

# CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY Biomarkers for Urinary Tract Infection

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## Children's Hospital of Pittsburgh Primary Care Center Oakland

4401 Penn Ave. Pittsburgh, PA, 15224

#### **Primary Care Center Mercy**

1515 Locust St. Floor 3- Ambulatory Pediatrics Pittsburgh, PA 15219

#### **Primary Care Turtle Creek**

108 Penn Plaza Turtle Creek, PA 15145

## **CCP Armstrong Pediatrics**

100 Medical Arts Building Kittanning, PA 16201

## **CCP Bass Wolfson**

Wilkins Building, Suite 202 5608 Wilkins Ave Pittsburgh, PA 15217

Cranberry Business Park Suite 120 3104 Unionville Rd. Cranberry Township, PA 16066

## **CCP GIL**

Village of East Side 6343 Penn Ave, Suite 201 Pittsburgh, PA 15206

1000 Infinity Drive Monroeville, PA 15146

## <u>CCP Monroeville Pediatric</u> Associates

4075 Monroeville Blvd Monroeville, PA 15146

#### **CCP Moon & Wexford**

Pine Center, Suite 105 11279 Perry Highway Wexford, PA 15090

#### **CCP Monroeville**

IT Building, Suite 700 2790 Mosside Boulevard Monroeville, PA 15146

#### **CCP South Hills Pediatric Assoc**

4411 Stilley Road Suite First Floor Pittsburgh, PA 15227

1925 Route 51 South Jefferson Hills, PA 15025

#### **CCP Pittsburgh Peds**

#### Bloomfield

4923 Centre Ave. Pittsburgh, PA 15213

#### Wexford

6000 Brooktree Rd., Suite 207 Wexford, PA 15090

#### **CCP-HealthQuest**

5321 William Flynn Highway Gibsonia, PA 15044

#### **CHP East**

Corporate One Office Park, Building One 4055 Monroeville Blvd. Monroeville, PA 15146

#### **CHP North**

2599 Wexford Bayne Rd. Sewickley, PA 15143

#### The Children's Pine Center

11279 Perry Highway, Suite 110 Wexford, PA 15090

## **CHP Emergency Department**

4401 Penn Ave., Floor 1 Pittsburgh, PA 15224

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**SOURCE OF SUPPORT:** Research Advisory Committee of Children's Hospital of Pittsburgh of UPMC and the National Institutes of Health.

#### DESCRIPTION

We invite your child to take part in our research study because your child has a urinary tract infection (UTI). Your child's doctor will treat the UTI in the usual way. We are trying to find the easiest way to tell if a UTI is in the bladder or the kidney by looking for proteins in the urine and markers in the blood. That information will help doctors to know how many days children should take antibiotics and if they need further tests. We plan to observe about 200 children who are 2 months to 10 years of age in this study. Today, we will ask you about your child's

- · current and past medical history, including medications,
- toilet training history (if toilet trained),
- date of birth and contact information,
- family history of urinary tract infections and kidney disease,
- and if your child is toilet-trained, if there has been any difficulty with urine or bowel movements.

For research only, we will collect 1 tablespoon of urine (11.5mL). If there is extra urine from the sample that your child's doctor collected, we will use that. If there is not enough urine for the protein test, your child can urinate in a cup or bag. If your child's urine culture is positive, your child can stay in the study and a DMSA (kidney scan) will be performed. If your child's urine culture is negative, your child cannot stay in the study and will not receive a DMSA scan.

About 1 teaspoon of blood (6mL) will be collected to check for signs of infection in the bloodstream. The blood and urine will be collected no later than 4 hours after the first dose of antibiotic treatment for the UTI. Before your child's samples are sent to laboratories to be processed, they will be labeled with a study identification number only. Any personal information such as name, address, and date of birth will be removed from the sample. Any personal information linking your child's identity to the sample will be kept in locked cabinets and password-protected computers only used by the study staff.

If you agree, we would like to collect another small amount of blood that will be sent to the University of Pittsburgh Graduate School of Public Health. The amount of extra blood will be about 1 teaspoon (3mL) depending on your child's age. Scientists will look at DNA (heredity material in cells) of the blood to help them develop new diagnostic tests, treatments and ways to understand urinary tract infections and urinary reflux. This sample can be collected during today's visit or at the time of your child's DMSA scan. Banked samples will be identified by a code number. You will not be informed of the results of future genetic testing of this sample because at this time we don't know how this information would be helpful. The DNA that your child provides as a participant in this research study is a donation. You and your child will not have any property rights to the samples, nor will you and your child have any property rights to or be entitled to compensation of any type for products, data, or other items or information that is developed from the samples. The samples that are collected will be de-identified to be stored and analyzed in the future. These tests will be paid for by the study. This visit will take about 1 hour. If you agree to participate in the research project, use of your child's biological sample and genetic material will be under the control of the principal investigator of this research project.



