

Finnish Social and Health Data Permit Authority

Date 13 May 2022

Issued on	13 May 2022
Effective date	1 November 2022
In effect	Until further notice
Legal basis	Section 46(2) of the Act on the Secondary Use of Health and Social Data (552/2019) (later also referred to as the 'Secondary Use Act')

Regulation of the Health and Social Data Permit Authority: Data content and data structures of data permit applications and data utilisation plans

1 Background

Under section 46, subsection 2 of the Secondary Use Act, the Health and Social Data Permit Authority Findata (later referred to as the 'Data Permit Authority') shall issue regulations on the data content and data structures of data permit applications and data utilisation plans.

The concepts of data permit and data utilisation plan used in the Regulation are defined in section 3, subsection 1, paragraphs 8 and 17 of the Secondary Use Act. Further provisions on the data permit application are also contained in Chapter 5 of the Secondary Use Act (sections 43 to 44 and 46 to 54). Under section 46, subsection 1 of the Secondary Use Act, a data utilisation plan shall be attached to a data permit application.

Before issuing this Regulation, the Data Permit Authority has consulted the stakeholders and other parties whom the Regulation concerns. This consultation took place on the web service lausuntopalvelu.fi, where the Draft Regulation was publicly available for commenting between 8 December 2021 and 24 January 2022. During this period, a total of 20 statements were given. The feedback received in these statements was taken into account when finalising the Regulation.

For the content of the Regulation, see Annex 1.

2 Scope of the regulation

This is the Regulation issued by the Data Permit Authority on the data content and data structures of a data permit application and data utilisation plan referred to in section 46, subsection 2 of the Secondary Use Act.

A provision on the authority to process data permit applications is contained in section 44 of the Secondary Use Act.

The Data Permit Authority is responsible for making decisions on data permits in all situations referred to in section 44, subsections 1 and 2 of the Secondary Use Act. For a detailed description of these situations, see section 2.1 of Annex 1. If the data permit covers data held by several controllers, the entire data set will, as a basic premise, always be compiled by the Data Permit Authority in compliance with section 14, subsection 1 of the Secondary Use Act.

Under section 44, subsection 3 of the Secondary Use Act, however, controllers referred to in section 6, paragraphs 1 to 8 of this Act are responsible for making the data permit decision when the data permit application only concerns data contained in the personal data files of the organisation in question.

If a controller referred to in section 6, paragraphs 1 to 8 of the Secondary Use Act has transferred their competence related to permits to the Data Permit Authority in compliance with section 11, subsection 3 of the Secondary Data Act, the Data Permit Authority is, under section 44, subsection 3 also responsible for making the data permit decision when the data permit application only concerns the register data of the organisation in question.

This Regulation applies to both the Data Permit Authority and all controllers referred to in section 6, paragraphs 1 to 8 of the Secondary Use Act.

In the interest of clarity it should be noted that the Regulation does not apply to data requests referred to in section 3, subsection 9 of the Secondary Use Act. Under section 45 of the Secondary Use Act, applications concerning data requests are always processed by the Data Permit Authority, with the exception of statistical authorities referred to in section 45, subsection 3 of the Act. Statistical authorities refer to Statistics Finland and the Finnish Institute for Health and Welfare to the extent that they are collecting data for statistical purposes.

3 Entry into force

This Regulation will enter into force on 1 November 2022 and remain in effect until further notice.

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As from 1 November 2022, this Regulation shall be complied with by the Data Permit Authority and all controllers referred to in section 6, paragraphs 1 to 8 of the Secondary Use Act.

The Regulation will be updated as necessary.

4 Applicable legislation

Section 46, subsection 2 of the Act on the Secondary Use of Health and Social Data (552/2019).

Johanna Seppänen
Director of Department

Päivi Lindström
Legal Adviser

This Regulation has been signed electronically.

Annex 1: Data content and data structures of data permit applications and data utilisation plans

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1 General information

This Annex contains the Regulation issued by the Data Permit Authority on the data content and data structures of a data permit application and data utilisation plan referred to in section 46, subsection 2 of the Secondary Use Act (Act on the Secondary Use of Health and Social Data, 552/2019).

