

FORM

Form to apply for the release of personal data/journal information for research purposes

In cases where journal information or other sensitive personal data is to be used for research purposes in accordance with Article 9 (j) of the GDPR, the application for the principal research entity shall be sent to the Centre for Health Data: halsodata.rst@sll.se. The application must contain the following information:

Responsible entity

- 1) Details of the organisation which is principally responsible for the research study in question.

The principal research entity is the organisation in which the research study is carried out.
[Click or press here to enter text.](#)

- 2) Contact details for the principal researcher:
Name, e-mail, telephone number and affiliation with educational institution.

[Click or press here to enter text.](#)

- 3) The application must be signed both by an authorised representative of the principal research entity and the principal researcher.

Authorised representative according to delegation of authority.

Objective

- 4) Describe the objective of the research.

[Click or press here to enter text.](#)

- 5) How many patients are included in the study?

[Click or press here to enter text.](#)

Retrieval of personal data/journal information

- 6) Describe the type of data that will be released by Region Stockholm.

Define the information to be retrieved from journals in the enclosed variable list.

[Click or press here to enter text.](#)

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- 7) Describe how the personal dataⁱ will be retrieved,ⁱⁱ as well as who will retrieve it and the period for which the data is required.
Click or press here to enter text.

Access

- 8) Who will gain access to the personal data that is released?
State name and contact details.
Click or press here to enter text.
- 9) Will the data be released, partially or fully, to any other organisation or private participant?
Click or press here to enter text.
- 10) Will the data be transferred to a third country (= outside of the EU or Great Britain)?
If yes, state the purpose and recipient organisation and enclose the Data Transfer Agreement as well as the recipient's compliance with EU legislation under the GDPR.
Click or press here to enter text.
- 11) Is a Personal Data Processing Agreement requiredⁱⁱⁱ?
For example, will IT support be utilised, or will another organisation process Region Stockholm's personal data on our behalf?
Click or press here to enter text.

Security

- 12) How is the personal data protected from the perspective of confidentiality and information security?
Describe how the personal data will be stored and handled during the period in which the research takes place. If a web-based system is used for storage of data/construction of a database, this must be outlined (including information on ownership/licensing agreement, IT security, etc.).
Click or press here to enter text.
- 13) Outline management of key codes, where relevant.
Click or press here to enter text.
- 14) How will the personal data be handled when the study is completed?
Outline the archive procedure that will be applied.
Click or press here to enter text.

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Appendices to be enclosed with the application

- The application to the Swedish Ethical Review Authority (EPM), including appendices and additional applications
- Decision from the EPM
- Information for patient and consent form
Please note! If there are multiple versions of the patient information and consent forms, all of these must be enclosed. If consent is not obtained, this must be indicated in the Swedish Ethical Review Authority's decision.
- Variable list with a specification of the personal data required for the purpose of research
- Data Processing Agreement
- Data Transfer Agreements or standard contractual clauses for transfers to third countries

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- i **Personal data** refers to any type of information that may be directly or indirectly attributed to a living physical person. This means that, if a registered item of data indicates to whom it relates, either directly or indirectly, it is considered personal data. Examples of personal data may include name, address and personal identity number, however, an image or a case reference number is also considered personal data.
 - ii A **service agreement** is drawn up in order to regulate an assignment defined by a principal. An assignment may comprise any conceivable task to be performed by the contractor on behalf of the principal. In the agreement, the parties set forth the conditions associated with the assignment.
 - iii The **(Personal Data) Processor** is any person or entity who processes personal data on behalf of the (Personal Data) Controller, for example, a service provider or web host. A (Personal Data) Processor is always outside of the organisation itself. An employee or other individual who processes personal data under the direct responsibility of the (Personal Data) Controller is not considered a (Personal Data) Processor.

A (Personal Data) Processor may be either a natural or legal person. If, for example, a (Personal Data) Controller engages a service agency, this agency becomes a (Personal Data) Processor who may process personal data in accordance with instructions of the Controller. A **written agreement** must be drawn up. The (Personal Data) Controller is responsible for ensuring an agreement is in place. In the agreement, it must be specifically stipulated that the (Personal Data) Processor may only process personal data in accordance with the instructions provided, and must apply the security measures to be adopted by the (Personal Data) Controller.

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