Consent i	for genetic sample banking:
Yes	Initials
No	Initials

Your child will have a DMSA kidney scan within 2 weeks of enrolling in this study to see if there is infection or scarring in the kidney. During this time, we will ask you to refrain from giving your child ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs) until after your child has completed the DMSA kidney scan. If any situations arise in which you would normally give your child ibuprofen (e.g. fever) the study team will encourage giving your child over-the-counter Tylenol instead. We will not ask you to stop any doctor-directed, prescribed, or ordered medicine for your child. If there is any uncertainty in handling any situation that arises during the course of the study, you can call Dr. Shaikh at the phone number listed on the front page of this consent form. This scan is commonly done after a UTI and will be paid for by the study. Your child's doctor will receive the test results. We will record the results of the kidney scan for the study information. The study nurse can give you printed information about the kidney scan from the Children's Hospital web site. There are no other visits in the study.

Sedation is not part of the research and is not required for the DMSA. If you request to have sedation for your child, a separate consent form will need to be signed for the radiology department before beginning any sedation procedures.

#### **RISK OR DISCOMFORT**

DMSA scans: A DMSA kidney scan is used to show areas of kidney infection or kidney damage. A DMSA scan requires inserting an intravenous (IV), injecting a radioactive substance into the blood stream, and taking a picture of the kidneys with a special camera. Commonly (10-25 out of 100), children may have some discomfort with the placement of the IV. IVs can fall out and some fluid can go into the arm outside of the vein, but this is rare (1 out of 100). The radiation exposure from a DMSA scan is less than half of the natural background radiation during one year. Participation in this research study involves exposure to radiation from a DMSA scan. The amount of radiation exposure that your child will receive from this procedure is approximately 0.14 rem (a unit of radiation exposure) to your child's kidneys, with minimal exposure of other body areas. For comparison, radiation workers are permitted, by federal regulation, a maximum annual radiation exposure of 20 rems to the most sensitive organs of their body. There is no known minimum level of radiation exposure that is recognized as being totally free of the risk of causing genetic defects (abnormal cells) or cancer. However, the risk associated with the amount of radiation exposure that your child will receive from this study is considered to be low and comparable to everyday risks.

Loss of Confidentiality: There is a rare risk of the loss of confidentiality (less than 1%). The study staff are trained and experienced in protecting health information (date of birth, medical record number, or names) as confidential information. Subjects will be identified only by a study number on the forms that are kept safe in a locked cabinet or in locked computer databases protected by password and firewall. Only the study staff will have passwords to the computers in secure offices.

Storage of Blood and Urine for Research Purposes: Rarely (less than 1 out of 100), there is a risk of loss of confidentiality. To minimize the risk of loss of confidentiality, before your child's sample is sent, the sample will be labeled with the study identification number only. Personal identifying information such as name, address, and date of birth will be removed from the sample. Personal information that could link the sample to your child's identity will be kept in locked cabinets and password-protected computers that are only used by study staff.

Blood draws: There is a risk of mild pain, bleeding, or bruising. Fainting and infection are rare

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complications. To protect children, all blood draws will be performed by qualified nurses, physicians and phlebotomists according to standard phlebotomy techniques.

Topical Anesthetic Lidocaine (cream to decrease pain with blood draw) will be available as an option to use before the blood is drawn. There is a risk of slight skin irritation when using this cream.

Urine Sample: If your child is toilet-trained, the urine sample can be collected in a cup which may cause your child to feel some anxiety. Sometimes, a urine bag may be applied to catch the urine, which may cause some discomfort.

#### **BENEFIT**

There may be no direct benefit from this study for your child but information discovered may improve the care of children with UTI in the future.

#### CONFLICT OF INTEREST

If your child's doctor is an investigator in this research study, s/he is interested both in your child's medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during study participation, you may discuss the medical care with another doctor who is not associated with this research study. You are not under any obligation to allow your child to participate in any research study.

#### **NEW INFORMATION**

You have been informed previously that the personal results of this research study will not be provided to you. You or your representative will be promptly notified if any other information about this research study develops during the course of the study which may cause you to change your mind about continuing to participate.

