Data Access Policy (DAP)

Core Registry and e-Reporting of Rare Conditions (e-REC)

		Page
1	Data Access Committee	2
2	The Role of The Data Access Committee	2
3	Utility Of The Core Registry	3
4	Utility Of The e-REC	3
5	Role Based Access Rules	4
6	Ownership Of Data	4
7	Ethics & Data Governance	5
8	Research & Data Analysis	5
9	Stakeholder-Specific Data Sharing Rules	6
9	Process For Seeking Access To Data	6
10	Dissemination Of Data Analysis Activity	6
Appendix 1	Data Flow Within The Core Registry	6
Appendix 2	Data Flow Within e-REC	7
Appendix 3	Overview of Data Access Approval Process	8

Version V10

Created: 17/01/19

Modified: 29/10/26

Revision Date: 29/10/28

Introduction

This Data Access Policy (DAP) applies to the two EuRREB registries (Core Registry and e-REC) that are run within the EuRREB project (https://eurreb.eu/). EuRREB is the merged continuation of two projects, EuRRECa (2018-2023) and EuRR-Bone (2020-2023). The DAP has been developed and updated by the Registries Team. It covers the entire process that will be followed for requesting access to the data in the two registries as well as the composition of the Data Access Committee (DAC) that will consist of a core DAC composed of Chair, the Registries Team, patient representatives, and representation from allied groups including ESPE, ESE, ECTS, and ISCBH. In addition, the DAC will rely on a group of experts who will be co-opted depending on the theme of the submitted application.

1. Data Access Committee (DAC)

The EuRREB Data Access Committee oversees all requests for access to data from the Core Registry and e-REC. The DAC ensures transparent, ethical, scientifically sound use of registry data and supports long term sustainability of the registries.

Composition

The DAC consists of:

- Chair
- EuRREB coordinator
- Registries Team (Project manager, Data Manager, Quality manager)
- Steering committee chair
- Representatives from ESPE, ESE, ECTS, ISCBH and/or others stakeholders
- Patient representatives

The actual composition and the remit for this committee is available at https://eurreb.eu/data-access-committee/

Terms & Conduct

- Members serve a 4 year term, renewable once.
- All members complete a Declaration of Interests and update it annually
- Members must declare specific conflicts of interest for each application.
- Members sign a confidentiality and non-disclosure agreement.
- All applications are treated confidentially.
- The DAC aims to respond promptly and transparently.

2. The Role of the DAC

The overall aim of the DAC is to promote the research use of the data that are being collected in the registries through a transparent and simple approach ensuring the long-term sustainability of the project. The DAC should advise on the maintenance of the highest levels of custodianship of the data. Whilst it should have a good knowledge of ethics and data protection, it should not act as another 'research ethics committee' which is a responsibility that rests at the level of the data controllers.

The DAC will review:
- all new applications
- existing projects
- end of project reports
- and any other outputs

Specific tasks of the DAC include:

- Check that the proposed work complies with the terms and conditions of the ethics approval provided to the EuRREB project;
- Look for evidence of the third party who is requesting the data is appropriately qualified for use of the data;
- Advise on improving the projects and any overlaps with ongoing projects;
- Advise on the dissemination and publication plans;
- Ensure that the effort of all those involved is appropriately acknowledged;
- Aim to respond to all data requests promptly;
- Communicate to the requestor with appropriate feedback;
- Be aware of their own conflicts of interest;
- Treat all data requests confidentially;
- Review and advise on the governance processes within DAC.

For further reading, Cheah, P.Y., Piasecki, J. Data Access Committees. *BMC Med Ethics* **21,** 12 (2020). https://doi.org/10.1186/s12910-020-0453-z

3. The Utility of the Core Registry

It is expected that the Core Registry will solely be used to perform Secondary Research on the data that shall be collected during routine clinical care and this form of research is approved under its current ethics approval and have also been described in the participant information sheet. It is anticipated that, in time, these data will be used for the following purposes by a wide range of stakeholders:

a. Provide a source population for the conduct of studies;
b. Provide the patient with details of their condition;
c. Provide information on specific interventions related to defined patient groups;
d. Provide for the follow-up of small patient populations;
e. Life-cycle assessment of the effectiveness and safety of interventions and medicinal products;
f. Provide robust data on disease epidemiology, patients' characteristics and current standard of care;
g. Provide source population data that can be linked to other datasets on specific outcomes;
h. Facilitate the designing of pragmatic trials for rare conditions as well as post-authorisation studies.

