

## Privacy statement for a scientific research

The privacy statement contains the information that must be disclosed to research subjects when processing personal data in scientific research. The statement also includes information on the records of processing activities. Provisions on the obligation to provide information are laid down in Articles 12 to 14 of the EU General Data Protection Regulation (EU 2016/679) and in Article 30 concerning the records of processing activities. The privacy statement describes the processing of personal data and demonstrates that the research complies with data protection legislation.

You can use this form to fulfil the information obligation, or use your own form or ensure you communicate the information in some other way. If the obligation to provide information is deviated from (Article 14(5)(b)), the controller must carry out a data protection impact assessment in accordance with the GDPR.

The controller is responsible for implementing the obligation to provide information, and Fimea does not assume any responsibility for fulfilling said obligation.

<b>1. Name of the research</b>	Name of the research
<b>2. Date</b>	Form filling date / date of update

## Contact persons

<b>3. Controller's contact details</b>	Name
	Address
	Other contact details (phone number, email address)
<b>4. Joint controllers and division of tasks</b>	<p>Controllers' contact details, a description of the jointly defined division of tasks and roles in the implementation of data subjects' rights in case of joint controllership (at least two controllers jointly determine the purposes and means of processing).</p> <p>Appended with an agreement concluded by the controllers, indicating the controllers' actual roles and relationships with the data subjects.</p>
<b>5. Contact person in matters concerning the register</b>	Name and contact details
<b>6. Contact details of the controller's data protection officer</b>	Name and contact details

<b>7. Parties participating in the research and their division of responsibilities</b>	Parties involved in the research and the division of responsibilities between different parties.
<b>8. Responsible research leader or supervisor</b>	Name and contact details

### Data processing

<b>9. Purpose of processing personal data</b>	<p><b>Personal data in the register is processed as research material in scientific research.</b> Personal data is processed only for the purpose and to the extent necessary to carry out the relevant research plan.</p> <p>Brief description of the research and its purpose.</p>
<b>10. Legal basis for the processing of personal data</b>	<p><b>In the research, the processing of personal data is based on the following sections of Article 6 of the GDPR</b></p> <ul style="list-style-type: none"> <li>Consent of the data subject (Article 6(1)(a).)</li> <li>Performance of a contract concluded with the data subject (Article 6(1)(b).)</li> <li>Compliance with the controller's legal obligation (Article 6(1)(c).) Regulations.</li> <li>Performance of a task carried out in the public interest or exercise of official authority vested in the controller (Article 6(1)(e) and section 4 of the Data Protection Act.): <ul style="list-style-type: none"> <li>scientific or historical research or statistics</li> <li>archival of research data and cultural heritage materials</li> <li>carrying out an official task in the public interest</li> </ul> </li> <li>Implementation of the legitimate interests of the controller or a third party (Article 6(1)(f)). Description of the legitimate interests.</li> </ul> <p>Has the controller carried out a balancing test and has it been demonstrated that the controller's legitimate interests override the data subject's rights.</p>

	<p><b>The research also processes special categories of personal data whose processing is based on Article 9 of the GDPR</b></p> <p>Data subject's consent to the processing of sensitive data (Article 9(2)(a).)</p> <p>Reasons of substantial public interest under Union or Member State law (Article 9(2)(g).)</p> <p>Reasons of public interest in the area of public health (Article 9(2)(i).)</p> <p>Archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (Article 9(2)(j), also see section 6 of the Data Protection Act.)</p>
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### Data collection

<b>11. Number of data subjects / research subjects</b>	Number of data subjects / research subjects
<b>12. Data sources and categories of personal data collected from them</b>	The research data is collected from the following data sources. Specify which personal identification data (such as name, personal identity code, contact details) and data groups (such as subjects' background information, diagnoses, used medication) are collected from each data source.
<b>13. Research sites and recipients of data</b>	The data is processed at the following research sites or transferred to the following recipients.

### Data disclosure, publication, and storage

<b>14. Transfer/disclosure of data outside the research group</b>	Personal data is disclosed to the following recipients.
<b>15. Transfer/disclosure of data outside the EU or EEA</b>	If the data is transferred to countries outside the EU and the EEA, mention the reason for the transfer, the country, the organisation, what data and in what format and for what purpose, and the safeguards that will be used.

