INSTRUCTIONS FOR USING THIS FORM

Data subjects (data subject) must be informed of the processing of personal data in accordance with Articles 12-14 of the General Data Protection Regulation (so-called data protection notice or privacy statement). You can use this form to fulfil the information obligation, use your own form or ensure you communicate the information in some other way.

When the data have been collected **from other sources than the data subject themselves**, a deviation from the communication may be made on the basis of Article 14 (5b) of the GDPR in the following cases:

1. the transmission of data proves impossible (in particular when processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes);
2. transmission of data would require disproportionate effort (in particular when processing data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes);
3. Where the provision of the information required is likely to impede or seriously impede the achievement of the purposes.

If the information obligation is deviated from on these grounds, the controller must carry out a data protection impact assessment in accordance with the GDPR.

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

Further information

<https://tietosuoja.fi/en/inform-data-subjects-about-processing>

<https://tietosuoja.fi/en/impact-assessments>

1. Registrar of the study

[ORGANISATION]

[ADDRESS INFORMATION]

Contact person for research issues: *[the person whom the subjects can contact on data protection matters related to the study]*

Name:

Address:

Telephone number:

Email address:

*[If there are several controllers, please also mention other controllers here.]*

1. Description of the research project and the purpose of the processing of personal data

The purpose of the processing indicates for which research personal data will be processed. Describe the project from a perspective from which the subject can understand how their data is processed.

1. Research parties and the division of responsibilities, if the research is carried out as a collaborative project

If this is a joint project between several parties (organisation/department), describe here the division of responsibilities of the parties in relation to the processing of personal data. If it is not a collaborative project, mark with "NON-collaborative project research".

If the research organisations jointly process the same personal data in the study and jointly define the purposes and means of the processing of personal data, they are **joint controllers**.

[For joint controllers, use the text below. In the case of joint controllers, delete the text below in this section 3.

The organisations listed in section 1 will act as joint controllers in this study, i.e. they will jointly define the purposes and means of the processing of personal data.

Subjects can make all requests related to this study to exercise the data subject's rights to the contact person below:

[contact person details]

If necessary, the contact person will also forward the request to other organisations acting as joint controllers.

The subject can exercise their rights under the GDPR in relation to each controller. In this case, the recipient may also forward the request or claim to other joint controllers, if necessary.]

1. Responsible research leader or responsible team

The accountable leader is a person appointed by the controller and who is responsible for carrying out the research. A responsible team may also be designated.

Name:

Address:

Telephone number:

Email address:

1. Contact details of the Data Protection Officer

[Contact details of the Data Protection Officer]

1. Parties carrying out the research

All those who have the right to process data from the study register during the study are entered here. It is not necessary to list individuals, but they can be listed as categories (e.g. researchers and research assistants in unit X).

1. Name, nature and duration of the research

Name of study: [name]

[ ] One-off research [ ] Follow-up study

Duration of the research (how long personal data will be processed):

If the exact duration is known, it is indicated here. If not, explain here how the duration of the processing is determined.

1. Legal basis for the processing of personal data

In accordance with Article 6 paragraph 1 of the EU General Data Protection Regulation, the basis for processing personal data is as follows:

[ ]  Consent of the subject

[ ]  Compliance with a legal obligation

[ ]  Scientific or historical public interest research, statistics or the exercise of official authority vested in the controller

[ ]  Legitimate interest

[ ]  Other, please specify:

1. Sensitive personal data

[ ]  The study does not process sensitive personal data.

The study will process the following sensitive personal data:

[ ]  Race or ethnic origin

[ ]  Political opinions

[ ]  Religious or philosophical belief

[ ]  Trade union membership

[ ]  Genetic data

[ ]  Processing of biometric data for the unambiguous identification of a person

[ ]  Health information

[ ]  Sexual behaviour or orientation of a natural person

The processing of sensitive data is based on the following special condition under Article 9 paragraph 2 of the GDPR:

[ ]  Explicit consent of the subject

[ ]  Scientific or historical research purposes or statistical purposes

[ ]  The subject has made public the processed sensitive data

[ ]  Other, please specify:

[ ]  The investigation processes information on criminal convictions or violations.