4. The Utility of e-REC

e-REC is a 'light-touch' registry. The data collection system is designed to minimise the reporting burden on health care professionals and as it does not collect any identifiable data, it does not require informed consent. Its purposes include:

- understanding the level of activity that is occurring amongst the participating centres;
- provision of data to participating European Reference Networks such as Endo-ERN and ERN BOND for their continuous monitoring exercise;
- understanding how many people are affected by a particular rare condition;
- providing feasibility data for future studies;
- understanding the process of diagnosis and initial presentation of rare conditions through secondary surveys.

5. The Based Access Rules

The following broad groups of stakeholders will require access to the data in the Core Registry:

Role	Access
Patient	This group will have read-only access to their own individual data. They are able to change their level of consent and preferences. In addition, they will be able to complete online questionnaires.
Clinical Contributor	This group will have access to all the cases at their centre. They will also be able to provide access to other members at their clinical team.
Centre Lead	Responsible for the governance at local centre and serves as the contact person of the local centre for the Registries Team. Is able to delete cases from his own centre.
Centre Administrator	Can create new users at centre and have read-only access to data.
Researcher	This group will not have access to any data and will need to complete a Data Request Form and a Data Sharing Agreement.
Registries Team	Access to all data and provides role-based access.

The following broad groups of stakeholders will require access to the data in the e-REC:

Role	Access
Patient	This group does not have access to this platform.
e-REC Reporter	This group will have access to the data of newly encountered cases in their centre and will be able to view the list of users within their centre.
e-REC Analyst	This group has read only access to the e-REC registry to perform analysis on data reported by all centres.
Registries Team	Access to all data and provides role-based access.
Researcher	This group will not have access to any data and will need to complete a Data Request Form and a Data Sharing Agreement.
European Commission	This stakeholder will have access to the aggregated data.

6. Ownership of Data

In the Core Registry, the patient participant (who is the 'data subject') is the primary owner of the data and will grant each of the users and the Leiden University Medical Centre a nonexclusive licence to use such data for research purposes. In case the patient participant is under the age of 16 or 18 years (depending on national law), or subject physically or legally incapable of giving consent, parent(s) or legal guardian(s), is/are the primary owner(s) of the data and will grant each of the users and the Leiden University Medical Centre a nonexclusive licence to use such data for research purposes.

The Leiden University Medical Centre is the current owner of the e-REC and the Core Registry platforms.

The institution of the clinician participant who has entered the data is the owner of the aggregated data of that patient participant and acts as the 'data controller' at the local centre.

The Leiden University Medical Centre is the sponsor of the EuRREB registries and acts as the custodian of the data, acts as the 'data controller' of the registries and also as the 'data processor' with responsibility for the protection of the data, its storage, use and access

When processed, the data become research data and are then the intellectual property of the investigator who is the 'third party'. This third party has to abide by the agreement reached in the Data Sharing Agreement whilst using the data supplied for the purpose stated in the Data Request Form.

7. Ethics & Data Governance

The Core Registry has been approved in the Netherlands by the institutional board of the LUMC 'research databases'. For further information visit https://eurreb.eu/registries/ethics-approval/.
The data governance standards in the e-REC and the Core Registry comply with General Data Protection Regulation (GDPR).
A research project using data from Registries will be considered to have ethics approval subject to the following conditions:

- The research project is within the fields of research described in the application.
- The research protocol has been subject to scientific critique by the Data Access Committee, is appropriately designed in relation to its objectives and is likely to add something useful to existing knowledge.
- The processing of the data in the Core Registry will comply with the terms of informed consent from data subjects.
- Research must be conducted in circumstances such that data subjects are not identifiable to the external researchers. Data must be effectively anonymised or pseudonymised prior to release to external researchers.
- The researchers should undertake to treat datasetsin confidence and not to attempt re-identification of data subjects through linkage with other datasets.
- A Data Sharing Agreement must be in place with all external researchers to ensure processing of the data in accordance with the terms of the ethics approval and any other conditions required by the Registries Team.

Any research project that requires external researchers to be able to identify data subjects for linkage with other datasets, for collecting further data from subjects or for undertaking other research procedures involving subjects, is not covered by this approval. Such projects should be the subject of further project-specific application for ethics review.
All centres who consider participating in the two registries (e-REC and Core Registry) should consider themselves as local data controllers and secure approval from local institution before contributing data.
On approval of any research project by the DAC, approval from individual centres will be obtained before their data are shared for any research project. Whilst ethics approval already exists to use the data for research under the conditions mentioned above, local regulations may vary and individual centres may also want to check whether they need any additional approvals locally.

