

ASD-CARC RESEARCH REGISTRY SUBJECTS CONSENT FORM
(for families with an Autism Spectrum Disorder)

Title of Research Study:

GENETICS OF AUTISM SPECTRUM DISORDERS (ASDs)

Principal Investigator:

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Purpose of the Study:

This study is part of ongoing research to try to identify any chromosomal, DNA, or biochemical changes that may be important links to discovering the causes of autism spectrum disorders (ASDs).

Description of the Research:

You and you children are being invited to participate in a research project directed by Dr. Jeanette Holden (Queen's University) to measure genetic and other factors that might contribute to autism spectrum disorders.

Genes are known to be important in the causation of some forms of autism spectrum disorders, but research is needed to help identify specific gene differences that may be important in a given family. This study is directed to that challenge. The accompanying information sheet provides more detail – if you have unanswered questions, please call Dr. Jeanette Holden, Program Director, Autism Spectrum Disorders – Canadian-American Research Consortium (ASD-CARC), and Director, Cytogenetics and DNA Research laboratory, Queen's University, at the number listed above

Participation as a subject in this study involves the following:

1. **Genetic studies:** A small blood, cheek swab, and/or saliva sample will be required from you and your children in order to identify and study genetic factors that may be relevant to your family member's developmental problems.
2. **Parent PDD Behaviour Inventory-C (Parent-PDDBI):** The PDDBI is an assessment tool that looks at symptoms of ASD in affected individuals. To be completed by a parent for each individual with an ASD. Takes about *45 minutes* to complete and can be completed on-line or on a paper copy.
3. **Families with two or more children with an Autism Spectrum Disorder:** To standardize the diagnostic information on families with 2 or more children with an ASD, families are being invited for either face-to-face or telephone interviews using the Autism Diagnostic Interview – Revised (ADI-R). This interview is the “gold standard” for research, and enables us to compare findings from our research with those of other researchers. *If you wish, a research report can be provided to you on the results.*
4. **Families with a single child with an Autism Spectrum Disorder:** As time permits, we will also contact some families to participate in the interview described in 3, i.e. the Autism Diagnostic Interview – Revised. This will help us to validate the information provided on the PDD-BI.

You may be invited to participate in additional studies, to help us understand autism and its related conditions, each time with separate consent. By studying a large number of subjects and families with similar problems, we hope to identify gene changes and other factors that might be associated with ASD. As you know, a variety of questionnaires are available at our website and in paper copies. We hope you will take some time to complete these at your convenience as they address different issues related to autism and will help us in sub-grouping families with similar characteristics.

Potential Risks:

You may be sent a kit to provide cheek swab or saliva sample for our DNA studies – in this case, you will be asked to provide two cheek swab samples or two saliva samples from you and your children. The samples are placed in a solution that will preserve the DNA. Since some studies require more DNA than we routinely get from the cheek

swabs or saliva, you *may* be asked to either repeat the cheek swab or saliva test at another time, or to provide a saliva sample or blood sample. In the latter case, a blood sample will be taken from the forearm by a trained person (20-30 cc or 1-2 tablespoons). There will be minor discomfort and a small bruise may develop at the site of needle puncture. This will usually disappear in a few days.

It is expected that the ADI-R interview will not trouble you, since the questions are straight-forward, and the interviewer will attend to any anxiety or uncertainty you might encounter.

Other risks relate to finding out that you may have a genetic abnormality that you had not been aware of before. This knowledge could cause psychological stress to you and your family, but you will be offered counselling to understand the full significance of any information that is discovered, if you indicate that you wish that information (see below).

Potential Benefits:

While you may not benefit directly from this study, results from the study will improve the understanding of how and what genetic and other factors are involved in ASD and may benefit families in the future.

All gene and DNA tests that will be performed are purely research in nature and the results will not be given to you. However, if a mutation in a gene is discovered (by ourselves or other investigators) that is shown to have a high probability of causing Autism in your family and you indicate that you would like this information, we will attempt to contact you by mail or telephone and the tests and potential benefits and risks (as they are known to be at that time) will be explained to you. *Please ensure that you update contact information annually to obtain relevant results.*

Confidentiality:

All information obtained during the course of this study is strictly confidential and your anonymity will be protected at all times by coding of information and keeping all information in locked files which are available only to Dr. Holden and those working with her. The records will not be used for any other reason or given to anyone else without your written permission. Name will not be used in any publication or reports of the results of the study.

Voluntary Participation:

Participation in this study is voluntary. You and/or your children can withdraw from this study at any time and withdrawal from this study will not affect future medical care.

Subject Statement and Signatures:

I have read and understand the consent form for this study. I have had the purposes, procedures, and technical language of this study explained to me. I have been given enough time to consider the above information and seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form. I will receive a copy of this consent form for my information.

If at any time I have further questions, problems, or adverse events, I will contact:

Dr. Jeanette Holden at (613)-548-4419 ext. 1165 or

Head, Dept. Psychiatry: Dr. Roumen Milev at (613)-545-6743.

