FPM-E-004-EN v1.0 30.03.2021

15-17-year-old - Information leaflet on the Processing of Personal Data - template: Appendix to the Informed Consent form

Processing of personal data and rights of trial participants in clinical trials on medicinal product or medical device for 15-17-year-old patients

1. Personal data

Personal data includes all data related to a person that allows them to be identified directly or indirectly or, for example, by linking a piece of information to other information. In a patient trial, personal data includes, for example, name, personal identity code, addresses and all patient information collected during the trial.

2. Controller

The controller is responsible for lawful processing of personal data in the trial. The controller of this trial is another sponsor / company. Only personal data that is strictly necessary for this study and the study plan is stored in the study register.

3. Grounds for processing personal data[1,2]

According to law[1], your personal data can be processed in this study because law requires it. Personal data can be processed in a patient study because studies are in the public interest[2] and authorities have to supervise them. In a drug or device trial, personal data is used to monitor the quality of the study and to ensure the safety of the studied drug or device and the people who are in the study.

4. Processing of personal data

In this study, only people working in the study team process your personal data. They are bound by confidentiality obligation. All information collected in the study is coded. This means that your name and personal identity code is removed and replaced with a unique code. After this, you can't be identified from this information without a code key that is stored by the study physician. No one else has access to this code key. The results of the study are also coded when they are interpreted and studied.

Finnish authorities responsible for medicines regulation and health safety can also process your information. Foreign supervisory authorities, employees authorized by the organization conducting this study or the sponsor of this study, laboratory staff and other research professionals can also process your data. In this study, information is collected from the following sources: __________. Your health information and personal data needed in the study is also collected from the following sources and registries: __________. The study team uses your personal identity code to collect this data with a separate permission from a competent authority. **The information collected in this study is not stored in your patient record[3].**

5. Disclosure of personal data

In this study, your personal data or samples are not disclosed to others. They are only processed for this scientific study. what is disclosed?.

In this study, your information can be transferred outside the European Union (EU) and the European Economic Area (EEA). In some countries, the data protection rules differ from the EU. The organization conducting this study or the sponsor of this study makes sure that the following protective measures are applied __________

6. Storing of personal data

The storage period of your personal data is based on law. In this study, information is stored for _____ years.

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The information is stored by ______. Your information is stored safely and deleted after the storage period. If you decide to terminate the study early, you withdraw your consent or your participation is terminated for another reason, your information and samples collected so far can be used as study material. This is necessary to ensure the safety of the research results and people participating in the study.

7. Rights of subjects

You have the right to receive information about the processing of your personal data and to request restriction of processing. You also have the right to inspect your information and ask that your information is corrected or completed, if you notice a mistake or if any information is missing or inaccurate. In connection with clinical drug and device studies, some rights related to the processing of personal data can be restricted to ensure the safety of the study subjects and the reliability of the study results.

You can ask any time if we process your personal data legally, where we have received your information and where your information or samples have been sent. You receive the reply free of charge as soon as possible within one month. In matters related to data protection, please contact **either** 1) the study physician **or** 2) the data protection officer of the controller (if appointed). If you feel that the processing of your personal data does not comply with the EU General Data Protection Regulation (EU) 2016/679[1], you have the right to lodge a complaint with the Data Protection Ombudsman (3).

1) Contact information of the study physician:
Title: ______
Name: ______
Unit/clinic: ______
Direct telephone number: ______ (not the switchboard)
Email address: ______

2) Contact information of the data protection officer of the controller; ______:
______, data protection officer
______ University Hospital
Email address: ______
Mailing address: ______

3) Office of the Finnish Data Protection Ombudsman, contact information:
Ratapihantie 9, 6th floor, 00520 Helsinki
Mailing address: P. Box 800, 00521 Helsinki, Finland
Switchboard: +358 29 566 6700
Email: (Registry): tietosuoja@otm.fi

I ______ have been told (explained) today, on ______, what my rights are and how my personal data will be used, processed, disclosed, stored and deleted in ______.

A detailed explanation of the references 1, 2 and 3 in sections 3 and 4 is on page 3.

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References 1, 2 and 3:

[1] **Grounds based on the EU General Data Protection Regulation (GDPR) (2016/679)**
(concerning a drug or a device study, modified text of Articles that are relevant for consent)

Article 6 (includes items 1-4 in whole)
Lawfulness of processing: Processing shall be lawful only if, and to the extent that, at least one of the following conditions defined in Article 6(1) applies**:** **c)** processing is necessary for compliance with a legal obligation to which the controller is subject; **and/or e)** processing is necessary for the performance of a task carried out in **public interest** or in the exercise of official authority vested in the controller; (sub-paragraphs (a), (b), (d) and (f) of Article 6 (1) do not apply to a medicinal product or medical device trial).

Article 9 (includes items 1-4 in whole)
Processing of special categories of personal data: Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited.

Article 9(1) shall not apply if one of the following sub-paragraphs of Article 9(2) applies: **i)** processing is necessary for reasons of **public interest** in the area of public health, such as protecting against serious cross-border threats to health, or ensuring high standards of quality and safety of health care and of medicinal products, or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy; **or j)** processing is necessary for archiving purposes **in the public interest**, scientific or historical research purposes, or statistical purposes in accordance with the law. The legislation must be proportionate in relation to the objectives. It must comply with the right to personal integrity and include regulations for appropriate and special measures to protect the basic rights and interests of the data subject. (sub-paragraphs (a), (b), (c), (d), (e), (f), (g) and (h) of Article 9(2) do not apply to a medicinal product or medical device trial).

[2] **Issues that are important for society as large (legal term: public interest):** Issues that are related to maintaining the order of society and promotion of public health, necessary for the protection of the legal rights, well-being and protection of citizens and issues related to health and health care.

[3] **Patient record:** A formal document that includes information about the patient’s illness, conducted examinations and administered treatment. In hospitals, patient records are usually stored electronically in patient information systems.

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