completed.

STUDY TEAM:

Principal Investigator: Dr. Edmond Chan, MD, FRCPC
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Why are we doing this study?

You are being invited to take part in a study to validate a new screening questionnaire for food allergy-associated anxiety at BC Children's Hospital (BCCH) Allergy Clinic. You have been invited to be a part of this study because you are a parent or caregiver of a child or teenager with a food allergy.

Living with and caring for a family member with a diagnosis of food allergy can be associated with unique challenges and concerns in day-to-day life. A new program called the Thriving Families Program (TFP) at BCCH Allergy Clinic has been created to provide supportive education and skills-building therapy to families interested in gaining help with managing life with allergies. For those who are interested in the TFP, we are also offering the chance to be a part of this optional study which will validate a clinical tool that physicians and other healthcare professionals working in the field of allergy can use to identify families with food allergy-related anxiety requiring further support. This will lead to more opportunities for empowerment that we hope will decrease stress and restrictions associated with food allergies, and overall, improve quality of life for families.

What happens to you in the study?

If you say 'Yes' to participating in the study, here is what we will do:
• You will be automatically linked to the questionnaires to be completed. The questionnaires will include questions regarding anxiety, quality of life, and demographics. You will be required to enter your child's/teen's first and last initial, and month and year of birth which will automatically alert the TFP Physician (Dr. Jennifer Tong) about your participation. Answering the questions will take about 20 minutes.
• You will then attend an appointment at the Thriving Families Program (TFP) with Dr. Jennifer Tong, which will offer supportive education and skills-building therapy to empower you and your family along your child's allergy diagnosis and treatment journey.

Your answers to the questionnaires will all be stored in an online program called REDCap, with servers located in Canada. Your answers will only be accessible to the study team. Your name will not be associated with your answers, so the research team will not be able to know who wrote which answers.

How do I find out the results of the study?

The main study findings will be published in academic journal articles, and links to the articles will be published on the study team website: www.bcchr.ca/foodallergy and shared in the study team monthly newsletter.

Is there any way being in this study could be bad for you?

We do not think there is anything in the study that could harm you or be bad for you. Some of the questions we ask might cause some stressful feelings for you. Please let one of the study staff know if you have any concerns. Some of the questions we ask may seem sensitive or personal. You do not have to answer any question if you do not want to.

Please let the researcher know if you require adjustments to be made in order to allow your participation. The researcher is obligated to accommodate reasonable changes and can discuss your situation with you. Examples could include providing the services of an interpreter.

Will being in this study help you in any way?

We do not think taking part in this study will directly help you. However, in the future, you or others may benefit from what we learn in this study.

How will your identity and privacy be protected?

Your confidentiality will be respected. Information that discloses your identity will not be released without your consent, unless required by law. All questionnaires will be identified by a code number and there will not be any way to identify which responses are yours. Your child's first and last initial, and month and year of birth will only be used to notify the TFP Physician about your participation in the research study and will be linked to the TFP Physician's survey responses. A list of names will be created and used solely for the purposes of tracking which TFP patients have been invited to the study. This list will be password-protected and will be saved on the research team server.

At any point in the study, if the researcher becomes aware that there has been abuse and/or neglect of a child (or that there is a risk of such occurring in the future) please be advised that the researcher must, by law, report this information to the appropriate authorities.

Will you be paid for your time in this research study?

You will not be paid for the time you take to be in the study.

Who can you contact if you have questions about the study?

If you have any questions or concerns about what we are asking of you, please contact the study leader or one of the study staff listed at the top of this page.

Who can you contact if you have complaints or concerns about the study?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, or privacy-related concerns, contact the Research Participant Complaint Line in the UBC Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877-822-8598.

PARTICIPANT CONSENT

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study. If you decide to take part, you may choose to pull out of the study at any time without giving a reason and without any negative impact on your care within the Allergy Clinic.

If you sign this consent electronically by selecting "yes," typing in your first and last name in the boxes below, clicking on the 'submit' button at the bottom of this page, and completing the questionnaires that follow, it will be assumed that consent has been given.

Do you consent to being part of this study?

◯ Yes
◯ No

Please enter your FIRST name.

Example only - please complete online

Please enter your SURNAME/LAST NAME.

Link to complete online is in study invitation letter

INFORMATION REGARDING FUTURE RESEARCH STUDIES

Are you interested in participating in future studies?

◯ Yes
◯ No

Please enter your email address to be contacted for future studies.

CONSENT TO RELEASE DATA TO THE MEDICAL CHART

To promote continuity of care, it can be beneficial for all healthcare providers involved in your child's care to have access to these survey responses to help inform care in the future.

Do you consent to having your survey responses transferred to your child's medical record after the study is complete?

◯ Yes
◯ No