1. Which personal data is contained in the research material

This section describes the data or types of data that are collected and stored of the research subject/data subject. The identification details of the person are specified (name, date of birth, contact details), as are other study details. A separate attachment can be used.

1. From which sources is personal data collected

Describe here from where the data to be stored is obtained.

1. Transfer or disclosure of data outside the research group

This section describes whether personal data is regularly transferred or disclosed outside the research group. What information is disclosed, where it is transferred, and the justification for the transfer. This also describes the possible transfer of personal data to the processor (e.g. a subcontractor).

1. Transfer or disclosure of data outside the EU or the European Economic Area

If data is not transferred, mark "Not transferred”

If transferred, identify a legal basis under the GDPR that allows for the transfer of said data (e.g. Commission decision on adequacy of data protection under Article 45 / Binding rules for businesses under Article 47 / Standard data protection clauses under Article 46 paragraph 2 / Exceptions and safeguards under Article 49, such as the subject's explicit consent to the proposed transfer after being informed of the risks associated with the transfer).

Where possible, the information should include a link to the document used or information on where and how the information on that document is available.

The most common safeguards are the Commission's standard contractual clauses (Article 46 paragraph 2 of the Regulation), see [*https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/model-contracts-transfer-personal-data-third-countries\_en*](https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/model-contracts-transfer-personal-data-third-countries_en)

1. Automated decision-making

No automatic decisions are made.

Scientific research generally does not involve automated decisions based on profiling that may have legal or other significant effects on the subjects.

1. Principles of personal data protection

 [ ]  The data is confidential.

Protection of manual material: \_\_\_

Information processed in information systems:

 [ ]  user ID [ ]  password [ ]  access registration [ ]  access control

 [ ]  other, please specify:

Processing of direct identifiers:

[ ]  Direct identifiers will be removed during the analysis phase

[ ] The data is analysed using direct identifiers because (justification for retaining direct identifiers):

1. Processing of personal data after the end of the study

[ ]  The study register will be destroyed

[ ]  The research register is archived:

[ ]  Without identification data [ ]  with identification data

Where the material is archived and for how long: \_\_\_

1. Rights of the data subject and their possible limitation

Data protection legislation guarantees a certain set of rights for the subject to ensure the privacy protection of fundamental rights. **If the subject wishes to exercise their right, contact [provide contact details]**

Withdrawal of consent (Article 7 of the GDPR)

You have the right to withdraw your consent if the processing of your personal data is based on consent. Withdrawal of consent shall not affect the legality of the processing carried out on the basis of consent prior to its withdrawal.

Right of data access (Article 15 GDPR)

You have the right to be informed of whether your personal data will be processed in the study and what personal data will be processed in the study. You can also request a copy of the personal data to be processed.

Right to rectification (Article 16 of the GDPR)

If there are inaccuracies or errors in your personal data to be processed, you have the right to request that it be rectified or supplemented.

Right to erasure (Article 17 GDPR)

You have the right to request the deletion of your personal data in the following cases:

1. personal data is no longer needed for the purposes for which they were collected or otherwise processed
2. you withdraw the consent on which the processing was based and there is no other legal basis for the processing
3. you object to the processing and there is no justified reason for the processing
4. the personal data has been processed unlawfully; or
5. personal data shall be erased in order to comply with a legal obligation imposed on the controller under Union or Member State law.

Deviation from rights

In this section 17, **What rights do you have and the deviation from the rights** described rights may be deviated from on grounds under data protection legislation to the extent that the rights prevent or significantly impede the achievement of scientific or historical research purposes or statistical purposes. The need to deviate from rights is always assessed on a case-by-case basis.

Right to appeal

You have the right to lodge a complaint with the Office of the Data Protection Ombudsman if you consider that the processing of your personal data has violated the valid data protection legislation.

Contact information:

**The Office of the Data Protection Ombudsman**

Visiting address: Ratapihantie 9, 6th floor, 00520 Helsinki

Postal address: P.O. Box 800, FI-00521 Helsinki, Finland

Switchboard: +358 29 56 66700

Fax: +358 29 56 66735

Email: tietosuoja@om.fi