This Regulation shall be complied with by the Data Permit Authority and all controllers referred to in section 6, paragraphs 1 to 8 of the Secondary Use Act.

The purpose of the Regulation is to ensure that the authority competent in each case processes data permit applications in a uniform and lawful manner. To facilitate its application, certain concepts and requirements of the Secondary Use Act and the General Data Protection Regulation are explained in this Regulation at a general level.

The Regulation contains references to the following acts:

- Act on the Secondary Use of Health and Social Data, 552/2019 (Secondary Use Act)
- Data Protection Act, 1050/2018
- General Data Protection Regulation of the EU, GDPR (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation))
- Language Act, 423/2003
- Statistics Act, 280/2004

1.1 Concepts

Data permit application

Data permit application is defined in section 3, subsection 1, paragraph 8 of the Secondary Use Act.

The purpose of a data permit application is to apply for a permit for processing confidential personal data held in registers subject to the Secondary Use Act. The data permit defines the purpose of use referred to in the Secondary Use Act for which the data may be processed.

Data utilisation plan

The data utilisation plan and the information it should contain are defined in section 3, subsection 1, paragraph 17 of the Secondary Use Act. Data utilisation plans are discussed in section 3.2 of this Regulation.

Data Permit Authority

Data Permit Authority refers to the Health and Social Data Permit Authority Findata.

Authority, or authority responsible for the data permit decision

Depending on the context, these concepts mean either the Data Permit Authority or some other authority referred to in section 6, paragraphs 1 to 8 of the Secondary Use Act which, under sections 11 and 44 of this Act, is competent to process the data permit application in question.

Controller

In keeping with the definition contained in Article 4(7) of the General Data Protection Regulation, controller means the party which, alone or jointly with others, determines the purposes and means of the processing of personal data.

Depending on the context, in this Regulation the controller also means public social and health sector authorities listed in section 6, paragraphs 1 to 8 of the Secondary Use Act.

Processor, or processor of personal data

Under Article 4 of the General Data Protection Regulation, processor of personal data means a party who processes personal data on behalf of the controller. For more information on the role of a processor, see the website of the Data Protection Ombudsman at <https://tietosuoja.fi/en/processors>.

Personal data

A data permit concerns certain confidential personal data defined in the permit. Under the General Data Protection Regulation, personal data means any information relating to a directly or indirectly identified or identifiable natural person. Under the GDPR, pseudonymised data is also personal data. For more information on the concept of personal data, see the website of the Data Protection Ombudsman at <https://tietosuoja.fi/en/what-is-personal-data>.

Permit applicant, or applicant

Permit applicant refers to the person or organisation named in the data permit application to whom the data permit applied for will be issued.

Permit applicant's/applicant's contact person

A person named in the data permit application who serves as the applicant's contact person in matters related to the application.

2 General information on the processing of data permit applications

2.1 Authorities competent to process data permit applications

Section 44 of the Secondary Use Act contains a provision on competence to process data permit applications.

Data Permit Authority's competence

Under section 44, subsection 1 of the Secondary Use Act, the Data Permit Authority is always responsible for making the data permit decision when the data permit application concerns

1. combining data in the files of several public sector controllers in the social and health sector referred to in section 6, paragraphs 1 to 8 of the Secondary Use Act;
2. extracting data saved in Kanta services; or
3. extracting register data held by one or several private social welfare and health care service organisers.

Competence of controllers referred to in section 6, paragraphs 1 to 8 of the Secondary Use Act

If the data permit application only concerns data contained in the files of a single public sector controller and no access to any other register subject to the Secondary Use Act is applied for in the same permit application, and the application or the data utilisation plan indicates no intention to combine the data with data held by other controllers subject to the Secondary Use Act, the data permit application should be addressed to the public sector controller in question (section 44, subsection 3 of the Secondary Use Act).

If the controller has transferred their competence to issue permits to the Data Permit Authority in compliance with section 11, subsection 3 of the Secondary Use Act, the Data Permit Authority is responsible for making the data permit decision instead of the controller.