#### **COSTS AND PAYMENTS**

There will be no costs to you or your insurance company for the study visit today or the urine and blood tests or the DMSA kidney scan. To help cover travel expenses you will be given \$25 today and a pass for free parking while you are here for the visit. You will also receive \$50 after your child has the DMSA kidney scan.

### **COMPENSATION FOR INJURY**

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

#### CONFIDENTIALITY

We may review your child's past, current and future medical information as part of the research study. The information that will be recorded will be limited to information concerning the recent UTI and follow-up DMSA scan. We will use your child's medical information for an indefinite period of time. If we use the urine results and medical information for other studies, we will never provide personal identifiers that would allow them to learn your child's identity. Any identifiable information about your child obtained from this research will be kept as confidential (private) as possible. All records related to your child's involvement in this research study will be stored in a locked file cabinet. Your child's identity on these

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records will be indicated by a case number rather than by name, and the information linking these case numbers with the identity will be kept separate from the research records. Your child will not be identified by name in any publication of the research results. This identifiable information will be made available to members of the research team, for an indefinite period of time, and may be shared with other groups, possibly including authorized officials from the Food and Drug Administration (FDA), the University of Pittsburgh Research Conduct and Compliance Office, and the National Institute of Health, but as described below, only for the purpose of monitoring the study. Although we will do everything in our power to protect your child's privacy and the confidentiality of your child's records, just as with the use of their medical information for health care purposes, we cannot guarantee the privacy of your child's research records, including information that we obtained from your child's medical records.

After collection, your child's urine sample will be stored in the Children's Hospital of Pittsburgh of UPMC Infectious Disease Lab, and the blood sample will be stored at the University of Pittsburgh Graduate School of Public Health. The purpose of this collection is to provide samples for future research of UTIs and help scientists to develop new diagnostic tests, new treatments, and new ways to prevent disease.

This research study will involve the recording of past, current and future identifiable medical information from your child's hospital and other health care provider (e.g., physician office) records. For research purposes, we will record your child's age, gender, and race; urine lab and VCUG results; and sick visits related to the UTI. The results of the DMSA kidney scan will be placed into your child's medical record and shared with your child's primary care provider. The results of the genetic tests or biomarkers will not be put into your child's medical records.

You will not get any direct benefit or payment for letting us collect the samples, but your child's sample may benefit other people with UTI. It is possible that data from the use of your child's sample may be used in a research publication. If that happens, your child's name and other personal information will not be included. There is no cost to you or your insurance company for the storage and use of the specimens. Your child's donation does not entitle you or your child to compensation from any commercial use of the products that may be come from the specimen. You and your child will not be informed about future use or results. The samples will be stored indefinitely.

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals may have access to identifiable information related to your child's participation in this research study:

- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may need access to the information for monitoring the conduct of this research study.
- In unusual cases, your children's research records may be released in response to an order from a court of law. If the investigators learn that any of your children or someone with whom they are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of (a) fulfilling orders, made by investigators, for hospital and health care services (e.g. laboratory tests, diagnostic procedures) associated with research participation; (b) addressing correct payment for tests and procedures ordered by the investigators; and/or (c) for internal hospital operations (i.e. quality assurance).

## **RIGHT TO PARTICIPATE OR WITHDRAW**

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Your child's participation in this research study will include the use and sharing of identifiable information for the purposes described above and is completely voluntary. Your decision regarding your child's participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh or medical care at a UPMC hospital or affiliated health care provider or relationship with a health care insurance provider.

You may withdraw your consent for your child's participation in this research study at any time. If you do so, your child will not be permitted to participate in this research study. Any information obtained from your child up to that point will, however, continue to be used by the research team. If your child's urine and blood samples have been stored, they will remain in the laboratory indefinitely. To withdraw your consent for your child's participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw your consent will have no effect on your current or future relationship with the University of Pittsburgh, medical care at a UPMC hospital or affiliated health care provider or relationship with a health care insurance provider.

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#### **Voluntary Consent and Authorization**

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation. By signing this form I agree to participate in this research study. A copy of this consent form will be given to me. Printed Name of Child (Research Subject) I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study and allow the use and sharing of my child's medical record information for the purposes described above. Printed Name of Parent Relationship to Child Date Signature of Parent **Certification of Informed Consent** I certify that I have explained the nature and purpose of this research study to the above-named individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about the study have been answered and we will always be available to address future questions as they arise. I further certify that no component of this protocol was begun until after this consent form was signed. Printed Name of Person Obtaining Consent Role in Research Study Signature of Investigator Date