



## The European Rare Kidney Disease Registry: Data Access Policy

### Background

The Data Access Policy (DAP) for the ERKReg Registry has been developed by the Work Package 1 (“Project Management”) of ERKReg. It covers the process that will be followed for requesting access to the data in the ERKReg Registry as well as the composition of the Data Access Committee.

The ERKReg Registry is a secure web-based application which has two major aims: (i) to identify contemporaneous cohorts of patients with rare renal disorders for clinical research across national borders, and (ii) to monitor treatment performance and patient outcomes in the participating centers. To this end, selected disease- or treatment-specific key performance and outcome indicators are monitored at the patient level. Moreover, the registry allows to integrate detailed disease-specific registries as extensions to the core database.

All patient data are entered and stored in a pseudonymized fashion. The Registry is fully compliant with the new EU Data Protection Directive as well as with national laws and regulations.

More information is available under [www.registry.erknet.org](http://www.registry.erknet.org)

### ERKReg Registry Team

#### ***Project Management Team:***

Project Coordinator	Franz Schaefer, Heidelberg University Hospital
Project Manager	Tanja Wlodkowski, Heidelberg University Hospital
Statistician	Marietta Kirchner, Institute of Medical Biometry and Statistics, Heidelberg University
Data manager	Heike Breitschwerdt, Heidelberg University Institute of Medical Biometry and Statistics
IT support	Bernd Will, will-be GmbH Clémence Le Cornet, Heidelberg University Hospital





## The registry is governed by a Registry Board composed of the following members:

- The Chair
- 4 members representing ERKNet thematic area working groups
- 1 member of the ERA-EDTA Workgroup for Inherited Kidney Diseases (WGIKD)
- 1 member of the ESPN Working Group for inherited renal disorders (WGIRD)
- 1 representative of the associated sub-registries
- 1 representative of the European Patient Advocacy Group (ePAG) for rare renal diseases

## Current Board members:

- Franz Schaefer, Heidelberg University Hospital
- Dario Roccatello, Torino San Giovanni Bosco Hospital
- Gema Ariceta, Barcelona Vall d'Hebron
- Pietro Manuel Ferraro, Rome Gemelli Hospital
- Olivier Devuyst, Brussels UCLouvain
- Aude Servais, Paris Necker Hospital
- Elena Levtchenko, Leuven University Hospital
- Marina Vivarelli, Rome Bambino Gesù Children's Hospital
- Clada Sproedt, ePAG Chair

## Role-based access rules

Access of authorized users to the registry is controlled by assignment of a secure, individualized password. A hierarchical access authorization system is implemented. The following broad groups of stakeholders will require access to the data:

Project Management Team ('super-administrator')	This group will have access to the global database.
ERKNet Workgroup Chairs ('administrator')	This group will have access to aggregated data from all centers related to associated diagnoses.
Sub-Registry Leads ('sub-administrator')	This group will have access to all data in the associated sub-registry.
Center users	This group will have access to their own center's data.
Investigators	This group may propose analyses of registry data by submitting an Analysis Request Form for review and approval by the Data access committee.



## Anticipated data analysis

The data in the ERKReg Registry shall undergo analysis at regular intervals by the Project Management Team for detailed data consistency evaluations. This analysis will focus on overall data accrual, content, quality, and headline descriptions of care. This analysis will not require approval from the Data Access Committee but shall be performed closely with oversight of the Data Access Committee to provide progress reports.

All other interested parties who request data must complete a Data Sharing Agreement and the Data Access Form/Registry Analysis Concept Sheet.

Only investigators of active contributing units (having enrolled at least 50 patients from their own center) are entitled to request data analyses.

## Process for seeking access to data

- The investigator shall need to complete the Data Access Form/Registry Analysis Concept Sheet and the Data Sharing Agreement.
- The completed forms shall be submitted to the ERKReg Project Management Team who will check their completeness and forward to the Data Access Committee
- The Data Access Committee shall provide their feedback using the Feedback Form within 6 weeks from initial application.
- In case the contents of a new application overlap with an existing active application, the investigators of the two application will be jointly advised to discuss the overlap.

All documents are accessible on the ERKReg Website and through the ERKReg project management team.