Competence of the Finnish Centre for Pensions, the Digital and Population Data Services Agency and Statistics Finland

Under section 44, subsection 2 of the Secondary Use Act and as noted in the detailed rationale of Government proposal 159/2017 vp., the Finnish Centre for Pensions, the Digital and Population Data Services Agency and Statistics Finland are competent to make permit

decisions regarding data subject to the Secondary Use Act held by them if the data permit application only requests data held by one of them, or combinations of data held by one of them.

The Finnish Centre for Pensions, the Digital and Population Data Services Agency and Statistics Finland make the permit decisions concerning all data held by them, also data subject to the Secondary Use Act, pursuant to other legislation applicable to them, and they do not apply the Secondary Use Act when making permit decisions. Consequently, this Regulation is not applied to the Finnish Centre for Pensions, the Digital and Population Data Services Agency and Statistics Finland.

Derogation concerning statistical authorities

Under section 7, subsection 1 of the Secondary Use Act, a permit application that concerns data referred to in the Secondary Use Act and data collected by a statistical authority for the purpose of compiling statistics is sent not only to the Data Permit Authority but also to the statistical authority whose data are requested.

A statistical authority refers to

1. Statistics Finland regarding all other data collected by it besides cause of death data, and
2. the Finnish Institute for Health and Welfare to the extent that it collects data as a statistical authority for statistical purposes. The Finnish Institute for Health and Welfare itself defines which registers maintained by it contain data collected by it as a statistical authority for statistical purposes.

Under section 7 of the Secondary Use Act, Statistics Finland and the Finnish Institute for Health and Welfare are responsible for issuing data permits for scientific research giving access to the data collected by them as statistical authorities for statistical purposes. Each statistical authority takes care of combining data for which the Data Permit Authority has issued a permit with data held by the statistical authority in question, as well as the pseudonymisation and anonymisation of these data in compliance with section 51, subsection 4 of the Secondary Use Act and the Statistics Act.

2.2 Application language

Pursuant to the Language Act, the applicant must be able to submit their application in either Finnish or Swedish.

At their discretion, the authority responsible for the data permit decision may also accept applications in other languages.

2.3 Data Protection Ombudsman's statement on a data permit application

Where necessary, the authority responsible for the data permit decision may exercise their right laid down in section 44, subsection 4 of the Secondary Use Act to ask for the Data Protection Ombudsman's statement on the data permit application.

For instance, a statement may be requested if the data permit application concerns an extremely large volume of register data, and it is unclear whether they are essential for the purpose indicated in the application. A statement may also be required when, for example, the data permit application concerns handing over a data set for the permit holder's use in a format in which individuals can be identified.

3 Contents of a data permit application and a data utilisation plan attached to it

3.1 Information contained in a data permit application

Details of the applicant, their contact person and the controller

The data permit application should give the name of the applicant, which may be a legal or a natural person. The application should also contain the name of a contact person for the application who responds to enquiries concerning it.

When the applicant is a legal person, the applicant's name and postal address and the organisation's business ID or other similar identifier should be given. If the applicant is a natural person, they must give their name and postal address.

The applicant's contact person must give their name and sufficient contact details in the application, at minimum a telephone number and e-mail address.

The application should clearly identify the controller referred to in the General Data Protection Regulation, or the controllers, if several. The controller may be either an organisation or a private individual. The controller determines the purpose and means of processing of the data set to be formed under the data permit decision. There may be more than one controller and the controllers may be joint controllers, which means that they will together determine the purpose and means of processing the data set to be formed under the data permit decision.

The controller may themselves be the applicant, or some other party. If the applicant serves as a processor of personal data on behalf of a third party (controller), the applicant and the

controller must enter into a written contract on the processing of personal data as required under the GDPR.

The relationship between the contact persons identified in the application and the applicant should be stated in the application. For example, it can be based on an employment or public-service employment contract.

Purpose of data use

The applicant should identify a purpose of data use referred to in the Secondary Use Act in their data permit application. Additionally, the general impression created by the application should correspond to the stated purpose of use compliant with the Secondary Use Act.

A data permit may be issued for one of the following purposes:

- scientific research
- statistics
- education
- planning and reporting duties of an authority

The data permit application or the data utilisation plan attached to it should indicate what the project is about and why the data are needed for the purpose stated in the data permit application.

