

Document No. T/108/2025 10 July 2025

Privacy policy for clinical trials

1. Data controller

National Committee on Medical Research Ethics (Tukija)

Visiting address: Valvira, Ratapihantie 9, FI-00520 Helsinki

Postal address: PO Box 43, FI-00521 Helsinki

Other contact details: tel. +358 (0)295 209 111 (switchboard), info@tukija.fi

2. Contact person for the register

Outi Konttinen, outi.konttinen@tukija.fi

3. Contact details of the Data Protection Officer

Jukka Tuomela, tietosuoja@valvira.fi

4. The personal data processed

The registered data is intended for Tukija's operations. For the purpose of the statement provided by Tukija, the register will process, where applicable, the following information about the persons in charge of the research project and its contact persons:

- name, date of birth and role in the research project
- address and contact information
- employer or company
- educational background
- professional information (work experience, publications) and other information provided in the CV submitted

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• the name of the processor and the presenter, contact details.

5. Grounds for processing personal data

Tukija's role is to provide a statement on a clinical trial on medicinal product as well as on a medical device study combined to the pharmaceutical trial. To fulfil this purpose, Tukija processes the personal data provided in the applications.

The processing of personal data is based on compliance with a legal obligation under the Article 6 (1c) of the EU General Data Protection Regulation (EU 2016/679).

Personal data is processed in the tasks assigned to Tukija in sections 7, 8, 9, 10, 12, 17, 18, 19, 20 and 28 of the Act on Clinical Trials on Medicinal Products (983/2021) and in the tasks defined in sections 18 and 19 of the Medical Devices Act (719/2021).

Personal data will not be processed for any purpose other than that for which it has been collected. Tukija will not use personal data in automated decision making or profiling.

6. Retention period of personal data

The retention period of personal data depends on the retention period of the document containing said data:

- The statement applications and their appendices (retained 25 years from the end of the study notification).
- Tukija's minutes and record extracts, statements, decisions (retained permanently).
- Documents related to an appeal, excluding the decision (retained permanently).

7. Regular sources of data

Tukija receives the data from the submitters of the statement applications.

8. Data processors

Tukija operates in connection with the National Supervisory Authority for Welfare and Health, Valvira. The data is also processed by Valvira's system administrators.

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9. Disclosure of data

Data can only be disclosed and the processing of personal data outsourced in compliance with valid legislation.

Tukija discloses data related to the processing of the application, as well as statements, to the Finnish Medicines Agency Fimea based on section 12 of the Act on Clinical Trials on Medicinal Products (983/2021) regarding cooperation in the evaluation of clinical trial applications and on section 28 regarding Fimea's right of access to information.

Data is disclosed to others only upon request in accordance with the Act on the Openness of Government Activities and the data protection legislation.

Personal data will not be transferred outside the EU or the European Economic Area.

10. Rights related to the processing of personal data

This is a register required by law. In this case, the data subject has the right to:

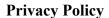
- obtain access to personal data concerning them in accordance with Article 15 of the General Data Protection Regulation. This request is addressed to the party in section 2.
- demand the rectification of erroneous data in the register concerning them in accordance with Article 16 of the General Data Protection Regulation. This request is addressed to the party in section 2.
- request restriction of processing of personal data in accordance with Article 18 of the General Data Protection Regulation.

Due to the fact that the register is required by law, the data subject does not have the right to:

- have the data controller erase the personal data concerning the data subject without undue delay in accordance with Article 17 of the General Data Protection Regulation.
- transfer their personal data from one system to another or have their data transferred directly from one controller to another in accordance with Article 20 of the General Data Protection Regulation.

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If the data subject considers that data protection legislation has been violated in the processing of personal data, the data subject has the right to lodge a complaint with the Office of the Data Protection Ombudsman.

Further information on the rights of the data subject can be found on the website of the Office of the Data Protection Ombudsman: https://tietosuoja.fi/en/know-your-rights

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