Data Access Policy (DAP)

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

This policy is part of the project '946831/EuRR-Bone' which has received funding from the European Union's Health Programme (2020-2023) and the EuRRECa project which is part of Endo-ERN. The content of this policy represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

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This Data Access Policy (DAP) applies to the two registries (Core Registry and e-REC) that are run within the EuRRECa project (www.eurreca.net) and EuRR-Bone project (https://eurr-bone.com/) that relies on the EuRRECa registries.

The DAP has been developed by Work Packages 1, 2 and 6 of EuRRECa and integrated by Work Package 1 and 2 of EuRR-Bone. Updates are provided by the Project Management Team (PMT). 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 & Co-Chair, the PMT and representation from allied groups including ESPE ECTS and ESE. In addition, the DAC will rely on a group of experts who will be co-opted depending on the theme of the submitted application.

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

1. Data Access Committee (DAC):

Chair[+]	Olaf Dekkers, Leiden University Medical Centre
EuRRECa PI[+]*	Faisal Ahmed, University of Glasgow & Leiden University Medical Centre
EuRR-Bone PI*	Natasha Appelman-Dijkstra, Leiden University Medical Centre
Project Manager*	Jillian Bryce, University of Glasgow
	Tess de Rooij, Leiden University Medical Centre
Chair steering committee	Agnès Linglart, Assistance Publique–Hopitaux de Paris
Endo-ERN ePAG	Arlene Smyth, Office for Rare Condition Glasgow
Endo-ERN representative	Pietro Maffei, Azienda Ospedaliera di Padova
ESPE Representative	Olaf Hiort, University of Lübeck
ESE Representative	Kristi Alexandraki, National and Kapodistrian University of Athens
ECTS Representative	Carola Zillikens, Erasmus Medical Centre, Rotterdam
ERN BOND ePAG	Tenna Toft, Denmark
EuRR-Bone representative	Roland Chapurlat, Université de Lyon
EuRR-Bone representative	Gabrielle Hausler, Vienna Bone & Growth Centre

DAC Project Management Team (PMT) - marked with *; this group is responsible for the day to day running of the DAC.
DAC Executive Group - marked with +; this group consists of EuRRECa Project Governing Board members from WP1, 2 and 6.

Future Composition of the Committee

The current composition of the DAC reflects the Project Governing Boards of the EuRRECa and EuRR-Bone project, originally funded by European Union's Health Programme (2014-2020) and supported by the European Reference Network on Rare Endocrine Conditions (Endo-ERN) and Bone Conditions (BOND), European Society of Endocrinology (ESE) and the European Society for Paediatric Endocrinology (ESPE). The composition fixed to a limited term of 3 years and the composition of the Committee will continue to reflect its principal stakeholders and supporters.

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 EuRRECa and EuRR-Bone registries through a transparent and simple approach ensuring the long-term sustainability of both projects. 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 should:

- Check that the proposed work complies with the terms and conditions of the ethics approval provided to the EuRRECa and/or EuRR-Bone 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 clinical trials;
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 The e-REC

The 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:

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

5. Role Based Access Rules

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

Patient	This group will have read-only access to their own individual data. In addition, they will be able to complete on-line 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.
Centre Administrator	Can create new users at centre and have read-only access to data.
Researcher	This user will not have access to any data and will need to complete a Data Request Form and a Data Sharing Agreement.
Project Management 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:

e-REC Reporter	This group will have access to the data of newly encountered cases seen monthly in their centre.
e-REC Analyst	Will have read only access to the e-REC registry to perform analysis on data reported by all centres.
External Researcher	This user will not have access to any data and will need to complete a Data Request Form and a Data Sharing Agreement.
Project Management Team	Access to all data and provide role-based access.
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 EuRRECa and EuRR-Bone 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://eurreca.net/ethics-approval-coreregistry/ or https://eurr-bone.com/core-registry-protocols/.

- 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 datasets in 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 PMT.

- 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 PMT 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 EuRRECa PMT on behalf of researchers and following approval by the DAC. The surveys will be designed jointly by the researchers and the PMT.

