

## Registry Information and Informed Consent Form

**Registry Title:** ASF Alport Patient Registry

**Registry ID:** Alport

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**Sponsor:** Alport Syndrome Foundation in collaboration with Pulse Infoframe Inc.

When reading this informed consent form, please note that “you” and “your” and “I” refer to individuals with Alport syndrome.

This informed consent form is for adults or the parents/legal guardians of children invited to participate in the ASF Alport Patient Registry [‘the Registry’]. A parent’s or legally authorized representative’s permission is required for a child to participate. Once a participating child reaches adulthood, the informed consent process will be repeated; at that time the individual can decide to continue participation or decide to stop participating in the Registry.

Patient participation in the Registry will support key collaborations between the patient community, healthcare professionals, academics, advocacy organizations and industry (like biotechnology and drug companies) to bring about change.

The Registry is funded by the Alport Syndrome Foundation, and there is no cost to participate. Participation is voluntary and will not affect your healthcare, treatment, or insurance.

If you choose to participate, you can withdraw from the Registry at any time and for any reason by contacting [Info@alportsyndrome.org](mailto:Info@alportsyndrome.org).

### Purpose of the Registry:

Because Alport syndrome is rare, more information about how the disease develops and how it impacts the patient is needed. A patient registry collects and stores participant medical information, family history and other related information for use in medical research. The purpose of the ASF Alport Patient Registry is to collect, store and analyze medical and other information from individuals living with this rare disease in order to document the natural history and outcomes of patients.

Rare diseases are challenging to study because it is difficult for researchers to access enough information to study. If you choose to participate, your information will be combined with other Alport patients’ data, allowing researchers to access a larger pool of information and conduct

improved research. Participant information in the Registry will be used for medical research and clinical trials to better understand Alport syndrome and to develop potential new treatments or a cure.

You can find more information about the Registry on the following website:

<https://alportsyndrome.org/aboutourpatientregistry/>

## Eligibility:

- Anyone having a confirmed diagnosis of Alport syndrome by a certified genetic counselor or treating physician.
- Provide a signed informed consent form, **and**, if applicable, an assent form for individuals ages 7 through 17.

## How Long Will the Data be Stored?

The Registry does not have a limit on how long the data will be collected and stored.

If in the future the Registry were to close to additional patients, the participant information would be stored for a minimum of seven additional years; this minimum storage time is set in order to fulfill regulations about this type of research

## What Am I Being Asked to Do?

By participating in the Registry, you are agreeing to complete a series of questionnaires about your experience and/or your child/ren's experience in living with Alport syndrome. This will be done using a secure login to the Registry participant portal, using your own credentials.

You will be asked to update your registry clinical information at least once per year, but ideally every four months so that more can be understood about your experience with Alport syndrome. You will be contacted via the email address you provided, to remind you to update your data. You can update/modify your contact information by logging into your portal.

## Permission to Contact

In this document you will be asked to give your consent to be contacted about future research opportunities. If you agree to be contacted, you may be sent information about opportunities to participate in research and clinical trials by the Registry staff through the secure Pulse infotrame portal. **Your contact information will NEVER BE PROVIDED to anyone, including pharmaceutical or biotech companies.**

## Data Access and Future Research

The purpose of the Registry is to make data available to researchers to learn more about Alport syndrome. This means that your de-identified information will be combined with the data of other Alport syndrome participants and may be made available to academic (university/hospital) or industry (drug/biotech) researchers. The information that identifies you specifically such as name and address, is removed from the data provided to researchers. The Registry data may also be used to support data for clinical trials. To access data in the Registry, interested

researchers will need to have their research plan approved by the Principal Investigator(s). Once a plan is approved, the researchers would have access to specific de-identified data required for their project.

## **Right of Withdrawal:**

You can decide to stop participating (withdraw consent) at any time without needing to provide a reason. Your information that was entered into the Registry up to the date of consent withdrawal will be kept in the Registry and used for research. You may withdraw your consent to participate in the Registry at any time by contacting [info@alportsyndrome.org](mailto:info@alportsyndrome.org) or selecting the 'withdrawal button' inside the Registry Patient Portal.

## **Possible Benefits**

Participation in the Registry is not likely to benefit you directly, medically or financially. However, participation in the Registry may help members of your family and others with Alport syndrome by increasing the understanding of your disease. Having an available registry of information about Alport syndrome may help speed up research. Such research could eventually help researchers to learn whether or how treatments work, or help medical professionals improve how they treat the disease.

## **Possible Risks**

There is minimal risk in taking part in the Registry. The Registry may ask you to answer questions that can be sensitive and you may feel uncomfortable answering. You do not have to share any information that you do not want to share. Another possible but unlikely risk is a potential breach in the Registry system itself. In the event that there is a breach in the Registry's system, you will be notified. There is a risk that your information could be misused. The chance of this happening is very small. We have protections in place to keep this potential risk at a minimum.

