Title of Research Project:
The Paediatric Urology Research Registry (PURR)

Investigator(s): Phone:
Principle Investigator: Darius Bägli, MD 416-813-6465 ext. 206465
Co-Investigators: Eli Bator, RN 416-813-6752
Walid Farhat, MD 416-813-6580
Martin Koyle, MD 416-813-6461
Armando Lorenzo, MD 416-813-6465

Team Members: Barbara Pannozzo, MD 416-813-6465
Megan Saunders, MD 416-813-6465

Purpose of the Research Registry:
As in all areas of medicine, the basis for the best care of all paediatric urology children is still not completely known. Very little quality clinical paediatric urology research based on planned data collection is available. Most is based on information collected before a study question is designed. This often leads to lesser quality results. This has long prevented or slowed meaningful advances in many areas of health care.

The patient population of the Division of Urology at The Hospital for Sick Children is one of the largest for paediatric urology in the world. As such, this group of patients presents an important opportunity to generate meaningful clinical studies to move the field of children’s’ urology forward. Such forward progress has the potential to improve diagnosis of urologic conditions, responses to care, and the medical and surgical outcomes in urologic function.

Description of the Research Registry:
We wish to use your child’s past and future medical urology data, and other relevant medical data as necessary, for any future urology research study questions we develop. We wish to include all 12,000 patients coming to the Paediatric Urology Clinic annually in this effort. This collection is called a research registry. We will still require Research Ethics Board permission before proceeding with any specific future studies coming from this registry.

We are asking for your consent—YES or NO—to list your child in this registry.

If you respond NO, we will retain your ‘No’ response with only your child’s name and medical record number in order to avoid approaching you more than once.
If you respond YES, the listing would include your child’s medical record number, age in years and months, year and month of birth, and your child’s urology diagnoses.

Also, if you respond YES, you may select any, or all, or none of 3 additional permissions:

A) Allow us to pool your child’s deidentified (your child cannot be identified), medical data with the data of similar children at other hospitals separate from The Hospital for Sick Children. This allows for very large patient numbers that produce more reliable answers to research questions that may apply to more children. Other institutions will need to get their own approvals (similar to this one) before they would be allowed to see data from other hospitals participating in the data pool, including your child’s deidentified data.

B) Allow us to contact you if your child appears to fit a research project requiring information that is not available in the medical record. This is only for permission to contact you. You would still be able to decide to participate or not in that particular research project at that time.

C) Allow us to keep you updated using the Internet – via your email address – about all ongoing urology studies.

To summarize, participating in this registry changes nothing about your child’s care. It does not add any work for you or your child. If you say YES, the medical data usually collected during a urology visit would now be available to answer research questions approved by the Research Ethics Board. We make every effort to keep your child’s data secure & private (e.g., de-identifying collected data, data encryption, firewall protection, secure physical storage). Only deidentified data is used in published research, or pooled with patients’ information from other hospitals.

Potential Harms:
The only potential adverse event would be related to a privacy breach if the password-protected electronic hospital security of the computers holding the REDCap servers were to be compromised.

Potential Discomforts or Inconvenience:
The only inconvenience is may be being contacted if your child is eligible for a study in the future, if you provide your consent for this contact (B. above).

Potential Benefits To individual subjects:
Your child will not benefit directly from being listed in this research registry.

Potential Benefits To society:
Future research utilizing this registry will inform and improve the care administered to the paediatric urology population over time.

Confidentiality:
We will respect your privacy. No information about who you are (your child is) 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 you if a child has been abused, if you have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the research registry papers.

Sick Kids Clinical Research Monitors, employees of the funder or sponsor [none], or the regulator of the research registry may see your health record to check on the registry. 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 record and give you a copy as well.

The data collected in this registry 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 research studies the data will be kept as long as required then destroyed as required by Sick Kids policy. Published study results will not reveal your identity.

**Participation:**
It is your choice to have your child listed in the Sickkids Paediatric Urology Research Registry. You can withdraw his/her name at any time. The care you get at Sick Kids will not be affected in any way by whether you take part.

