



EuroELSO Publication Policy and Data Access

This document covers below topics and applies to institutions within Europe or other contributing parties based on specific arrangements:

- A. Access to data collected by EuroELSO for researchers, submitting institutions and other entities**
- B. Publication of reports produced by EuroELSO**
- C. Publication of data, reports and scientific manuscripts based on EuroELSO data**
- D. Authorship**

Ad A. Access to data collected by EuroELSO for researchers, submitting institutions and other entities

Data are collected in compliance with the relevant legislation in EU and UK, mainly the WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>, Quality assurance framework, version 9 (QAF v9, UK), <https://www.gov.uk/government/publications/quality-assurance-framework-version-nine-qaf-v9> and GDPR, <https://gdpr-info.eu/>.

Anonymized data are provided by the submitting institution, EuroELSO is the custodian of the submitted data. All submitting institutions have unrestricted access to their own data and routine reports generated using this data. Reports are produced by EuroELSO which include standard outcome reports, data analyses as a result of specific requests to EuroELSO and scientific publications using submitted data. EuroELSO supports research using data held in the EuroELSO registries.

Ethics committee approval is required for all intended scientific publications in peer reviewed journals. This should be coordinated by the lead researcher or person in charge of the project from the local institution prior to release of data.

Ad B. Publication of reports produced by EuroELSO

Any abstract, presentation or manuscript resulting from use of data requested from EuroELSO must be presented to the EuroELSO Scientific Committee or its delegate (i.e. the relevant working group) for review before presentation or submission for publication and must comply with the “EuroELSO Publication Policy and Data Access”.

The lead researcher approved by EuroELSO Steering or Scientific Committees is responsible for the security of any data and analyses, and for compliance with the EuroELSO Publication Policy and Data Access. The lead researcher must notify the EuroELSO Scientific Committee or its delegate (i.e. the relevant working group) of any potential risks to individuals, institutions or to EuroELSO that might result from provision of data for research.

Data and reports will be provided through a secure transfer mechanism and will comply with the GDPR EU regulation, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679>.



EuroELSO Steering Committee reserves the sole right to control all reports produced by EuroELSO, reports identifying a submitting body will not be provided to any external party.

Ad C. Publication of data, reports and scientific manuscripts based on EuroELSO data

Potential publications produced by researchers or other external bodies must be submitted for review by the EuroELSO Scientific Committee or relevant delegate (working group) and approved by the EuroELSO Steering Committee.

The purpose of the review is to:

- Ensure that the quality and limitations of the data provided have been properly understood and interpreted by the user.
- Provide potential advice on data interpretation and analysis if required.
- Ensure appropriate acknowledgement of EuroELSO.
- Ensure appropriate recognition of individuals, groups or collaborating agencies for the work performed in pursuit of the objectives of EuroELSO.
- Ensure that only institutions who have previously granted permission are identified or identifiable by inference.
- Ensure that a statement about Ethics Committee review has been included.
- Ensure that EuroELSO supports the scientific validity and conclusions.
- Ensure that potential financial conflicts of interest have been disclosed.

Presentation of research findings at public forums such as national and international conferences must be notified in advance to EuroELSO to receive approval. Review of the presentation and support for presentation will be at the discretion of the EuroELSO Scientific Committee or its delegate. Publications must include a statement about requirement for review by a Human Research and Ethics Committee.

Ad D. Authorship

Authorship reflects the International Committee of Medical Journal Editors (ICMJE) guidelines, <http://www.icmje.org/>, and stands for a substantial participation where all of the below conditions are met:

- Conception, design, or data acquisition, analysis or interpretation.
- Drafting the article or revising it critically for important intellectual content.
- Final approval of the version to be published.
- Acquisition of funding, collection of data, or general supervision of a research group, alone, does not justify authorship.
- Authors are required to provide a detailed description of their own contribution, to enable editors to publish such information.
- Any person who has participated in a substantial way in conceiving, executing or interpreting research (or any part thereof), should be given the opportunity to be included as an author.
- The order in which authors are listed should be defined and explained upfront and approved upfront by all authors.



First or corresponding author:

- First or corresponding author (based on all authors' agreement) should be the person who initiated the research activity and therefore holds the intellectual property of the project. The same person is also the lead investigator with the responsibilities of reporting and asking the EuroELSO for an approval as outlined in EuroELSO Publication Policy and Data Access.
- The corresponding author is responsible for obtaining written approval of all authors before the paper can be submitted.
- The corresponding author should also obtain approval of all authors before the submission of a revised version of a manuscript.
- The corresponding author is responsible for providing to the journal accurate information on authors email and affiliations at the time of submission.
- Most peer reviewed journals now require that all authors email addresses be provided at the time of submission. If this is not the case, the corresponding author should inform all authors real-time of the status of the paper.

Where authorship is attributed to a group, e.g. multi-centre projects and trials:

- Group authorship is encouraged for publication of the results of large clinical series or trials including a large number of centers.
- All members of the group who are named as authors should meet the criteria for authorship.
- Where the research is published, including electronically, all co-authors should certify their authorship in writing.
- Authors of publications should disclose potential conflicts of interest.
- A writing committee and a corresponding author should be named upfront and approved upfront by all members of the working group.
- All others who are not authors but have contributed to the production of the potential publication (e.g. who for example collected data) should be named as collaborators or if not possible acknowledged with a description of their contribution. Their affiliation should also be mentioned. Individuals or organizations providing facilities or resources should be acknowledged.

Forms of acknowledgement:

- If appropriate, a working group within the EuroELSO should be acknowledged as well as the writing committee assigned by the EuroELSO Scientific committee to the relevant registry/project.
- Any member of a working group may initiate a substudy or re-analysis of prior data. Substudies must be approved by the leading investigator and the working group, ultimately approved by the EuroELSO Scientific a Steering Committee.
- The following wording should be used to acknowledge EuroELSO contribution to publication: „.....the Working Group on XY, on behalf of EuroELSO“
- Institutions which have, through submission to EuroELSO registry, contributed to the dataset used for the publication should be acknowledged and listed as a list of



contributors or collaborators. The following wording or similar should be used: “The authors and the EuroELSO Steering and Scientific Committees would like acknowledge and thank clinicians, data collectors and researchers at the following contributing sites.....”.

Expectations:

- Publication of multiple papers based on the same set(s) or subset(s) of data is unacceptable except where there is full and appropriate cross-referencing between papers and EuroELSO approval.
- If data are to be used in a presentation, then EuroELSO should be acknowledged as the provider of the information in the presentation slides.
- Publications should include information on sources of financial support for research.