There may be other risks of taking part in the Registry that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to participate in the Registry.

## **Confidentiality: How is it Protected and Who Can See My Information?**

Information identifying you will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your identifiable registry data and copies of medical reports that you upload; this would be done for quality assurance (to check that the information collected for the Registry is correct and follows proper laws and guidelines):

- Personnel from Pulse Inframe Inc. (Pulse), the software company and platform hosting the Registry.
- The North Star Review Board, which oversees the ethical conduct of the Registry.
- The Principal Investigator, a doctor/researcher involved in the conduct of the Registry.

All of the organizations listed in the above confidentiality sections are required to have strict policies and procedures to keep the information they see or receive about you confidential, except where disclosure may be required by law. There are federal laws that these organizations must comply with to protect your privacy. We will only disclose your information if required by law.

## **Information About Pulse’s Data Collection Platform**

The Registry will collect data through an online platform owned by Pulse.

Pulse is the data controller who will securely store your data and will use it for research purposes as approved by the Institutional Review Board (IRB) [North Star Review Board] as well as a transparent governance structure. This ensures your data is used in a way that meets all data privacy and security requirements. The Registry will collect data about you from the answers you will provide within this online platform.

You will be assigned a Patient Identifier within the Registry to protect your privacy. Your name and contact information will only be used by Pulse to send you reminders when it is time to answer registry questions. In this online platform, your name and contact information are stored separately from your answers to the Registry related surveys.

## **Conflict of Interest**

If you would like information about the funding for the Registry, or about the role of the Principal Investigator (the person in charge of the Registry), please contact [info@alportsyndrome.org](mailto:info@alportsyndrome.org)

## **Who Do I Contact With Questions?**

If you have any questions or concerns about the registration process or about participation in the Registry, please contact [info@alportsyndrome.org](mailto:info@alportsyndrome.org)

To inquire about your rights as a participant in the Registry, you may also contact North Star Review Board at [info@northstarreviewboard.org](mailto:info@northstarreviewboard.org) or toll free: 1-877-673-8439.

The North Star Review Board is an Institutional Review Board (IRB) that has reviewed this Informed Consent Form (ICF) for the Registry for the purpose of protecting your rights. An IRB is a group of people who are responsible for protecting the rights and welfare of people who participate in studies. For questions about your rights as a registry participant in the Registry or to discuss other registry related concerns or complaints with someone who is not part of the Registry team, you may contact North Star Review Board.

## Signing the Consent Form

By signing this form, you do not give away any legal rights or benefits to which you are otherwise entitled. If you do join, you can change your mind and withdraw from the Registry at any time.

Providing informed consent in the Registry system means: (a) you have been given your requested background or supplemental material and the opportunity to ask any questions; (b) you understand the content of the informed consent; (c) you have had the time to consider fully whether you want to join the Registry, and (d) you agree to participate in the Registry.

### Consent statement

1. I understand that my participation in the Registry is voluntary and that I can change my mind and withdraw at any time.
2. I understand that all attempts will be made to protect my privacy and my family's privacy. I understand that my personal information will be encrypted and password-protected. However, there is a very small risk that my identity could be revealed.
3. I understand that by agreeing to participate, I will be contacted by the Registry research staff via email to update or possibly to clarify or correct my health information regularly.
4. I am willing to provide my de-identified medical information to be used for medical studies related to Alport syndrome.
5. I understand that my de-identified information may be used for approved research on conditions not associated with Alport syndrome.
6. I understand that my de-identified information may be shared with other researchers.
7. I understand that I may not directly benefit from participating in the Registry or from the use of my de-identified medical information in any research registry.
8. I understand that I can withdraw from the Registry at any time. I also understand that any information I provided prior to this withdrawal request will not be removed from the Registry.
9. I understand that I can choose to be notified of any future clinical trials or other studies that I may be able to participate in by ticking the appropriate box in the registration section.
10. I agree that I am willing to provide information about my experience with Alport syndrome on this online platform.
11. I understand that Pulse will store and use the identified and de-identified data as part of their data integration and maintenance work.
12. I understand the content of this form and all my questions were answered. I had enough time to decide that I want to participate in the Registry.

13. I understand that I will be emailed/can download a copy of this consent form after signing.

I agree to be contacted by Pulse through the secure platform about future research opportunities.

## Signature Page

Participant or  Parent/Legally Authorized Representative's Digital Signature

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Date: \_\_\_\_\_

Complete the following section if you are registering a child less than 7 years of age

Child's Name: \_\_\_\_\_  
*Print Name*

Complete the following section if you are registering a child 7-17 years of age

Child's Name: \_\_\_\_\_  
*Print Name*

**You will be directed to a page where your child 7-17 years of age can provide their assent.**