8. Research & Data Analysis

The data in the Core Registry and e-REC shall undergo 6-12 monthly analysis by the Registries Team to provide progress reports to the DAC. This analysis will focus on overall data accrual, content, quality, and headline descriptions of care. This analysis will not require approval from the DAC but shall be performed closely with the oversight of the DAC.
All other analysis will require completion of a Data Sharing Agreement and the Data Request Form.
It is anticipated that the data from the e-REC may be required for performing secondary surveys. These surveys will be brief and performed by the Registries Team on behalf of researchers and following approval by the DAC. The surveys will be designed jointly by the researchers and the Registries Team.

9. Stakeholder-Specific Data Sharing Rules

Stakeholder	Data Provided	Level	Fees
EuRREB contributors	Full dataset	Pseudonymised	Free (depending on the frequency of the data extractions – fees may apply)
Academic researchers (ERN-affiliated)	Selected fields	Anonymised	Free
Academic researchers (non-affiliated)	Selected fields	Anonymised	Fees may apply
Industry	Selected fields	Aggregated or anonymised	Fees apply
Patient organisations	Selected fields	Aggregated	Fees may apply
Regulators (EMA, national authorities)	Selected fields	Aggregated	Fees may apply

10. Process For Seeking Access To Data

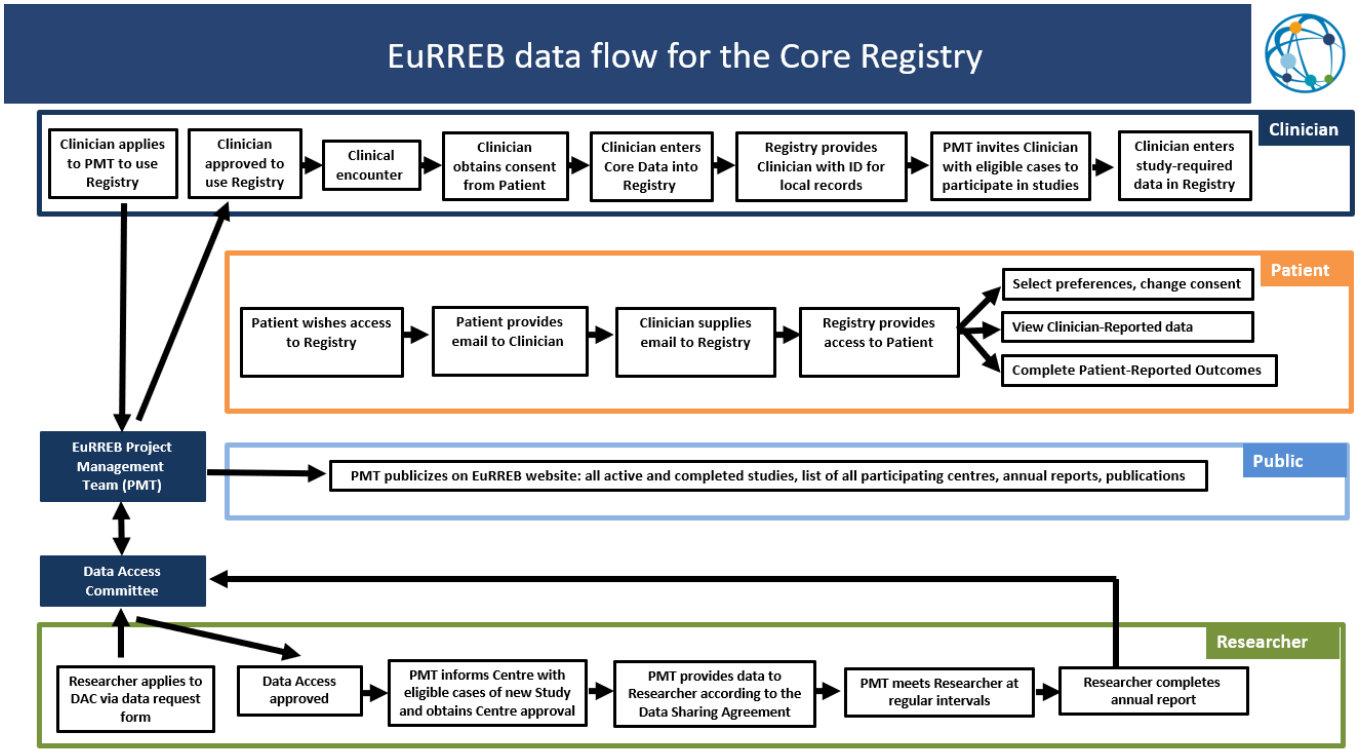
- Access to the data in e-REC and the Core Registry shall follow the path outlined in Appendix 1 and 2.
- The investigator shall need to complete the Data Request Form and the Data Sharing Agreement (Joint Data Registry Agreement) https://eurreb.eu/obtaining-registry-data/.
- The completed forms will be forwarded to the DAC by the Registries Team
- The DAC shall provide their feedback using the Feedback Form within 6 weeks (https://eurreb.eu/obtaining-registry-data/)
- The process for seeking access is summarised in Appendix 3.
- In case the contents of a new application overlap with an existing active application, the investigators of the two applications will be jointly advised to discuss the overlap.