9. Process For Seeking Access To Data

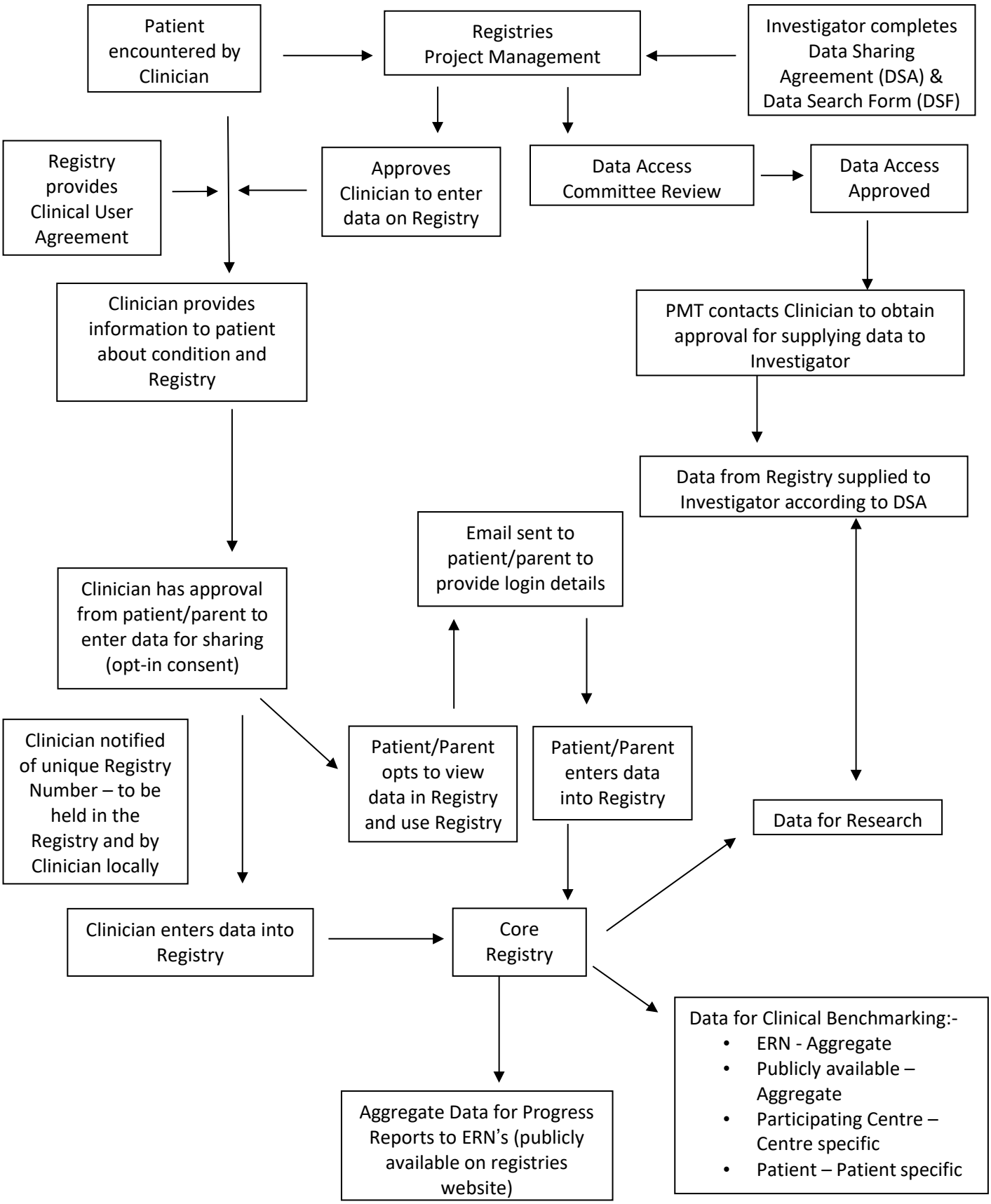
- Access to the data shall follow the path outlined in Appendix 1 and 2.
- The investigator shall need to complete the Data Request Form (Appendix 3) and the Data Sharing Agreement (Appendix 4).
- The completed forms shall be submitted to the registries PMT that will check their completeness and forward to the DAC.
- The DAC shall provide their feedback using the Feedback Form (Appendix 5)
- The Process for seeking access is summarised in Appendix 6.
- 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.

