

AKU Global Patient Registry – Privacy Notice

[Version 2 – April 2024]

1. Information about us

The AKU Global Patient Registry is an international database for patients diagnosed with the ultra-rare genetic condition alkaptonuria (AKU) which tracks the progression and prevalence of AKU in participants globally (the "AKU Global Patient Registry"). The AKU Global Patient Registry will provide us, and our approved researchers (such as educational / research institutions and pharmaceutical companies), with a unique resource to accelerate: (A) research into understanding, treating and curing AKU; and (B) universal access to new AKU treatments by encouraging further international AKU societies to form.

The Alkaptonuria Society Ltd is a charity registered with the Charity Commission for England and Wales under number 1101052 ("AKU Society", "we", "our" or "us"). The AKU Society is the data controller (or equivalent term under local privacy laws) responsible for personal information collected about individuals who have voluntarily chosen to participate in the AKU Global Patient Registry, including individuals acting on behalf of AKU patients, such as healthcare practitioners, legal guardians and those acting under a power of attorney who give personal information to us on an AKU patient's behalf ("participants", "you" or "your").

This privacy notice explains how we process the personal information of participants who have chosen to participate in the AKU Global Patient Registry. You can contact us at any time using the details set out at the end of this privacy notice.

2. What personal information do we collect?

We collect, use, store and transfer the following types of personal information:

- Identity Data which includes your name, age, gender and country of birth. Date of birth is also collected at time of registration for patients under 18 years old, but this is not contained within the clinical registry itself. Its sole purpose is to enable the AKU Society to be able to identify those patients that were consented by a parent or guardian and, when reaching the age of 18, the AKU Society will then be able to contact the patient to invite them to provide their own explicit consent.
- Contact Data which includes your email address
- Medical Data which includes data concerning your health and medical history such as details of your AKU diagnosis, AKU symptoms, lifestyle, treatments,

family medical history, fertility history, health conditions other than AKU, joint or spine pain, pain management and activity levels.

We collect this personal information through a questionnaire when participants initially register for the AKU Global Patient Registry and as participants update their records and journal entries over time. We also collect personal information when participants contact us. Data may also be collected from individuals acting on behalf of AKU patients, such as healthcare practitioners, legal guardians and those acting under a power of attorney.

3. How do we use your personal information ?

We use the personal information of participants to provide you with the AKU Global Patient Registry and to accelerate research into understanding, treating and curing AKU. This involves us collecting, using and storing your personal information to:

- a) ensure you have secure access to the AKU Global Patient Registry;
- b) improve and maintain the AKU Global Patient Registry and provide technical support;
- c) conduct scientific research;
- d) track the prevalence of AKU, monitor the progression of AKU, evaluate the effectiveness of current treatments and identify new hotspots of AKU;
- e) respond to your queries;
- f) receive and manage complaints;
- g) communicate with you;
- h) produce annual reports;
- i) pursue our charitable objectives and encourage other international AKU societies to form;
- j) deal with any enquiries or issues you have about how we collect, store and use your personal information, or any requests made by you for a copy of the information we hold about you;
- k) comply with any procedures, laws and regulations which apply to us – this may include where we reasonably consider it is in our legitimate interests or the legitimate interests of others to comply, as well as where we are legally required to do so;
- l) establish, exercise or defend our legal rights – this may include where we reasonably consider it is in our legitimate interests or the legitimate interests of others, as well as where we are legally required to do so; and
- m) Enable us to contact patients who were initially consented and registered by a parent or guardian before they reached their 18th birthday so that we can invite them to provide their own consent shortly after their 18th birthday.

4. What is our legal basis for using personal information in this way?

If you are located in the European Economic Area (EEA), UK or Switzerland we must explain the legal basis we rely on for collecting and using your personal information for the purposes outlined above.

Informed consent to participate in research is as at the heart of ethical research. It also helps organisations like us to act fairly and transparently, and to manage your confidential information in line with your reasonable expectations. The AKU Global Patient Registry is a research-led initiative and so we seek informed consent from all participants for their participation in the AKU Global Patient Registry. However, as explained in that informed consent form, the AKU Society does not rely on the informed consent it captures in that form as our legal basis to use your personal information. Instead the AKU Society uses “legitimate interests” as the primary legal basis on which to process your personal information. We provide further information about our legitimate interests below.

Where we process Medical Data in connection with the AKU Global Patient Registry we do so in the public interest in the area of public health relating to scientific or historical research purposes or statistical purposes (as provided for by Article 9(2)(j) of the EU GDPR or UK GDPR).

