Research Consent Form - General

Title of Research Project:

Healthy Infants and Children Clinical Research Program (HICCUP)

Investigators: Dr. Adam Kirton (403) 955-7424
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Purpose of the Research:

The purpose of this study is to establish the Healthy Infants and Children Clinical Research Program (HICCUP): a structured, population-based registry aimed to directly facilitate child health research. Many types of research require a comparison between people with a disease or condition and those who are normal (i.e. they do not have the disease or condition). Such people are called controls. Many studies require these controls to closely resemble the subjects with the disease in terms of important factors such as age or gender. This is called matching. Generating samples of controls, especially well matched controls, is a difficult and time consuming process for researchers. This is particularly true in pediatric research where unique factors such as age and development create added challenges. The Alberta Children's Hospital Department of Pediatrics represents a unique and ideal environment to change this.

The HICCUP program will provide investigators with easy, equal, systematic access to healthy controls to be used in their own studies. In turn, this should directly enhance all child and family health clinical research in southern Alberta and potential serve as a model to advance such systems in other pediatric research settings. The HICCUP program will also provide a direct opportunity for children, families, and communities to directly contribute to the advancement of research and child health in Alberta. HICCUP promises to establish a novel pediatric clinical research model while directly enhancing ACH child health.

Description of the Research:

Participation in this study will help establish the HICCUP database to be used by approved study investigators. This study will only serve to connect you and your family as potentially interested subjects with potential researchers. Actual participation in studies will only occur following subsequent contact from researchers who will explain all elements of their individual study before requesting your informed consent.

You will be asked to provide contact information for you and your family along with some simple information that will allow us to match the needs of the researchers with the appropriate level of your willingness to participate. This information will only include simple information about each family member willing to participate, the type of research studies you would be interested in participating in, the contact frequency you are comfortable with, and your preferred method of contact.

Potential Harms, Discomforts or Inconvenience:
The only potential harm of this study, as in any study where data is stored in a computer, would be the unlikely compromise of data confidentiality. The protection of your personal information is the highest priority. All information is carefully collected, stored, and accessed using the highest security measures including password protected computers and databases locked within secure areas with 24 hour security. The team at our Hospital has taken the same very high security precautions it uses for the rest of the hospital's data, so the risk is extremely low.

Potential Benefits:
There are no direct medical benefits to participation. HICCUP will provide a direct opportunity for children, families, and communities to directly contribute to the advancement of research and child health in Alberta. Families wanting to "give something back" will have a meaningful alternative or addition to traditional means of supporting child health such as financial donations by instead offering to volunteer their time to help child and community health in a different way. This also provides children with direct opportunity to help other children and learn the values of empathy and charity.

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Confidentiality:
You and your family's name and other personal information will remain strictly confidential to protect your right to privacy. Your personal information will be made anonymous by assigning them a study identification number that will be used in all databases and communications between researchers. Confidentiality will be respected and no information that discloses you or your family's identity will be released or published without consent unless required by law. This legal obligation includes a number of circumstances, such as suspected child abuse and infectious disease, expression of suicidal ideas where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities.

Participation:
Participating in the study will not change your family's regular care in anyway. Participation in research is voluntary. If you choose not to participate, or if you choose on behalf of your child not to participate, you can withdraw your child at any time. You and your family will continue to have access to the same quality care at ACH. New findings developed during the course of the research which may impact on your willingness to continue will be provided to you in a timely fashion. Participating in this study does not mean you can't enroll in another study in this hospital or elsewhere. If changes are made to the study or new information that might affect your willingness to continue to participate in the research becomes available, you will be informed immediately. In no way does signing this form waive your legal rights or relieve the investigators, sponsors or involved institutions from their professional responsibilities.

Compensation:

In the event that your child suffers injury as a result of participating in this research, no compensation will be provided to you by the Alberta Children's Hospital Foundation or the University of Calgary, Alberta Health Services, or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

Signatures:

Once you have reviewed this form, please return to the webpage. Here you will see two tick boxes.

Ticking the first box will confirm that all adults you are enrolling have read this consent form and provided their consent.

Ticking the second box will confirm that all minors you are enrolling and deem capable of providing their permission have read and approved the assent form.

Both steps are required and indicate that you and all enrolled subjects have understood to your satisfaction the information regarding you and your family's participation in the project. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw you and your family from the study at any time without any consequence. If you have further questions concerning matters related to this research, please contact: Dr. Adam Kirton (403) 955-7424 or the study coordinator (403)955-2472.

If you have any questions concerning your rights as a possible participant in this research, please contact The Chair, at the Conjoint Health Research Ethics Board, University of Calgary, at (403) 220-7990.