10. Dissemination Of Data Analysis Activity

- All approved requests for data analysis shall be available on the EuRRECa and/or EuRR-Bone website(s) and shared with other parties as appropriate.
- Six monthly reports of all such 'research activity' will be obtained from investigators and a lay summary shall be posted on the EuRRECa and/or EuRR-Bone website(s) and shared with other parties as appropriate.
- Acknowledgements and attribution of any publications should follow the conditions in Section 6.3 of the Data Sharing Agreement

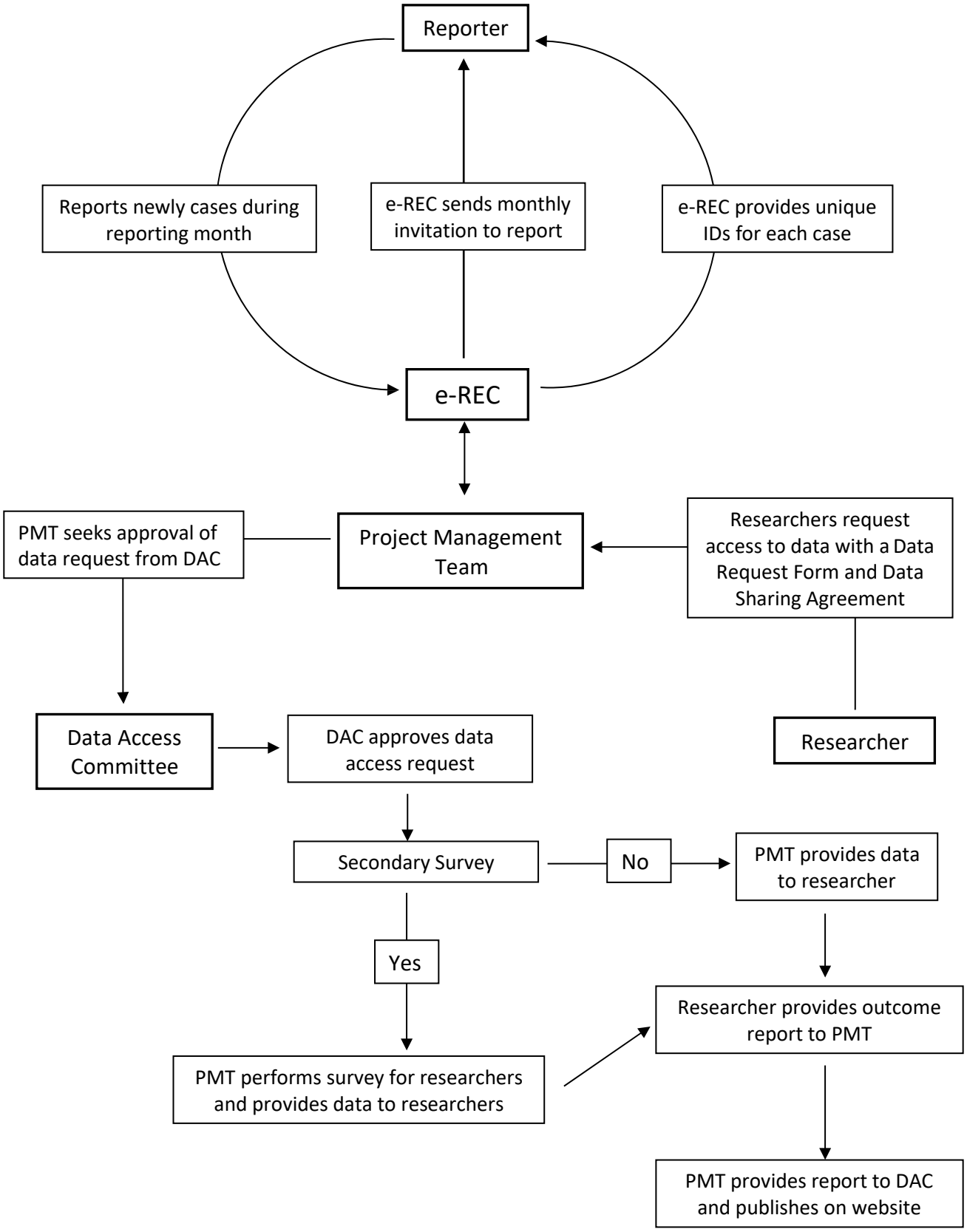
Appendix 1

Data Flow Within The Core Registry Platform



Appendix 2

Data Flow Within e-REC



Appendix 3

Data Request Form

Before completing the form please

- **Discuss your data needs with the registries office(s)**
- **Read - Terms and Conditions for approval of the Core Registry and e-REC**
- **Read - Procedure for obtaining data from the e-REC and the Core Registry**

Please select which registry are the data required from

☐ Data required from e-REC ☐ Data Required from Core Registry

Items marked in asterisk will be shared with the Registry users who are invited to participate in the study.

Name of the Principal Investigator*:
Contact details including institution*:
Coinvestigators*:
Date:
Name of study*:
Summary of the proposed work to be performed with the registry data*: (maximum 500 words)
Lay summary for the public (for websites and other publicity materials)* (maximum 50 words)
Background of the study
Research question/hypothesis
Primary aim
Need for further ethical approval*: *Any research project that requires additional procedures that are not part of routine clinical care, is not covered by generic approval for the Registry. These additional research procedures would require further ethical review, either as an amendment to the current terms of approval of the Registry, or a separate application for ethical review of a specific project. Please state whether the investigators aim to perform any procedures or measurements that are not undertaken as part of routine clinical practice.*

Expected outputs (include plans for dissemination)*
Publication Plan for authorship in outputs*
Timeline from start of study to expected outputs
