



Dear Parent/Guardian:

Your child is invited to take part in a research study about Prader-Willi Syndrome (PWS). The study is being conducted by Dr. Andrea Haqq, a pediatric endocrinologist at the Stollery Children's Hospital. The study involves a review of medical records to determine the clinical characteristics of Canadian children and adolescents with PWS.

An information letter about the study is attached for you to review. Participation in this study is voluntary. If you are interested in participating in the study please contact Michelle Mackenzie (the study coordinator) at **780-407-7241** or michelle.mackenzie@ualberta.ca. Michelle will send you a parent consent form for you to sign and an envelope with return postage. If you provide consent, health information in your child's medical records including your child's symptoms, findings on physical examination, diagnostic tests, medical treatments, and health outcomes will be recorded. You will not have to come for any visits to participate in this study.

If you have any questions or would like more information, please feel free to contact Michelle.

Sincerely,

A handwritten signature in black ink that reads "Andrea M. Haqq".

Andrea M. Haqq, MD, MHS, FRCP(C)

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Clinical Characteristics of Canadian Children and Adolescents with Prader-Willi Syndrome

Principal Investigator: Andrea Haqq, MD, MHS, FRCP(C)

INFORMATION LETTER

Your child is invited to take part in a research study. This letter has information to help you decide if you want to participate. Take your time, read this form carefully, and ask the study doctor or coordinator any questions you may have.

Background: Prader-Willi Syndrome (PWS) is often associated with impaired growth, obesity, skeletal disorders such as scoliosis, sleep and respiratory problems, and endocrine (hormone) disorders such as growth hormone deficiency and hypothyroidism. Most of the research on the occurrence of these associated disorders in children with PWS has been completed in countries other than Canada. We do not know the rates of occurrence in Canadian children.

Purpose: The purpose of this study is to determine the prevalence of disorders associated with PWS and the treatments provided for these disorders in Canadian children and adolescents with the syndrome. We will also look at factors that may influence the occurrence of these disorders such as type of PWS (deletion, UPD, imprinting) and age of diagnosis.

What is Involved: Participation in this study is voluntary and will not affect the medical care of your child in any way. If you choose to participate, health information in your child's medical records including your child's symptoms, findings on physical examination, diagnostic tests, medical treatments, and health outcomes will be recorded.

Possible Benefits: There are no direct benefits to you or your child from participation in this study. However, we will learn more about the disorders associated with PWS which might benefit your child in the future.

Possible Risks: There are no risks of physical harm by participating in this study. Participation in this study does involve the potential risk of a breach of confidentiality of your child's health information and associated privacy. The following will minimize such risks:

1. The information will be stored on a secure server.
2. The participant identifiers (i.e., names, date of birth, and medical record numbers) will be removed from data stored and used for analysis.
3. Only study research personnel will have access to the information collected.

Confidentiality: Personal health records relating to this study will be kept confidential. Any research data collected about your child during this study will not identify him/her by name, only by a coded number. For this study, the study doctor will need to access your child's personal health records for health information such as past medical history and test results. He/she may also need to contact your family physician and other health care providers to obtain additional medical information.

The health information collected as part of this study will be kept confidential unless release is required by law, and will be used only for the purpose of the research study. By signing the consent form you give permission to the study staff to access any personally identifiable health information which is under the custody of other health care professionals as deemed necessary for the conduct of the research.

In addition to the investigators(s), the Health Research Ethics Board may have access to your child's personal health records to monitor the research and verify the accuracy of study data.

Voluntary Participation: You are free to withdraw your child from the research study at any time, and their continuing medical care will not be affected in any way. You may withdraw your consent for us to use your child's data that has already been collected (other than data needed to keep track of your withdrawal).

Payments: You will not be paid to take part in this study.

Contact Names and Telephone Numbers: If you have concerns about your rights as a study participant, you may contact the Research Ethics Office at (780)492-2615. This office has no affiliation with the study investigators.

Please contact any of the individuals identified below if you have any questions or concerns:

Dr. Andrea Haqq, Principal Investigator (780) 407-3329 or (780) 938-3474
Michelle Mackenzie, Study Coordinator (780) 407-7241 or (780) 707-7970