Scientific research

When the purpose of use is scientific research, the data permit application or its attachments must contain a research proposal. The data permit application or its attachments must indicate the person or group responsible for the research. The name, degree and background organisation of the responsible person must also be given. In case of a thesis, the responsible person is the supervisor.

If a research permit issued by the responsible organisation or target organisation is required, the research permit should also be attached to the data permit application. The research permit shows that the organisation is aware of the research project and, for its part, committed to carrying it out. The purpose of this requirement is to prevent situations where it turns out that the organisation does not support the project and the data permit application proves unnecessary.

If an ethics review conducted in advance is required under the legislation applicable to the research project, the statement of a research ethics committee should also be attached to the data permit application.

If the study design requires an evaluation by a research ethics committee in the humanities, the statement of the ethics committee must be attached to the application.

Statistics

The data permit application should indicate which actor would compile the statistics and for what purpose.

Education

The data permit application should indicate that the personal data requested for educational purposes will be used to produce teaching materials for personnel who process social and health care client data and for those studying to become social and health care professionals. The data permit application should describe why access to the data sets is essential for delivering the education. These requirements are based on section 39, subsection 1 of the Secondary Use Act.

Under section 39, subsection 2 of the Secondary Use Act, identifiable data may only be used in teaching situations if the education cannot be delivered using anonymous data because of the rare nature of the case to be dealt with, the nature of the education or other similar reason. The person providing teaching must inform their students of the confidentiality provisions in legislation and the sanctions resulting from their violation.

Planning and reporting duties of an authority

The data permit application should justify why the data it concerns are essential for performing the authority's planning and reporting duties or meeting the information needs it concerns.

The provision in section 40 of the Secondary Use Act concerns specifically the planning and reporting duties of an *authority*. As a basic premise, the planning and reporting duties of an authority may only be carried out by an authority. If the authority is not itself the applicant in the data permit application, it should be the controller of the data, however. The controller of personal data is the party who determines the purposes and means of processing the data. In case of the duties of an authority, the need and purpose are determined by the

authority in question. In work contracts, as a basic premise the contractor is the processor of personal data.

Building of the data set the data permit application concerns (extraction description)

The data set requested in the data permit application should be described, either in the application or its attachments, making clear what data sets the application concerns (later referred to as the 'extraction description'). The extraction description should only focus on the necessary volume of personal data, following the principle of data minimisation of the General Data Protection Regulation.

The purpose of the extraction description is to enable the extraction of data from the controller's personal data files on the one hand and, on the other, to produce permanent documentation on the data which the data permit decision issued by a competent authority concerns.

The data permit application should justify why the requested data are needed for the purposes stated in the application. Based on the information provided in the data permit application, the authority processing it must be able to assess if the requested data are necessary and appropriate in proportion to the purpose stated in the application.

For example, the extraction description should provide the following information:

- Which persons' data will be extracted? How will the subject group be formed? Are controls to be extracted for the subject group? Will data concerning the subject group members' relatives be extracted?
- From which registers will the data be extracted? Which are the names of the registers, and which controllers are they maintained by?
- Which data will be extracted, and over which period?
- If the extraction takes place in multiple stages, the application should show the order in which the requested data will be extracted.

Other data to be combined with the requested set

All other data sets to be combined with the set to be extracted under the data permit should be listed in the data permit application. Any permit applications pending with other authorities should also be mentioned.

For data accessed by permit, at least the following information must be provided, either in the data permit application or attached to it:

- The authority issuing the permit,
- the register number or other identifier of the permit,
- the date of the permit decision and the expiry date of the permit.

For a pending permit application, this information should be submitted once the authority in question has issued the permit.

This information should also be submitted for the subject group and any control group or group of relatives if they were formed under a permit issued earlier. If the subject group and any control group and/or group of relatives has already been formed, the application must indicate the criteria on which the subject group was formed, and if the data permits concerning it are still valid.

If the plan is to combine the data referred to in the data permit application with data collected by the data subjects' consent, or if the subject group whose register data the data permit application concerns has been formed on the basis of data collected by consent, samples of the information and consent forms used must be attached to the data permit application.