Overall data management and statistical plan
Would you like statistical support from EuRRECa/EuRR-Bone?
Will the study require contacting collaborating centres to collect additional routinely collected data? **Yes/No**
Source of funding
If no current funding, are you applying for funding?
Deadline for funding application
Have you received data from e-REC or the Core Registry as a PI previously? **Yes/No**
If Yes, provide further details (to complete for each previous study) **1. Date of data supply** **2. Date of last report** **3. Date of final report** **4. Outcome of final report** **5. Outputs from study**
What data would you like us to provide you? (Please specify the variables that you need for answering your research question). **E.g. Number of cases that match recruitment criteria, geographical location, etc.**

Appendix 4

The Core Registry and e-REC Data Sharing Agreement

1. Purpose of this document

1.1 This document describes the minimum arrangements for data provision **by the EuRRECa and/or EuRR-Bone Core Registry and e-REC**. It is to be used as the basis of agreements made about specific services with individual bodies. In those agreements, all its provisions from paragraph 3 onwards must be included. The sections in boxes are to be composed to suit the specific information sharing agreement.

1.2 Parties to the agreement

Party A – Supplier of Data	Party B – Requestor of Data
The EuRRECa Core Registry and e-REC Office for Rare Conditions University of Glasgow* RHC/QEUH Campus Glasgow G51 4TF	

*The University Court of the University of Glasgow, incorporated under the Universities (Scotland) Act 1889 and having its principal office at University Avenue, Glasgow G12 8QQ, a registered Scottish charity in terms of Section 13 (2) of the Charities and Trustee Investment (Scotland) Act 2005 (Charity Number SC004401, Charity Name 'University of Glasgow Court')

2. Exclusions

2.1 Some bodies have rights in law in certain circumstances to be given certain patient identifiable information without an information sharing agreement being needed. Examples include the Audit Commission or other statutory auditor when undertaking an audit that requires such information, but there are many others. This subject is not covered in this protocol.