5. Our legitimate interests

The ultimate goal of the AKU Society is to find a cure for AKU. If you are located in the EEA, UK or Switzerland then to use the legal basis of legitimate interests to process your personal information we must satisfy a three part test and we have assessed that we satisfy that test, as follows:

- a. The AKU Society has a legitimate interest to process this data

Data processed through the AKU Global Patient Registry will provide us, and our approved researchers, with a unique resource to accelerate: (A) research into understanding, treating and curing this debilitating disease; and (B) universal access to new treatments by

encouraging further international AKU societies to form. Participants, their families, healthcare practitioners and the wider public benefit from advances made in the prevention, diagnosis and treatment of this disease. Processing ultimately supports our core charitable goals of preserving and advancing human health and finding a cure for AKU.

- b. The processing is necessary to meet that legitimate interest

Without the personal information that participants provide to the AKU Global Patient Registry, we would not be able to establish the resource and neither we, nor our approved researchers, would have the data needed to do the research.

- c. The interests of participants to process the data is balanced

We have assessed that our legitimate interests or need to process your data to conduct the research, is balanced and proportionate and does not present any material risks to you. In particular, participation in the AKU Global Patient Registry is voluntary and you can choose to no longer participate in the registry (see the "Your Data Protection Rights" section below for further details).

6. How do we share your personal information?

Access to your personal information is strictly limited to;

- Authorised staff acting on behalf of the AKU Society using an approved user account with a secure password;
- Our third party service providers who provide services to us (such as our database developer and hosting provider who provide data processing services); and
- Approved partners (such as educational / research institutions and pharmaceutical companies) whose scope of use of your personal information has been approved by us. Contact details will not be shared with third parties.

7. How long do we hold your personal information for?

The AKU Society will store participants' data for as long as it has a legitimate interest in doing so. The AKU Global Patient Registry is a long-term project and participants' data will be kept for the duration of the project. However, should a participant wish to leave the registry they can do so at any time (please see below).

8. Security

We have put in place appropriate security measures to protect your personal information. In addition, we limit access to your personal information to those employees, agents, contractors and other third parties who have a need to know. They will only process your personal information on our instructions and they are subject to a duty of confidentiality.

9. Can I remove my data from the registry?

Participation in the AKU Global Patient Registry is voluntary. At any time you can choose to no longer participate in the registry or request for your data to be removed from the registry. If you opt out of the registry your data will be securely removed and deleted. If you would like your data to be removed from the registry you can contact registry@akusociety.org who will initiate the process for your data being securely removed and deleted from the registry.

10. Your Data Protection Rights

Depending on where you are located and the privacy laws that apply to your personal information, individuals may have a number of rights:

Withdrawal and Deletion: Please see the section above titled "Can I remove my data from the registry?" for further details.

Correction: You may request that we correct, complete or update your personal information if you think it is inaccurate or incomplete.

Access: In certain circumstances you have a right of access to any personal information we hold about you. Where this right applies you can ask us for a copy of your personal information; confirmation as to whether your personal information is being used by us; details about how and why it is being used; and details of the safeguards which are in place if we transfer your information outside of the EEA, UK or Switzerland. Requests to see what data is held on the AKU Global Patient Registry about you can be made through the [AKU Society website](#) or by contacting registry@akusociety.org

Object: You may have a right to ask us to consider any valid objections which you have to our use of your personal information where we process your personal information on the basis of our or another person's legitimate interest.

Lodge a complaint: If you believe we are using, disclosing, or otherwise processing your personal information in a way that is not in accordance with applicable law, you can lodge a complaint with the relevant data protection authority in the country where you are located.

We will consider all such requests and provide our response within a reasonable period. Please note, however, that certain personal information may be exempt from such

requests in certain circumstances, for example if we need to keep using the information to comply with our own legal obligations or to establish, exercise or defend legal claims.

11. International Data Transfers

The primary server for storage of data collected in connection with the AKU Global Patient Registry is Dublin in a tier three data centre.

Approved partners (such as educational / research institutions and pharmaceutical companies) and the AKU's Society's charitable partners and service providers may operate around the world. This means that your data may be processed in these countries. Nevertheless, we take the appropriate safeguards to ensure that your personal information will remain protected in accordance with this Privacy Notice. Such safeguards include mechanisms approved by the UK GDPR such as Standard Contractual Clauses, the International Data Transfer Addendum to the European Commission's Standard Contractual Clauses and data transfers to countries covered by an "adequacy decision".

12. Contact Us

If you require any further information or have any questions, please contact:

Email: registry@akusociety.org

Post:

AKU Society,
66 Devonshire Road,
Cambridge,
CB1 2BL