Further information

Should they wish, the applicant must be able to provide freely worded additional information in the data permit application to state any essential considerations.

3.2 Data utilisation plan attached to a data permit application

The data permit application must contain the information of a data utilisation plan. At the discretion of the authority, the data utilisation plan information can be requested either as part of the data permit application or in a separate attachment.

In the data utilisation plan, the applicant describes how they will address and fulfil their obligations under the General Data Protection Regulation and the Secondary Use Act. The data utilisation plan must address the entire processing life cycle of the data requested in the data permit application.

The data utilisation plan should contain the following information:

- Purpose of use referred to in the Secondary Use Act of the data requested in the data permit application (see section 3.1/Purpose of data use above).

- All persons who will participate in processing the data, and their possible employer or other background organisation.
 - The application should list all persons who will process the data, both as controllers or a controller's representatives referred to in the General Data Protection Regulation, and processors of personal data or processor's representatives.
- The legal basis of processing personal data concerning both the data that the data permit application concerns and any data sets that may be combined with them. The legal basis means one of the legal bases referred to in section 6, subsection 1 of the Secondary Use Act and grounds referred to in Article 4 of the Data Protection Act. For special categories of personal data, the legal basis is usually selected among the grounds listed in Article 9, paragraph 2 of the General Data Protection Regulation and section 6 of the Data Protection Act. For the legal bases, see the website of the Office of the Data Protection Ombudsman: <https://tietosuoja.fi/en/when-is-the-processing-of-personal-data-permitted>
- The data utilisation plan should also state the processing environment and type of processing for which the data are requested.
 - Under section 51, subsection 3 of the Secondary Use Act, data sets provided subject to a data permit are primarily delivered for the permit holder to process in the environment offered by the Data Protection Authority referred to in section 20, subsection 1 of the Secondary Use Act. If the data are requested for processing in some other secure environment referred to in section 20, subsection 3 of the Secondary Use Act, the data permit application or the data utilisation plan should justify why this is essential for the project as laid down in section 20, subsection 3 and section 51, subsection 3 of the Secondary Use Act.
 - Other secure environment referred to in section 20, subsection 3 of the Secondary Use Act means a secure environment that meets the requirements of the Regulation on secure operating environments issued by Findata and has been audited in compliance with the Secondary Use Act and entered in Valvira's register. For more information, see the website of the Data Permit Authority: [Regulation on secure operating environments - Findata](#)
 - As a rule, data may only be disclosed in a pseudonymised format under a data permit. A permit for data in which persons can be identified may only

be issued in exceptional cases. If data sets in which persons can be identified are exceptionally requested for processing by the permit holder, the application should justify why access to data in an identifiable format is essential for fulfilling the purpose of use. Government proposal for the Secondary Use Act (159/2017 vp.) notes that access to data in an identifiable format could be essential when, for example, it is necessary in individual cases to separately combine data in electronic personal data files with data found in old patient documents or social welfare client documents for research purposes.

- The application should also describe the special measures by which the applicant will ensure the security of identifiable personal data and minimise the possibility of information security violations.
- Identifiable data may be used in educational situations due to the rare nature of the case to be dealt with, the nature of the education or other similar reason. Before using them in teaching situations, photographs of persons and other similar identifying data should be edited to make identifying the person based on them as difficult as possible. If a person can be identified in teaching material, as a basic premise only data concerning persons who have been informed of the teaching use of data concerning them and who have consented to it should be used in educational situations. In addition, the duty imposed on persons delivering education laid down in section 39, subsection 2 of the Secondary Use Act to inform those attending the teaching of the duty of secrecy laid down in the law and the sanctions for breaching it should be fulfilled.
- The data permit application should indicate the length of the period during which it will be necessary to process the data for the purpose stated in the application.
 - A data permit may be issued for a fixed period and at most for the period required by the purpose of data use. The fixed term of the data permit ensures that the requirements of minimisation and necessity laid down in the General Data Protection Regulation are met and that personal data are not stored or otherwise processed for longer than what is necessary. As the data permit expires, the necessity of processing the data may, if necessary, be reassessed, and if the need to use the data continues, the validity of the data permit may be extended. If necessary, new conditions may be imposed on the permit holder in the data permit decision if, for example, this is made necessary by legislative amendments or other reasons.