2.2 The Core Registry collects minimal personally identifiable information except date of birth, and this can only be obtained from the reporting clinician subject to information governance approvals at the centre of the clinician.

2.3 The e-REC does not collect any personally identifiable information.

2.4 Information exchanged as part of research is covered by research governance.

3. Definitions

3.1 Information sharing

This means the database and third parties sending in either direction information using any physical (including handwritten notes or completed forms) or encrypted electronic medium. All information shared will be through a secure server with appropriate encryption.

4. Principles

4.1 Information sharing between organisations shall adhere to the principles of the UK Data Protection Act (2018) and the EU GDPR (2018) and the 'Conditions of Ethical Approval' as stipulated by the West of Scotland Research Ethics Service on 10/01/19.

4.2 Staff at the Office for Rare Conditions at the University of Glasgow must always abide by the organisation's information governance policies and guidance.

5. Details of the agreement

5.1 Purpose/s for sharing information.
Why is the information being shared? – To be completed by Party B

5.2 Information to be shared.
Specifically what information is being shared? - To be completed by Party B

5.3 When and how often is the information to be shared? - *To be completed by Party B*
e.g. on an ad hoc basis, at the beginning of every quarter etc.

5.4 What media is used for transferring the data (format *and* method)? - *To be completed by Party B after discussion with Party A*
How will the information be transferred and in what format? (e.g. documents by fax, post, courier, messages by answer machine, encrypted CD by special delivery, etc.).

5.5 How is the information to be stored? - *To be completed by Party B What format is it in? e.g. secure server database, encrypted CD etc.*

5.6 Who will handle the data? Please state the authorised users. *To be completed by Party B. Who will handle this information?*

5.7 How long will the data be held, i.e. retention period? *To be completed by Party B*
The Core Registry and e-REC will store information for 30 years. It will also store details of all information it has shared with Party B. It is advised that Party B should hold any data that have been used for a publication for 15 years after the date of publication. Information should not be retained for any longer than is necessary for the purpose that it was obtained for. Please give details.

5.8 What is the destruction process? *To be completed by Party B*
How will the information be destroyed when no longer required? (e.g. shredding) Please give details.

5.9 Responsibilities

The applicant(s) must treat the patient information received from the Core Registry and e-REC with a level of confidentiality that is at least equivalent to the following principles.

Assurance by the receiving organisation that it has confidentiality policies and that their employees are trained in confidentiality, including citation of the relevant policies

5.10 How often will you report back to the Office for Rare Conditions, Glasgow on the use the data has been put to?

This may vary depending on the level of support you have requested from the Registry, but should as a minimum involve a brief update on output from the analysis once per year and a full list of outputs at the end of the project. To be completed by Party B

6. Conditions on release of data

6.1. Secondary release of data

Data are released for specific projects to specific people. Data cannot be used for other research projects by the same researchers or used by other researchers for any purpose. The release of data to other people or research projects is not permitted without prior approval.

6.2 Special precautions for rare conditions

The Parties acknowledge and agree that the data will be stripped of direct patient identifiers and will therefore by pseudonymised before Party B is given access to it for research purposes. However, the Parties both further acknowledge and agree that circumstances may arise in which it may be or become possible to identify one or more living individuals from the data contained within the data set in which case such data shall be or become personal data for the purposes of data protection laws ("Personal Data"). If any such circumstance should arise, either the Party first becoming so aware shall notify the other Party and the Parties shall discuss how to proceed or Party B may reject such data until it is pseudonymised such that it is not possible to identify one or more living individuals.

6.3. Acknowledgement and attribution of publications

If data from the Core Registry and e-REC are used for a report or publication without any statistical or clinical input from the EuRRECa and/or EuRR-Bone project team(s) at the Office For Rare Conditions the use of data must be acknowledged along with a disclaimer (see disclaimer below).