11. Dissemination Of Data Analysis Activity

- All approved requests for data analysis shall be available on the EuRREB website and shared with other parties as appropriate.
- Annual reports of all such 'research activity' will be obtained from investigators and a lay summary shall be posted on the EuRREB website and shared with other parties as ppropriate.
- Acknowledgements and attribution of any publications should follow the conditions in Publication guidelines https://eurreb.eu/publication-guidelines/

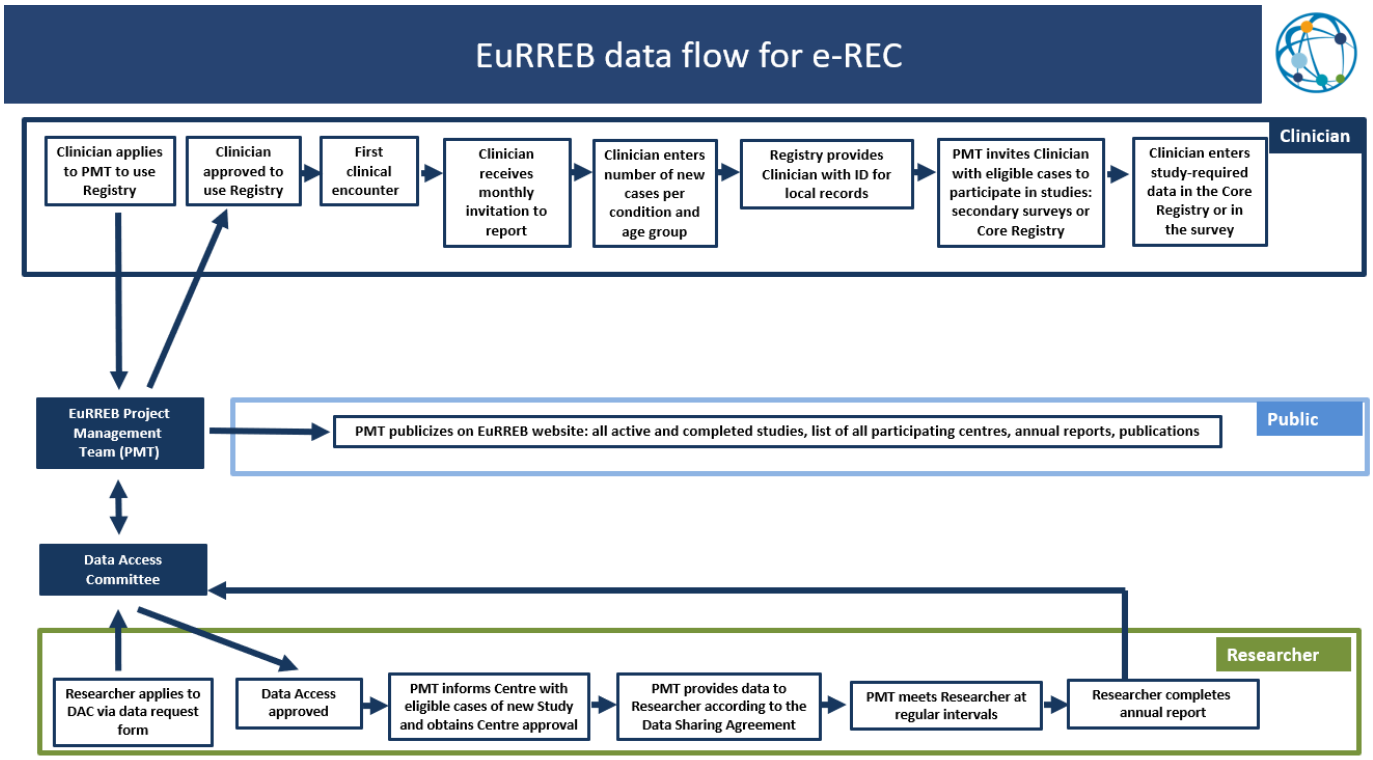
Appendix 1

Data flow for the Core Registry



Appendix 2

Data flow for e-REC



Appendix 3

Data Access Committee (DAC) approval process