Dr. Albert Clark, Chair, Research Ethics Board at (613) 533-6000, ext 77000

**FOR CONSENTING ADULTS
(16 years or older)**

Participant's name: _____ DOB: _____

By signing this consent form, I am indicating that I will participate in this study and be registered in the project's data bank under the following conditions:

I agree:	YES	NO
<ul style="list-style-type: none"> • To being contacted about completing the ADI-R on my child/children through an interview. <i>A separate consent will be completed with the interviewer at the time of the interview.</i> 		
<ul style="list-style-type: none"> • To provide cheek swab samples or a saliva sample or a blood sample for the genetic studies. 		
<ul style="list-style-type: none"> • That such sample be used as a source of DNA for studies for the specific aims of the Genetics of Autism Spectrum Disorders Project. 		
<ul style="list-style-type: none"> • To be contacted and receive information if a mutation is identified which is shown by Dr. Holden or others to have a high probability of causing Autism in your family – at that time, possible benefits and risks for this testing (i.e. implications to family members, possible affects on insurability, etc) will be explained and I will be asked whether I would like to have results on such tests. I further agree to provide an update on my mailing information annually so that I can be contacted about such findings in the future. 		
<ul style="list-style-type: none"> • That my DNA/blood sample can be used <i>in coded form</i> (i.e no identifying information) in other research by the principal investigator – for example, as <i>part of a comparison group</i> for a study on developmental disabilities or attention deficit disorder. 		
<p>That my DNA (<i>in coded form – i.e. no identifying information</i>) can be shared with other researchers doing research on the Genetics of ASDs with whom the principal investigator collaborates – <i>this is to enable studies that are not possible in the principal investigator's laboratory (for example, the equipment is not available or a new method is developed that is not possible in her laboratory).</i></p>		
<ul style="list-style-type: none"> • FOR YOUR INFORMATION: Information on this study will be retained while the principal investigator or her successors are conducting research on the Genetics of Autism Spectrum Disorders as part of ASD-CARC. When such studies are no longer being carried out, all identifying and cross-referencing information will be destroyed and only the actual data will be retained – with alpha-numeric coding. <i>In other words, no one will ever be able to link your samples or any results to you or your family.</i> 		

Printed Name & Signature of Participant

Date

Address: _____

Telephone number: _____

Printed Name & Signature of Witness

Date

STATEMENT OF INVESTIGATOR:

I, or my delegate, have reviewed the responses to this consent form and, if there were questions, I have contacted the family to respond to any questions they have.

- I contacted _____ and certify that, to the best of my knowledge, he/she understands clearly the nature of the study and demands, benefits, and risks involved to participants in this study.
- There were no questions, and thus there was no further contact with the family regarding this consent form.

Printed Name & Signature of Investigator/Delegate

Date

(file name: Consent Forms/Genetics Research Registry Family Version 2008-03.doc)

**FOR THOSE UNDER 16 YEARS OLD OR THOSE UNABLE TO CONSENT
– to be completed by parent or guardian**

Participant's name: _____ DOB: _____

By signing this consent form, I am indicating that my child will participate in this study and be registered in the project's data bank under the following conditions:

I agree:	YES	NO
• To being contacted about completing the ADI-R on my child through an interview. <i>A separate consent will be completed with the interviewer at the time of the interview.</i>		
• To provide cheek swab samples or a saliva sample or a blood sample from my child for the genetic studies.		
• That such sample be used as a source of DNA for studies for the specific aims of the Genetics of Autism Spectrum Disorders Project.		
• To be contacted and receive information if a mutation is identified which is shown by Dr. Holden or others to have a high probability of causing Autism in your family – at that time, possible benefits and risks for this testing (i.e. implications to family members, possible affects on insurability, etc) will be explained and I will be asked whether I would like to have results on such tests. I further agree to provide an update on my mailing information annually so that I can be contacted about such findings in the future.		
• That my child's DNA/blood sample can be used <i>in coded form</i> (i.e no identifying information) in other research by the principal investigator – for example, as a part of <i>comparison group</i> for a study on developmental disabilities or attention deficit disorder		
That my child's DNA (<i>in coded form – i.e. no identifying information</i>) can be shared with other researchers doing research on the Genetics of ASDs with whom the principal investigator collaborates – <i>this is to enable studies that are not possible in the principal investigator's laboratory (for example, the equipment is not available or a new method is developed that is not possible in her laboratory).</i>		
• FOR YOUR INFORMATION: Information on this study will be retained while the principal investigator or her successors are conducting research on the Genetics of Autism Spectrum Disorders as part of ASD-CARC. When such studies are no longer being carried out, all identifying and cross-referencing information will be destroyed and only the actual data will be retained – with alpha-numeric coding. <i>In other words, no one will ever be able to link your samples or any results to you or your family.</i>		

Printed Name & Signature of Participant _____
Date

Address: _____

Telephone number: _____

Printed Name & Signature of Witness _____
Date

STATEMENT OF INVESTIGATOR:

I, or my delegate, have reviewed the responses to this consent form and, if there are questions, I have contacted the family to respond to any questions they have.

- I contacted _____ and certify that, to the best of my knowledge, he/she understands clearly the nature of the study and demands, benefits, and risks involved to participants in this study.
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Printed Name & Signature of Investigator/Delegate _____
Date

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