The current recommended text for use in publications is available on the website https://eurreca.net/publication-plan/

Personnel from the EuRRECa and/or EuRR-Bone PMT(s) must be included as co-authors in any publication or report when statistical or clinical input and analysis has been required from the PMT. Any document to be distributed or published must be made available to EuRRECa and/or EuRR-Bone for review well in advance of the distribution or publication date. A copy of published research based on data from the Core Registry and e-REC must be sent to the EuRRECa and/or EuRR-Bone PMT(s).

6.4. Disclaimer

The disclaimer to be included in publications and reports based on data from the Core Registry and e-REC that have not, with prior agreement, involved any statistical or clinical input from the EuRRECa and/or EuRR-Bone project team(s) is available on the website https://eurreca.net/publication-plan/ *(Recommended text)*

The source and data handling methods should be made clear in the 'Methods' section. The abstract should also include 'EuRRECa' or 'EuRR-Bone' and 'Core Registry' or 'e-REC' which would allow for searching for publications with these key words (as appropriate). Logos for inclusion in publications and reports are available on the EuRRECa website (www.eurreca.net) and/or the EuRR-Bone website (eurr-bone.com/)

Data published in the Endo-ERN and ERN-BOND reports are in the public domain, but EuRRECa and EuRR-Bone (as appropriate) should be acknowledged as the source of the data and the disclaimer used.

7. Agreement formalities

Agreement to be signed by responsible lead officer for the Core Registry and by the equivalent office holder of the partner organisation in Party B

Core Registry or e-REC reference number: DSA[…….] Period of

agreement

- **Data shared and available for analysis: [dd/mm/yy] to [dd/mm/yy]**
- **Data shared for storage only: [dd/mm/yy] to [dd/mm/yy]**

Review date: [dd/mm/yy]

Signed on behalf of Core Registry and e-REC PMT by Name

(print)

Role

Signature

Date

Signed on behalf of by

Name (print)

Role

Signature

Date

Copy of agreement to be provided to the Core Registry and e-REC PMT for inclusion on the information sharing register.

Once the end date of the agreement has been reached then Party B will confirm, using the form below, to Core Registry and e-REC PMT that:

1. **The data have been used in accordance with this agreement.**
2. **The data have not been shared with other parties not mentioned in this agreement.**
3. **The data have only been used for the purposes outlined in this agreement.**
4. **The data have been destroyed in accordance with the criteria set out in this agreement**

Core Registry or e-REC

End of Agreement Sign off

Core Registry or e-REC reference number: DSA[…….]

Party B ……..……..……..……..……..

Confirms that:

1. **The data have been used in accordance with this agreement.**

2. **The data have not been shared with other parties not mentioned in this agreement.**

3. **The data have only been used for the purposes outlined in this agreement.**

4. **Any data that were not used for analysis for the purpose of an output have been destroyed in accordance with the criteria set out in this agreement and were destroyed on [dd/mm/yy]**

5. **Data were used for analysis for the purpose of an output have been stored and shall be destroyed by [dd/mm/yy]**

Signed on behalf of..... by

Name (print)…….

Role……..

Signature……..

Date / /

Appendix 5

Core Registry and e-REC Data Access Committee Feedback Form

Committee members should complete this template when reviewing any requests for data in the Core Registry or e-REC and return to the Project Manager (within 2 weeks) who will collate them and seek approval from the Project Coordinator to send feedback to the study lead.

Study Title:	
Study Lead name:	
Date submitted:	
Is the study relevant?	
Is there a clear primary /secondary aim description?	
Is the project feasible?	
What are the expected results?	
What is the timeline? Is this realistic?	
Are the requested data sufficient to answer the primary aim?	
Is there a satisfactory plan for publication and dissemination?	
General Comments	
Name of person providing feedback	
Decision of the Data Access Committee member	
Approved	
Revision	

All documents (Data Search Forms, Data Sharing Agreements, Panel feedback, Study lead responses, etc) are accessible to Committee members through the Registries Project Management Team(s).

Appendix 6

Registries Data Access Committee Approval Process