<b>16. Publication of research results</b>	<p>The research results are to be published in:</p> <ul style="list-style-type: none"> <li>Finnish journals</li> <li>International journals</li> <li>As theses</li> <li>Elsewhere, specify</li> <li>Results will not be published</li> </ul>
<b>17. Duration of the research and the storage, destruction or archiving of research material</b>	<p>The retention period of personal data consists of the duration of the research (research data is collected, analysed, written, published and possibly corrected post-publication), possible archiving in the public interest and possible statutory retention periods. Sufficient time should be reserved for conducting the research.</p> <p>Duration of the research (start and end date).</p> <p>The research data will be destroyed (date).</p> <p>If the research material is archived (retained permanently):</p> <ul style="list-style-type: none"> <li>with identification data</li> <li>without identification data</li> <li>and where</li> </ul>
<b>18. Personal data protection measures during the research</b>	<p>How the personal data collected in connection with the research is processed (with identification / pseudonymised / anonymised). Where the materials containing personal data are stored and who can access them. How databases are protected and who can access data and information systems. Also fill in the Data utilisation plan. How the material is processed.</p>
<b>19. Ensuring information obligations</b>	<p>How has the obligation to inform data subjects according to Articles 13 and 14 of the GDPR been handled (data protection notice or other similar document).</p>
<b>20. Automated decision-making and profiling</b>	<p>An automated decision means a decision that is used to evaluate the specific characteristics of a person, is based solely on automated data processing and produces legal effects concerning the person or otherwise significantly affects them. Some examples of automated decision-making include creditworthiness decisions and profiling.</p> <p>In scientific research, the processing of personal data is not used for decision-making or profiling concerning the participants.</p>

## Rights of the data subject

<p><b>21. Rights of the data subject and their limitation</b></p>	<p>The data subject has rights under data protection legislation. The scope of these rights depends on the legal basis for the processing of personal data.</p> <p><b>Right to withdraw consent</b> If it is determined that the processing of personal data is based on consent, the research subject has the right to withdraw their consent at any time during the research without justification. Personal data collected before the withdrawal may be used as part of research material if it is necessary and permitted by legislation.</p> <p><b>Right to receive information on the processing of personal data</b> The data subject has the right to receive information on measures related to the processing of their personal data.</p> <p><b>Right to check data concerning the data subject</b> The data subject has the right to be informed of whether their personal data is processed and what personal data is processed in the research.</p> <p><b>Right to rectification</b> If there are inaccuracies or errors in the personal data to be processed, the data subject has the right to request that it be rectified or supplemented.</p> <p><b>Right to the erasure of personal data</b> The data subject has the right to request the deletion of their personal data from the research in question. However, the party conducting the research has the right to process the data collected on the data subject before the withdrawal of consent in the research to which the subject has consented.</p> <p><b>Right to object</b> The data subject has the right to object to the processing of personal data on grounds related to a particular situation relating to them. The controller may not process the personal data unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject or for the establishment, exercise or defence of legal claims.</p>
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	<p><b>Deviation from the data subject's rights</b></p> <p>It is possible to deviate from the rights of the data subject (the right of access, right to rectification, right to restriction of processing and the right to object) in connection with scientific research if legislative requirements are met (section 31 of the Data Protection Act) and if the necessity and appropriateness of the deviation has been assessed on a case-by-case basis. The possibility of deviation is assessed in individual cases in connection with each request.</p> <p>The following rights under the EU General Data Protection Regulation of the data subject are likely to be derogated from in this research:</p> <p>The data subject's right to receive information about the processing of personal data (the obligation to provide information may be waived in scientific research on the basis of Article 14 Section 5b of the GDPR, in which case a data protection impact assessment must be carried out and the research data made publicly available.)</p> <p>Right of access by the data subject (Art. 15.)</p> <p>Right to rectification (Art. 16.)</p> <p>Right to restriction of processing (Art. 18.)</p> <p>Right to object (Art. 21.)</p> <p>Reasons for deviating from the data subject's rights.</p> <p>The data subject may exercise their rights by contacting the contact person of the research or the data protection officer. For more information on the rights of the data subject, contact the contact person of the research and/or the data protection officer of the research.</p>
<p><b>22. Right to lodge a complaint with a supervisory authority</b></p>	<p>The data subject has the right to lodge a complaint with the supervisory authority if the data subject considers that existing data protection legislation has been violated in the processing of personal data concerning the data subject. Contact details of the supervisory authority in Finland:</p> <p>Office of the Data Protection Ombudsman  Visiting address: Lintulahdenkuja 4, 00530 Helsinki  Postal address: P.O. Box 800, FI-00531 Helsinki, Finland</p> <p>Switchboard: +358 29 566 6700  Telephone advice: +358 29 56 66777  Email (registry): tietosuoja(at)om.fi</p>