Our record of your response to this consent will ensure that you will not be approached in the future to consent again. As stated above, you may choose whether to participate in the research registry, and may separately choose whether you wish to be contacted for research requiring additional information outside of your child’s medical record.

**Sponsorship:**
The sponsor/funder of this research is Dr. Darius Bägli, Division of Urology, The Hospital for Sick Children,

**Conflict of Interest:**
Dr. Bägli and the other research team members have no conflict of interest to declare.
**Consent**

By signing this form, I agree that:

1) You have explained this information collection registry to me and answered all of my questions.
2) You have explained the possible harms and benefits of participating.
3) I understand that I have the right to refuse to be included/include my child in the registry and that this has no effect on my/my child’s care. I also have the right to withdraw myself/my child out of the registry at any time. My decision to keep myself/my child out of the registry will not affect my/my child’s health care at Sick Kids.
4) I am free now, and in the future, to ask questions about the registry.
5) I have been told that my/my child’s medical records will be kept private except as described to me.
6) I agree, or consent, that:

I/My child, ___________________ may be included in the Paediatric Urology Research Registry, which permits the use of my/my child’s medical urology data for present and future urology research questions.

**IN ADDITION:**

A) My/My child’s deidentified medical data ☐ MAY ☐ MAY NOT ☐ be pooled with the data of children from other hospitals, and used for multi-hospital urology research.

B) I ☐ MAY ☐ MAY NOT ☐ be contacted in the future if I/my child am/is eligible for a research project requiring information that is not available in my/his/her medical record.

C) I ☐ WANT ☐ DO NOT WANT ☐ be contacted using my email address; _____________________ to receive updates about research studies using data from the Paediatric Urology Research Registry.

__________________________________________
Printed Name of Patient OR Patient’s signature & date OR
Printed Name of Parent/Legal Guardian Parent/Legal Guardian’s signature & date

__________________________________________
Printed Name of person who explained consent Signature of Person who explained consent & date

Printed Witness’ name (if the Patient OR Parent/ Witness’ signature & date
Legal Guardian does not read English)

If you have questions about this registry, please email: urology.research@sickkids.ca

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.
ASSENT FORM

Title of Project: The Paediatric Urology Research Registry (Research Sign-Up List)

Investigator(s):

Principle Investigator: Darius Bägli, MD 416-813-6465 ext. 206465

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Why are we doing this research sign-up list?
We want to know who would like us to use their past and future medical information for research. Research can help us learn new ways to give you and other children better care.

What will happen to me if I join the research sign-up list?
Nothing at all will change. You will still receive the same care, and the health care team will still ask the same questions during your visit. The only difference is that researchers who want to answer a scientific question will be able use medical information from patients who have given their permission. These patients are on our sign-up list.

If you agree to our second question, your medical urologic information will be grouped with other children’s information at other hospitals. No one will be able to find out who you are because we keep your personal information private. If you agree, it would be helpful because it allows researchers do research with lots of patients from lots of different places. This helps us to find better answers to our research questions!

If you agree to our third question, your family will be called if our researchers have other questions about information that was not collected when you came to the hospital. You can choose then if you want to give them that information.

If you agree to our fourth question, your family will receive updates about the projects that are using the medical information from people on the urology research sign-up list.

Are there good things and bad things about the research sign-up list?
The good thing about our list is that by collecting medical information from lots of patients, we can get better answers for our research questions, and make our health care even better! There are also NO bad things about the list since you do not need to do anything different.
Research Ethics Board

Who will know that I am on the research sign-up list?
No one except your health care team in urology and urology researchers will be able to see that you are on the research sign-up list. If we tell other health care workers about what we learn from our research questions, they will never know who you are, or that you signed up.

Can I decide if I want to be on the research sign-up list?
Nobody will be angry or upset if you do not want to be on the research sign-up list. We are talking to your parent/legal guardians about the sign-up list and you should talk to them about it too.

Assent:

I was present when _____________________________ read this form and said that he or she agreed, or assented, to take part in this Paediatric Urology Research Registry.

_________________________ ____________________________
Printed Name of person who obtained assent Signature & Date