



THE HOSPITAL FOR
SICK CHILDREN

Research Ethics Board

Participant name:

DOB:

HSC #:

Research Ethics Board

Consent Form

Phenotype Assessment

Title of Research Project:

Molecular and Genomic Analysis of Autism Spectrum and Associated Neurodevelopmental Disorders

Investigator(s):

STEVE SCHERER; (416) 813-7613
JOHN VINCENT (416) 535-8501 X6487
WENDY ROBERTS; (416) 813-8748
JESSICA BRIAN; (416) 425-6220 X3716
PETER SZATMARI; (416) 813-7654 x227201
BRIDGET FERNANDEZ; (709) 777-4363
ROSANNA WEKSBERG; (416) 813-6386
ANDREW PATERSON; (416) 813-6994
ERIC FOMBONNE; (514) 412-4400 X22174
LONNIE ZWAIGENBAUM; (780) 735-8280
EVDOKIA ANAGNOSTOU; (416) 425-6220 X6005
PAUL ARNOLD; (416) 813-2483
RUSSELL SCHACHAR; (416) 813-6564
ANNE BASSETT; (416) 535-8501 X2732
IRENE DRMIC; (416) 813-8748
MARC WOODBURY-SMITH; (905) 521-2100 X73504
WILLIAM MAHONEY; (905) 521-2100 X77605
ROB NICOLSON; (519) 685-8427
MELISSA CARTER; (416) 813-7654 x28986
XUDONG LIU; (613) 548-4419 x1192

Genetic Counsellors:

CHERYL CYTRYNBAUM; (416) 813-5334
NY HOANG; (416) 813-8749

Research Coordinators:

BARBARA KELLAM; (416) 813-7654 X301289

SANNE JILDERDA; (416) 813-6307
BONNIE MACKINNON (416) 813-7654 x203337

Purpose of the Research:

We hope to use this study to help us find genes that may predispose or cause autism spectrum and/or associated neurodevelopmental disorders. By finding the gene(s), proteins and/or epigenetic alterations involved, we hope to improve our knowledge of autism, which, in turn, may help in diagnosis as well as the design of new treatments.

Description of the Research:

Your medical records from SickKids as well as any additional institutions will be requested for review. We may also collect the following clinical information: detailed clinical interview and a standardized observation session (involving the observation of a play sequence, providing information about social situations, play skills, verbal and gestural communication, and repetitive behaviours), an evaluation of your thinking and language skills and/or evaluation of everyday living skills. You will also be asked to complete questionnaires regarding your behavior and emotional functioning. An examination of physical features and growth measurements will be done. This will take between 2-3 hours with yourself, and an additional few hours with one parent. This may be during the same visit or on a separate occasion. Many of these measures may have already been done as part of a previous clinical assessment.

Potential Harms:

We know of no harm that taking part in this study could cause you.

Potential Discomforts or Inconvenience:

During the course of the study, if we identify any information that may have clinical significance to you, one of the investigators will contact you about these observations and arrangements will be made for counselling and assistance for you in understanding the personal and family significance should you need it. This knowledge could cause psychological stress to you and your family. In rare cases, knowing about a presence of a clinical or genetic problem might possibly affect your extended health and/or life insurance coverage in the future.

Potential Benefits:

To individual subjects:

You and your family may or may not benefit from participating in this study. It is possible that we will be able to identify the molecular or genomic cause of the autism spectrum and/or other neurodevelopmental disorders in your family which may help with treatment options. While we cannot know this for sure, we do know that the participation of your family will allow researchers to gain insight into the causes of autism spectrum and/or associated neurodevelopmental disorders.

To society:

Although you may not benefit directly from this study, results from the study will improve the understanding of autism spectrum and/or other neurodevelopmental disorders and may benefit patients in the future. There will be an annual group information session for parents where any general findings of interest will be shared.

Confidentiality:

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about your child if a child has been abused, if your child has an illness that could spread to others, if your child or someone else talks about violence (killing themselves or others) or if the court orders us to give them the study papers

SickKids Clinical Research Monitors, employees of Genome Canada, Autism Speaks, Networks of Centres of Excellence of Canada, Canadian Institutes of Health Research, and the Ontario Ministry of Research and Innovation may see your research study record to check on the study. By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your patient health records.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required then destroyed as required by SickKids policy. Published study results will not reveal your identity.

The results of the tests we describe in this form will be used only for this study. If another doctor or caregiver caring for you needs to see these results, you will have to give us your permission. We will ask you to sign a form saying that you agree that this person can see your results. We recommend that only a registered psychologist or doctor tell you what the results of these tests mean.

Confidentiality will be maintained at all times by assigning number codes rather than names to assessments. The codes will be kept in locked files and available only to the investigators or those working with them. No information that reveals your identity will be released or published without your consent. In addition, information regarding the results of this research may become part of your child's health record.

Reimbursement:

We will pay for your parking expense for visiting SickKids for assessments. If you stop taking part in the study, we will pay you for your parking expense for taking part in the study so far.

Participation:

If you choose to take part in this study you can take yourself out of the study at any time. The care you get at SickKids will not be affected in any way by whether you take part in this study.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study.

During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this study.

In some situations, the study doctor for the study may decide to stop the study. This could happen even if the service provided by the study is helping you. If this happens, the study doctor will talk to you about what will happen next.

If you become ill or are harmed because of study participation, we will treat you for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

Sponsorship:

This study is directed by Dr. Steve Scherer and the Hospital for Sick Children. The current funders of this research are Genome Canada, Autism Speaks, Networks of Centres of Excellence of Canada, Canadian Institutes of Health Research, and the Ontario Ministry of Research and Innovation.

Conflict of Interest:

Dr. Steve Scherer and the research team members have no obvious conflict of interest to declare.

Consent:

By signing this form, I agree that:

1. You have explained this study to me. You have answered all my questions.
2. You have explained the possible harms and benefits (if any) of this study.
3. I know what I could do instead of taking part in the study. I understand that I have the right to refuse to take part in the study. I also have the right to take myself out of the study at any time. My decision about taking part in the study will not affect my health care at SickKids.
4. I am free now, and in the future, to ask questions about the study.
5. I have been told that my medical records will be kept private except as described to me in the confidentiality section of this consent.
6. I understand that no information about who I am will be given to anyone without first asking my permission or will it be published in a way that would disclose personal identity.
7. When requested I will provide information from my medical record regarding autism spectrum and/or other neurodevelopmental disorders;
8. That you will attempt to contact me (by telephone or mail) in the future if any information about the molecular and genomic analysis of autism spectrum and/or

associated neurodevelopmental disorders that is specifically relevant to me comes to light or if there are additional studies I/we may be interested in.

9. I will inform you of any change in address or contact information

10. I have read and understood pages 1 to 5 of this consent form. I agree, or consent, to take part in this study.

Printed Name of Subject & Age

Subject's signature & date

Printed Name of person who explained consent

Signature & date

Printed Witness' name (if the subject/legal guardian does not read English)

Witness' signature & date

If you have any questions about this study, please call **Barbara Kellam at (416) 813-7654 X301289**

If you have questions about your rights as a subject in a study or injuries during a study, please call the Research Ethics Manager at (416) 813-5718.