GDPR and ESCRS Registry and Dataset Studies

ESCRS would like to make participation in their registry studies, EUREQUO and the ECCTR, and the development of open access datasets as easy as possible for our members. You may want to participate, but you may worry that it is not legal to share the data you collect in your clinics.

You may also worry that you need ethical approval in order to perform new analyses on data that has already been collected. This includes registry data, data from clinical trials that have already been performed, and data collected from routine clinical practice in your own clinic.

ESCRS has commissioned a legal review to help you.

Here are the main findings:

- You do not need consent in order to share healthcare data if information identifying the individual patient has been removed.

- You do not need ethical approval in order to perform analyses on registry data or data collected in your clinic, provided that information identifying the individual patient has been removed.

- Ethical approval is still required in some countries for re-use of data collected in clinical trials

Implementation of GDPR law varies between current and former EU/EEA member states. Advice was sought for France, Germany, Holland, Italy, Spain, Sweden, and the UK from specialist law firms in each country coordinated by:

Latham Watkins (www.lw.com) – advice on when consent is required
Bevan Brittan (www.bevanbrittan.com) – advice on when ethical review is required

Copies of their consolidated reports can be obtained by email from Tom Oglivie-Graham (ESCRS Managing Director) tog@md.escrs.org

Advice in other countries is likely to be similar, but may vary and should be checked locally. For example, in Austria, ethical approval may be required for both new analyses of registry data and clinical trials data. In Spain, Holland and Italy, local institutional policy may still require notification or ethical review for registry studies, but there is no basis for this in GDPR law.

What is Personal Healthcare Data?

Personal Healthcare Data has two components:

The **healthcare data** – information in healthcare records

The **personal data** – anything that would allow you to identify individual patients.

What is de-identification?

There are 2 ways in which personal data can be separated from healthcare data

Anonymisation – irreversible separation. Only the healthcare data is passed on to researchers.

Pseudonymisation – reversible separation. The healthcare data is passed on to researchers together with a code that links back to personal data. The key to this code (the database connecting the code to individual patients) is not normally accessible to the research team.

Maintaining a link with personal data can help individual patients if early feedback from research findings is relevant to their care.

When can healthcare data be shared in registry studies?

Healthcare data in registry studies is normally either pseudonymised or anonymised. Our legal review indicates that:

Pseudonymised data – can be shared for **non-commercially sponsored studies**

Anonymised data – can be shared for **commercially sponsored studies**

What elements of GDPR are most relevant?

General Data Protection Regulation (GDPR) was introduced in May 2018 to harmonize privacy laws across Europe. It determines when and how we can collect, share and analyze personal healthcare data.

ESCRS will not archive personal healthcare data without de-identification (either pseudonymization or anonymization). Even when personal data has been removed, special considerations apply to healthcare data under Article 9 “processing of special categories of personal data”. But processing of de-identified healthcare data is permitted where:

GDPR clause 9.2.(i) – processing is necessary for "ensuring high standards of quality and safety of health care and of medicinal products or medical devices…"

GDPR clause 9.2.(j) – processing is necessary for "archiving purposes in the public interest, scientific or historical research purposes or statistical purposes…"