- In addition to the planned processing period of the data, the storage period and the location in which the data will be stored as well as the date on which the data will be destroyed should be contained in the data utilisation plan or elsewhere in the application. If the applicant finds that the data should be kept for some time after the purpose of active use of the data laid down in section 2 of the Secondary Use Act no longer applies, the application must justify why and for how long retaining the data will be necessary. The data may not be retained once the data permit decision has expired.
- If the data were to be stored and actively processed in different locations, this should be stated in the application, in which case the location where the data will be processed at any one time (including the location where it will be stored) can be entered in the data permit decision. The requirements concerning a secure environment laid down in section 51, subsection 3 of the Secondary Use Act apply to the entire life cycle of the data, and also their storage.
- The application must state how the controller intends to fulfil their duties of informing the data subjects referred to in Articles 13 and 14 of the General Data Protection Regulation as well as contain a privacy notice or other similar document used to inform the data subjects. For more information on informing the data subjects, see the website of the Office of the Data Protection Ombudsman: <https://tietosuoja.fi/en/inform-data-subjects-about-processing>
- A Data Protection Impact Assessment (DPIA) should be attached to the application if preparing this assessment is required under the General Data Protection Regulation or the Data Protection Act. In addition, information on the date on which the DPIA was submitted to the Office of the Data Protection Ombudsman should be provided with the impact assessment if, under the General Data Protection Regulation or the Data Protection Act, the DPIA must be submitted to the Data Protection Ombudsman. For more information on the Data Protection Impact Assessment, see the website of the Office of the Data Protection Ombudsman at: <https://tietosuoja.fi/en/impact-assessments>
- The data permit application should indicate the countries in which the data will be processed or where the processors will be based. If the data are to be processed by a controller or processor based in a non-EU/EEA country, the application must state the grounds for transferring personal data to third countries referred to in Chapter V of the General Data Protection Regulation. Processing of personal data by actors based in third countries also comprises a transfer of personal data to third countries even if the personal data to be processed resided in a remote use environment in Finland. Guideline 05/2021 of the European Data Protection Board EDPB published

on 18 November 2021 discusses in detail the question of when personal data are transferred to a third country. Link to the Guideline:

[edpb_guidelinesinterplaychapterv_article3_adopted_en.pdf \(europa.eu\)](https://edpb.europa.eu/news/news/2020/statement-court-justice-european-union-judgment-case-c-31118-data-protection_en.pdf)

- If data are transferred to a third country subject to the European Commission's standard contract clauses, the parties transferring and receiving the data must, in the light of Schrems II judgement of the European Court of Justice, assess if the data recipient can ensure de facto compliance with the standard clauses. For more information on making this assessment, see the European Data Protection Board's statement and the European Data Protection Board's recommendation 01/2020:
 - https://edpb.europa.eu/news/news/2020/statement-court-justice-european-union-judgment-case-c-31118-data-protection_en
 - https://edpb.europa.eu/our-work-tools/our-documents/recommendations/recommendations-012020-measures-supplement-transfer_en
- The data permit application should indicate if the controller engaging in scientific research or compilation of statistics intends to restrict the data subjects' rights laid down in Articles 15, 16, 18 or 21 of the General Data Protection Regulation. Under section 31 of the Data Protection Act, the precondition for restricting the data subjects' rights is that the controller carries out a Data Protection Impact Assessment (DPIA) and submits it to the Office of the Data Protection Ombudsman for information.
- Under section 39, subsection 3 of the Secondary Use Act, the data subject does not have the right to object to the processing of their personal data referred to in Article 21 of the General Data Protection Regulation for education purposes if processing of the data is essential because of the rare nature of the case.

4 Information updates

The permit authority receiving data permit applications must ensure that its application form is up to date. The application form must comply with the requirements of the Regulation on the data content and data structures of data permit applications and data utilisation plans issued by the Data Permit Authority valid at each time.