

**University of Minnesota Department of Pediatrics**  
**Alport Syndrome Treatments and Outcomes Registry**  
**ASTOR**  
**Parental Consent Form**  
*(For parents of participants under 18 years of age)*

## **Introduction**

Your child is invited to be a participant in an international registry. The registry is being organized by the University of Minnesota, under the direction of Dr. Clifford Kashtan, in collaboration with other medical centers in the United States and Canada. The registry is funded by private donation. Your child was selected as a possible participant because your child has been diagnosed with Alport Syndrome. We ask that you read this form and ask any questions you may have before agreeing to have your child in this registry.

Before agreeing to allow your child to participate in this registry, it is important that you read and understand the following explanation of the proposed registry procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with being a participant in this registry. It also describes your right to refuse to give permission for your child to participate and your right to withdraw your child from the registry at any time. This is known as the informed consent document. Please ask the registry doctor or staff to explain any words that you do not understand before you sign this consent form for your child. Make sure all your questions have been answered to your satisfaction before signing.

## **Registry Purpose**

The purpose of the registry is to collect health information about your family and particularly your child's health history. You will be asked to complete a questionnaire about your family and child's health history. The data will be stored at the University of Minnesota's ASTOR central office.

## **Registry Procedures**

If you agree to have your child participate in this registry, you will be asked to permit the sharing of personal health information with the central office at the University of Minnesota. The information you provide may be used at some future date to study other options for diagnosing or treating Alport syndrome.

## **Risks of Registry Participation**

The registry has the following risk: The registry will contain your family and child's personal health information. There is a small risk that this information could be made public accidentally. In order to make sure this is as unlikely as possible; the researchers will follow the University of Minnesota's policies and procedures for the protection of personal health information.

## **Benefits of Registry Participation**

Your child may not derive any direct benefits to registry participation. However, the information gathered may eventually improve the care of all patients with Alport syndrome.

## **Alternatives to Registry Participation**

Your agreement to allow your child to participate in this registry is voluntary. You may choose not to have your child participate in this registry or you may withdraw your child at any time. His medical care will in no way be affected if you decide to forgo your child's participation in this registry or if, at a later date, you decide to withdraw him from this registry.

## **Registry Costs/Compensation**

Participation in this study offers no compensation and your child will not incur any costs.

## **Confidentiality**

The records of this registry will be kept private. We will not include any information that will make it possible to identify your child as a subject in any publications or presentations. His health information and record for the registry may, however, be reviewed by the research staff at the University of Minnesota or by departments at the University with appropriate regulatory oversight. Information about your child's participation in the registry will not be documented in his medical record. In some instances, data will be transmitted via the internet. Numerous data transmittal and monitoring protocols have been established to reduce the likelihood that anyone other than study personnel will gain access to the information. To these extents, confidentiality is not absolute.

## **Protected Health Information (PHI)**

Any of your protected health information (name, date of birth, social security number, address, and medical history) created or received for the purposes of this registry is protected under the "Privacy Rule," a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. See separate authorization form.

## Contacts and Questions

The researcher coordinating the activities for this registry is Dr. Clifford Kashtan. You may ask any questions you have now, or if you have questions later, you are encouraged to contact him at 612-622-2922 or the research coordinator Theresa Cassidy, MPH at 612-626-7632. If you have any questions or concerns regarding the registry and would like to talk to someone other than the researcher(s), you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, #815 Professional Building, and 2200 Riverside Avenue, Minneapolis, MN 55454.

You will be given a copy of this form to keep for your records.

## Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the registry.

Signature of Subject \_\_\_\_\_  
Date \_\_\_\_\_

Signature of Registry Recruiter \_\_\_\_\_  
Date \_\_\_\_\_